We Add **Quality** to the World of Nutrition.

Human Nutrition
Technical Information
2010

BASF Nutrition – the healthy decision.

The Chemical Company
Introduction

Dear Customer,

In response to the high interest shown in the technical information on human nutrition, we have prepared a revised edition with many new and interesting features.

This handbook is a comprehensive source of information on our human nutrition products, which include vitamins, carotenoids, omega-3 fatty acids, caffeine and beverage processing polymers. Here you can find details about their role in human nutrition, together with intake recommendations, and plenty of useful background information besides. The intention behind it is to give you all the help you need in your daily nutrition business.

This user guide also contains a collection of single technical information data sheets available for each of our human nutrition products. They provide chemical and physical data, information on product stability, and possible applications.

The data supplied are those valid at the time of printing (November 2009).

With our vitamins, carotenoids, omega-3 fatty acids, and more, we provide one of the widest ranges of nutritional ingredients for the food, beverage, and dietary supplements industries.

BASF has been active for decades in the field of human nutrition. During this time, BASF has become one of the leaders in the nutrition industry, supplying high-quality products throughout the world. All activities are centered around product safety and efficacy. All products are the result of responsible research, combined with extensive technical knowledge in the fields of synthesis, biotechnology, and formulation. You can depend on BASF’s expertise in all matters of human nutrition.

BASF Nutrition – the healthy decision.
BASF’s nutritional ingredients make your choice easier:

<table>
<thead>
<tr>
<th>SAFETY</th>
<th>BASF products meet highest safety standards and regulatory requirements worldwide.</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUALITY</td>
<td>BASF supplies products of excellent purity, stability, and performance. The product quality is constant and reproducible. BASF applies the highest quality management standards possible.</td>
</tr>
<tr>
<td>TRACEABILITY</td>
<td>BASF provides traceability information about its nutritional ingredients and the raw materials used in production via GTNet®—flexibly and independently accessible for customers at any time and anywhere in the world.</td>
</tr>
<tr>
<td>SUSTAINABILITY</td>
<td>BASF integrates ecological and social responsibility into its business activities and makes sustainability quantifiable via independently certified eco-efficiency analyses.</td>
</tr>
<tr>
<td>RELIABILITY</td>
<td>BASF is an absolutely reliable supplier in all matters. BASF has an integral supply chain and logistics management—regional distribution centers allow high supply reliability in major markets. Customer service centers are available in all regions and in major countries.</td>
</tr>
<tr>
<td>INNOVATION</td>
<td>BASF’s latest innovation is starch-based lycopene (LycoVit® 10 CWD/S) for application in beverages. Recently, BASF has launched a highly concentrated omega-3 powder that is rich in DHA (Dry n-3® DHA 11) and is mainly intended for use in infant and maternal nutrition. BASF has also launched Crosspure®, an innovative filter excipient for diatomaceous earth-free, one-step filtration and stabilization of beer.</td>
</tr>
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<td>COMMITMENT</td>
<td>BASF is a world leader in nutritional ingredients forming the best team in the industry, and fully committed to the food, beverage, and dietary supplements industries.</td>
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BASF Nutrition – the healthy decision.

www.nutrition.basf.com
www.set-initiative.com
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Abbreviations

BG = Beverage grade
BHT stab. = Stabilized with 3,5-di-tert-butyl-4-hydroxytoluene
BSE = Bovine spongiform encephalopathy
CWD = Cold-water dispersible
DC = Direct compressible
EU = European Union
FG = Food grade
GFP = Gelatin-free product
HP = High potency
HS = Heat stabilized
MCT = Medium-chain triglycerides
Toc. stab. = Stabilized with DL-alpha-tocopherol
TSE = Transmissible spongiform encephalopathy
/F = Fish gelatin
/O = Orange
/R = Red
/S = Starch
F/O = Fish gelatin/orange
F/R = Fish gelatin/red
S/Y = Soy/yellow
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<td>Dry Vitamin K₁ 5% GFP</td>
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Vitamins are essential micronutrients required for healthy development, growth and maintenance of life. So far, 13 compounds have been classified as vitamins. They display a wide variety of functions within the body, regulating the metabolic process, converting carbohydrates and fat into energy, and forming tissue and bone.

The distinguishing feature of vitamins is that they generally cannot be synthesized by humans and, therefore, must be supplied in the diet. Yet, in contrast to essential amino or fatty acids, vitamins are neither used as building materials nor for the generation of energy. They mainly participate in enzymatic and control function, hence the body only needs tiny amounts of them. Nevertheless, it is difficult to meet the requirements for vitamin intake through a normal diet, as most foods contain only small quantities of the vital micronutrients. Furthermore, eating a wide variety of foods is necessary to provide an adequate vitamin intake, for all vitamins are equally important but no single food contains all of them at once.

Due to vast changes in our daily life, a balanced diet of fresh and diversified food is getting more and more difficult to realize. Furthermore, reduced physical activity, a hectic lifestyle, alcohol or nicotine abuse, and increased consumption of fast food contribute to an insufficient vitamin supply.

In addition, disease, intake of certain medication, or impaired intestinal absorption can reduce the effectiveness of vitamins. As a result, a significant portion of the population fails to reach the recommended daily intake of vitamins. Especially children, the elderly, and pregnant women show particular nutritional needs and therefore belong to a risk group for lack of vitamins. Thus, to avoid deficiency symptoms or even severe illness, supplementation with vitamin products can be of particular importance.

Next to classical deficiency diseases, vitamin research presently concentrates more and more on reducing the risk of chronic degenerative diseases through vitamin supply.

The vitamins used for nutritional and therapeutic purposes are primarily produced in chemical and fermentation processes on an industrial scale. As their chemical structure is usually identical to naturally occurring vitamins, they are at least of equal if not superior quality due to high purity, stability, and method of formulation.
Vitamin A

**Chemical names of active ingredient**
All-trans retinol (vitamin A alcohol) and its esters

**Units**
1 International Unit (IU) = 0.3 µg vitamin A alcohol
1 USP unit = 0.3 µg vitamin A alcohol

**Physiological importance**
Vitamin A plays an important role in the visual system of the eye. Retinol is converted into retinal in the retina located at the back of the eye. In conjunction with the protein opsin, they form the visual purple (rhodopsin) of the retinal rods, which are the light-sensitive cells responsible for night vision. In addition, vitamin A protects the eye from bacteria that may cause the softening of the cornea (keratomalacia).

Vitamin A plays a critical role in reproductive processes. All higher forms of life require retinol for reproduction. As far as humans are concerned, women need retinol for the development of placenta and fetus, while men require vitamin A both for the production of testosterone and to maintain sperm production in the testes.

Vitamin A provides protection for the entire ectoderm and benefits growth and functionality of the skin as well as the mucous membranes. It is involved in the healing process of tissue injuries by promoting rapid regeneration of the epithelium. Vitamin A is also essential for the growth of cartilage and bones and for the skeletal development.

Furthermore, vitamin A plays a crucial role within the immune system. Intake of vitamin A increases the formation of antibodies, and thus leads to enhanced resistance against disease.

**Occurrence**
Vitamin A (retinol) is naturally only found in foods of animal origin. Liver, butter, and egg yolk, for example, contain particularly large amounts. Other good sources of vitamin A include unskimmed milk, cheese, and certain species of fish, e.g., shark, halibut, and mackerel. The vitamin A content of some animal products is so high that toxic reactions may occur if they form a major part of the diet. Such symptoms have been observed in polar explorers after consumption of large amounts of liver from bears and other marine animals.

Foods of vegetable origin merely contain vitamin A precursors, the carotenoids. In humans, these act as provitamins, as they are converted to vitamin A in the body by oxidation, with different degrees of efficiency. Compared to retinol, their vitamin A activity is lower.

Several hundred carotenoids occur in foods, but only approx. 50 can be metabolized into the active retinoid forms; among these 50 compounds, beta-carotene, a retinol dimer, has the most significant provitamin A activity.

Vegetables with a rich yellow color, such as carrots, apricots, mangoes and certain potato varieties contain more than 80% of their provitamin A in the form of beta-carotene. Other good sources of beta-carotene are vegetables with dark-green leaves, such as spinach, cabbage, broccoli, lamb’s lettuce, and fennel leaves.
### Recommended dosages

The required vitamin A intake is covered by actual vitamin A (retinol) from foods of animal origin and by vegetable provitamins (carotenes, some of the other carotenoids, and apocarotenal). To enable calculation of the required amounts, the provitamin A carotenoid activity is converted into Retinol Equivalents (RE) or Retinol Activity Equivalents (RAE):

| 1 µg Retinol Activity Equivalent (RAE) | = 1 µg retinol |
| (US) | = 2 µg supplemental beta-carotene |
| | = 12 µg dietary beta-carotene |
| | = 24 µg other dietary provitamin A carotenoids |

| 1 µg Retinol Equivalent (RE) | = 6 µg beta-carotene |
| (Europe) | = 12 µg other provitamin A carotenoids |

### Dietary reference values for vitamins

The tables below provide recommended intake levels as well as reference values for nutrition labeling.

### Recommended intake levels

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg RAE¹/day</td>
<td>µg RE²/day</td>
</tr>
<tr>
<td>Men</td>
<td>900</td>
<td>1,000</td>
</tr>
<tr>
<td>Women</td>
<td>700</td>
<td>800</td>
</tr>
</tbody>
</table>

1. Recommended Dietary Allowance (RDA)
2. 1 µg RAE (Retinol Activity Equivalent) = 1 µg retinol = 2 µg supplemental beta-carotene = 12 µg dietary beta-carotene = 24 µg other dietary provitamin A carotenoids
3. Recommended Intake
4. 1 µg RE (Retinol Equivalent) = 1 µg retinol = 6 µg beta-carotene = 12 µg other provitamin A carotenoids = 1.15 µg retinyl acetate = 1.83 µg retinyl palmitate

The Recommended Dietary Allowances (RDA) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).

The Recommended Intakes within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

### Current labeling standards

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
<th>RDA (2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe</td>
</tr>
<tr>
<td>Unit</td>
<td>IU</td>
<td>µg</td>
</tr>
<tr>
<td>Nutrition Labeling</td>
<td>5,000</td>
<td>800</td>
</tr>
</tbody>
</table>

The Reference Daily Intake (RDI) is the value established by the US Food and Drug Administration (FDA) used in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Community for Nutrition Labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

When calculating the required amounts, processing losses of approximately 20% must be included. The amount of carotene absorbed from vegetables is dependent on the method of preparation, e.g., whether the vegetables are cut or mashed, and how much fat is used during cooking.

The presence of protein and fat in food as well as increased production of bile acid promote absorption. 20 – 25% of the vitamin A intake (calculated as Retinol Equivalents) originates from provitamins.
Deficiency symptoms
Vitamin A deficiency is the most common type of vitamin deficiency in the world. Deficiency of vitamin A is found among malnourished populations, the elderly, and chronically sick individuals. Initial symptoms include increased light sensitivity, dry eyes, and impaired adaptation to the dark or even night blindness (hemeralopia).

In the advanced stage of this disease, yellowish horny spots appear in the conjunctiva and the production of tear fluid is severely reduced (xerophthalmia). Keratomalacia can ultimately lead to severely impaired eyesight and even complete blindness, particularly in small children.

Vitamin A deficiency may also cause reduced resistance to infection, which in turn results in higher morbidity and mortality rates caused by diarrhea, respiratory infections, and measles. Reproductive disorders (reduced fertility, sterility, malformation in the fetus) often occur. Further symptoms include alterations in the mucous membranes of the respiratory, and reproductive organs, the intestinal mucosa, and the urogenital tract. These symptoms are accompanied by unpleasant changes of the skin: it becomes dry, slightly squamous and wrinkled, and develops an acne-like appearance. In children, vitamin A deficiency stunts their growth, is responsible for bone deformation, and adversely affects the development of teeth.

Acute toxicity
Acute toxic symptoms from a single overdose of vitamin A initially include headaches, caused by an increase in cerebrospinal fluid pressure. This is usually followed by a lack of appetite, vomiting, dizziness, hair loss, and peeling of the skin. Additional typical symptoms include nosebleeds and other hemorrhages. Single dosages of more than 100,000 IU can cause acute vitamin A poisoning in children (exception: in developing countries, extremely malnourished children with severe vitamin A deficiency symptoms, such as eye damage, can be treated with single dosages of up to 200,000 IU). The risk threshold for adults is higher, i.e., 500,000 – 1.0 million IU of vitamin A.

Vitamin A dosages potentially causing acute intoxication:

<table>
<thead>
<tr>
<th></th>
<th>Vitamin A dosages potentially causing acute intoxication:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (depending on the age)</td>
<td>&gt; 100,000 IU of vitamin A</td>
</tr>
<tr>
<td>Adults</td>
<td>500,000 – 1.0 million IU of vitamin A</td>
</tr>
</tbody>
</table>

Chronic toxicity
Chronic vitamin A intoxication (particularly caused by retinoids, such as retinoic acid) results in severe changes of the skin and mucous membranes, including typical peeling reactions, reddening and itching, an increase in the size of the liver, pain in the bones, cerebrospinal pressure increase accompanied by headaches, poor sleep, painful alterations in the skeletal structure, and hemorrhage. Musculoskeletal effects include pain and tenderness, particularly in the long bones of the upper and lower extremities, which may be exacerbated by exercise; epiphyseal capping and premature epiphyseal closure may occur in children. Neurological effects include frontal headache and blurred vision.
Depending on the duration of intake (months or years), body weight and general state of health, symptoms of chronic intoxication can be expected, if the following daily dosages are exceeded:

<table>
<thead>
<tr>
<th>Vitamin A dosages potentially causing chronic intoxication:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (depending on the age) 12,000 – 60,000 IU of vitamin A/day</td>
</tr>
<tr>
<td>Adults 50,000 – 100,000 IU of vitamin A/day</td>
</tr>
</tbody>
</table>

**Teratogenic effects**

In animal experiments, high dosages of vitamin A have been found to be teratogenic. Similarly, evidence of a possible link between very high retinol intake during pregnancy and malformation of the fetus exists for humans. Typical malformations include dysplasia and aplasia of the ear, harelip, cleft palate, malformation of the jaw, and alterations in the urogenital tract.

Due to the established risk factors, women of childbearing age are recommended to limit their daily vitamin A intake to 10,000 IU (3 mg), particularly during pregnancy. It is generally acknowledged that daily dosages of less than 5,000 IU and single dosages of less than 3,000 IU of vitamin A do not pose a risk.

However, as an inadequate intake of vitamin A during pregnancy itself presents a teratogenic risk factor, suitable vitamin A preparations may be required as a preventive measure in some cases.

**Safety summary**

The CRN (Council for Responsible Nutrition) recommendation is as follows:

- The ULS (Tolerable Upper Intake Level from Supplements) of 10,000 IU (3 mg) preformed retinol is safe for most consumers except for persons consuming large amounts of fortified foods or food naturally high in retinol (e.g., liver). For these people, a ULS of 5,000 IU (1.5 mg) is appropriate. A value of 3 mg was also established by FNB (American Food and Nutrition Board) and SCF (Scientific Committee on Food, EC). The EVM (Expert Committee on Vitamins and Minerals, UK, 2003) concluded that the safe supplement in terms of bone mineral density and bone fragility is 3 and 1.5 mg, respectively.

- The LOAEL (Lowest Observed Adverse Effect Level) for birth defects is at least 25,000 IU (7.5 mg) of retinol. No credible data in regard to levels below 21,675 IU (6,500 µg RE) are available.

- Many companies are decreasing the maximum amount of vitamin A in multivitamin products to 5,000 IU (1,500 µg RE) to address concerns regarding bone fragility and high vitamin A intake from liver.
Applications
Established indications for intake of vitamin A are the prevention and therapy of deficiencies, as these cannot be alleviated fast enough just by modifying the diet.

Possible causes of vitamin A deficiency are:
• unbalanced or poor diet over a longer period of time,
• maldigestion and malabsorption as a result of gastrointestinal disease (Morbus Crohn, sprue, ileojejunal bypass, mucoviscidosis, intestinal infections),
• total parenteral feeding,
• diseases of the pancreas, alcoholism.

As promoters of the development of the skin’s base layers, vitamin A and a number of its derivatives are frequently used in dermatology. Vitamin A has been used successfully in the treatment of psoriasis, pityriasis, pemphigoid, and ichthyosis as well as follicular hyperkeratosis and acne.

The use of vitamin A in the food industry is subject to controls due to the risk of overdose. Currently, it may only be used in certain product groups. Depending on the country, these product groups include food products for babies and small children, dietetic food products for weight loss, balanced diets, margarine, spreads, milk, and dairy products.

In cosmetic products, vitamin A is used primarily for the care of sensitive dry skin. It is said to promote regeneration of the skin, increase local blood circulation, and improve the skin’s tone.

Properties
Vitamin A is sensitive to oxygen and other oxidizing agents, particularly with simultaneous exposure to light and heat. Antioxidants, such as alpha-tocopherol and BHT (t-butylhydroxytoluene), are frequently added for protection against oxidation. Vitamin A is stable toward bases, but very sensitive toward acids. Retinol and its esters are readily soluble in fats, oils, and solvents, which dissolve fats at room temperature. However, they are practically insoluble in water.
Dry Vitamin A-Acetate 500

Chemical names of active ingredient
Retinyl acetate, all-trans retinol acetic acid ester

CAS-No. 127-47-9
EINECS-No. 204-844-2

PRD-Nos. Articles
30041009 Dry Vitamin A-Acetate 500, 40 Mesh
50050735 25 kg bag in box
30041011 Dry Vitamin A-Acetate 500, 60 Mesh
50050523 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.344 µg vitamin A-acetate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition
Ingredients in descending order of weight: sucrose, gelatin, vitamin A-acetate, modified starch, t-butyl-hydroxytoluene (BHT), sodium aluminum silicate.

Solubility
Dispersible in warm water (35 – 40 °C), to form a milky emulsion.

Specification
Assay min. 500,000 IU vitamin A (= 150,000 RE) per gram


Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with BHT (E321). The stability of vitamin A in the dry powder is excellent even in the presence of minerals. The product has a high mechanical integrity and little or none of the vitamin A is expressed during tabletting, resulting in good stability of the tablets.

Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.
Applications

*Dietary supplements:*
Because of its excellent tabletting properties, this product is suitable for direct compression. It has been especially developed for use in high-dosage vitamin A tablets, multivitamin/mineral tablets, and hard gelatin capsules.

**Note**
Dry Vitamin A-Acetate 500 must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Acetate 325 GFP

Chemical names of active ingredient
Retinyl acetate, all-trans retinol acetic acid ester

CAS-No. 127-47-9
EINECS-No. 204-844-2

PRD-No. 30056973*

* The product is kosher.

Article 50051212 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.344 µg vitamin A-acetate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification
Assay min. 325,000 IU vitamin A (= 97,500 RE) per gram


Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with DL-alpha-tocopherol (E307). It is sensitive to moisture, atmospheric oxygen, heat, and light.

Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.

Applications
Food products:
The product has been developed for the fortification of food products including dietetic products and dried milk, as well as vitamin mixtures for the food industry. Regulatory provisions for the use of tricalcium phosphate (E341) in the different product categories have to be considered. In the EU, the application in infant foods is limited to fortification with vitamin A and calcium. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.
**Dietary supplements:**
For use in multivitamin preparations where cold-water dispersibility is required.

**Note**
Dry Vitamin A-Acetate 325 GFP must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Acetate 325 GFP/E

Chemical names of active ingredient
Retinyl acetate, all-trans retinol acetic acid ester

CAS-No. 127-47-9
EINECS-No. 204-844-2

PRD-No. 30253192*

* The product is kosher.
Sold in the US and the EU only.

Article 50491815 25 kg bag in box

Country of origin Denmark

Units 1 International Unit (IU) = 0.344 µg vitamin A-acetate

Description Free-flowing, light-yellow powder, consisting of spherical particles.


Solubility The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification Assay min. 325,000 IU vitamin A (= 97,500 RE) per gram

Monographs The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density Approx. 0.6 g/ml

Stability The product is stabilized with DL-alpha-tocopherol (E307). It is sensitive to moisture, atmospheric oxygen, heat, and light. Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.

Applications

Food products:
The product has been developed for the fortification of food products including dietetic products and dried milk, as well as vitamin mixtures for the food industry. In the EU, the application in infant foods is limited to fortification with vitamin A and calcium. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Dietary supplements:
For use in multivitamin preparations where cold-water dispersibility is required.

Note
Dry Vitamin A-Acetate 325 GFP/E must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Acetate
250 DC/GFP

Chemical names of active ingredient
Retinyl acetate, all-trans retinol acetic acid ester

CAS-No. 127-47-9
EINECS-No. 204-844-2

PRD-No. 30281866*

* The product is kosher.

Article
53285286 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.344 µg vitamin A-acetate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition
Ingredients in descending order of weight:
sugar, acacia gum, starch, vitamin A-acetate,
sodium ascorbate, sodium aluminum silicate,
DL-alpha-tocopherol, sodium citrate.

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification
Assay min. 250,000 IU vitamin A (= 75,000 RE) per gram


Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with DL-alpha-tocopherol (E307). Stored in its original packaging in a cool place (max. 15 °C), the product is stable for at least 24 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.
Applications

*Dietary supplements:*

The product has been designed for direct compression of multivitamin mineral tablets as well as for hard-shell capsules. It is also suitable for single entities sugar- or film-coated tablets.

**Note**

Dry Vitamin A-Acetate 250 DC/GFP must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Acetate 250 FM

**Chemical names of active ingredient**
Retinyl acetate, all-trans retinol acetic acid ester

**CAS-No.** 127-47-9
**EINECS-No.** 204-844-2

**PRD-No.** 30280824*

* The product is kosher.

**Article**
53253539 25 kg bag in box

**Country of origin**
Denmark

**Units**
1 International Unit (IU) = 0.344 µg vitamin A-acetate

**Description**
Free-flowing, light-yellow powder, consisting of spherical particles.

**Composition**
Ingredients in descending order of weight: corn starch, gum arabic, sucrose, vitamin A-acetate, modified starch, t-butyl-hydroxytoluene (BHT), sodium ascorbate, tricalcium phosphate, trisodium citrate, sodium hydroxide.

**Solubility**
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

**Specification**
Assay min. 250,000 IU vitamin A (= 75,000 RE) per gram


**Monographs**
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with BHT (E321). It is sensitive to moisture, atmospheric oxygen, heat, and light.

Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

**Storage/Handling**
The product should be stored in the original packaging in a cool (8 – 15 °C), dark, dry place.

**Applications**
**Food products:**
This fine powder has been developed for the fortification of flour and milk, as well as for use in vitamin mixtures for the food industry. As it does not contain proteins, the product is suitable for use in hypoallergenic foods. The regulations governing the use of BHT must be observed.

**Note**
Dry Vitamin A-Acetate 250 FM must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Palmitate 500

Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmitic acid ester

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<td>201-228-5</td>
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PRD-No.
30041047

Article
50048562  25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition
Ingredients in descending order of weight:
vitamin A-palmitate, sucrose, modified starch, gelatin, t-butyl-hydroxytoluene (BHT), sodium aluminum silicate.

Solubility
Dispersible in warm water (35 – 40 °C), to form a milky emulsion.

Specification
Assay  min. 500,000 IU vitamin A (= 150,000 RE) per gram


Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with BHT (E321). The stability of the vitamin A in the dry powder is excellent even in the presence of minerals. The product is resistant to pressure and very little vitamin A is expressed during tabletting, thus resulting in good stability of the tablets.

Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.
Applications

*Dietary supplements:*
Should the product be subject to severe strain during processing or storage, it is recommended to use the palmitate version of the vitamin. Since the palmitate contained in vitamin A is the ester with the best resistance to hydrolysis, vitamin A-palmitate is recommended particularly for preparations with a high moisture content as well as preparations, which will be stored in environments with a high relative humidity. It is equally suitable for use in multivitamin/mineral tablets and hard gelatin capsules.

**Note**
Dry Vitamin A-Palmitate 500 must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Palmitate
250 Food Grade

Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmitic acid ester

<table>
<thead>
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<th>CAS-No.</th>
<th>79-81-2</th>
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<tr>
<td>EINECS-No.</td>
<td>201-228-5</td>
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</table>

PRD-No. 30041045*
* The product is kosher.

Article 50051265 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification
Assay min. 250,000 IU vitamin A (= 75,000 RE) per gram

Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with DL-alpha-tocopherol (E307). It is sensitive to moisture, atmospheric oxygen, heat, and light.

Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling
The product should be stored in the original packaging in a cool (8 – 15 °C), dark, dry place.

Applications

Food products:
The product has been developed for the fortification of dry or powdered food products that need to be dissolved or dispersed in water prior to use, such as dried milk, dietetic products, cocoa powder etc. Regulatory provisions for the use of tricalcium phosphate (E341) in the different product categories have to be considered. In the EU the application in infant foods is limited to fortification with vitamin A and calcium. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Note
Dry Vitamin A-Palmitate 250 Food Grade must be handled in accordance with the Safety Data Sheet.
Dry Vitamin A-Palmitate
250 MS CWD

Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmitic acid ester

CAS-No. 79-81-2
EINECS-No. 201-228-5

PRD-No. 30242287*

* The product is kosher.

Article
57335333 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

Description
Free-flowing, very fine, light-yellow powder, consisting of spherical particles, possibly containing a few whitish particles.

Composition
Ingredients in descending order of weight: modified starch, dextrin, vitamin A-palmitate, sucrose, medium-chain triglyceride, t-butyl-hydroxytoluene (BHT), sodium aluminum silicate.

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification
Assay min. 250,000 IU vitamin A (= 75,000 RE) per gram


Monographs
The product complies with the current “Vitamin A concentrate (powder form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with BHT (E321). It is sensitive to moisture, atmospheric oxygen, heat, and light. Stored in its original packaging in a cool (8 – 15 °C), dry place, the product is stable for at least 24 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place. It is recommended to use up the remaining contents quickly once the package has been opened.
Applications

Food products:
This fine powder has been developed for the fortification of sugar. The regulations governing the use of BHT must be observed.

Note
Dry Vitamin A-Palmitate 250 MS CWD must be handled in accordance with the Safety Data Sheet.
Vitamin A-Palmitate
250 GFP BG

Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmic acid ester

CAS-No. 79-81-2
EINECS-No. 201-228-5

PRD-No. 30193213*
* The product is kosher.
Sold in North America only.

Sold in North America only.

Country of origin
North America

Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

Description
Free-flowing, light-yellow powder, consisting of spherical particles.

Composition
Ingredients in descending order of weight: modified starch, sucrose, vitamin A-palmitate, medium-chain triglyceride, t-butyl-hydroxytoluene (BHT), silicon dioxide, sodium ascorbate, sorbic acid, sodium benzoate

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion.

Specification
Assay min. 250,000 IU vitamin A (= 75,000 RE) per gram


Monographs
The product complies with the current “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with BHT (E321). Stored in its original packaging in a cool place (max. 15 °C), the product is stable for at least 18 months.

Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, the product should be stored in the original packaging in a cool (8 – 15 °C), dry, and dark place.
It is recommended to use up the remaining contents quickly once the package has been opened.
Applications
Specially developed for the fortification of dairy and/or soy-based beverages, for fortifying dry or powdered food products and vitamin mixtures for the food industry that must be dissolved or dispersed in water prior to use. Suitable for hypoallergenic foods as it contains no proteins. The regulations governing the use of BHT must be observed.

Note
Dry Vitamin A-Palmitate 250 GFP BG must be handled in accordance with the Safety Data Sheet.
Chemical names of active ingredient
Retinyl acetate, all-trans retinol acetic acid ester

CAS-No. 127-47-9
EINECS-No. 204-844-2

PRD-No. 30041021*
* The product is kosher.

Article  
55796214  5 kg plastic can  
55796108  25 kg plastic bucket

Country of origin
Germany

Units
1 International Unit (IU) = 0.344 µg vitamin A-acetate

Description
Yellow, oily liquid at room temperature, with a mild odor. At the recommended storage temperatures, some of the vitamin A-acetate may crystallize. The assay is adjusted by adding pharmaceutical-grade sunflower oil.

Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvent should not contain peroxides. Insoluble in water.

C_{22}H_{32}O_2  Molar mass 328.5 g/mol

Specification
Assay  min. 1.5 million IU vitamin A (= 450,000 RE) per gram


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “Vitamin A concentrate (oily form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Stability
Stored in its unopened original packaging in a cool (8 – 15 °C), dry place, Vitamin A-Acetate 1.5 million IU/g is stable for at least 24 months.
Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, it should be stored in a cool (8 – 15 °C), dark place in the unopened original packaging. Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.

Prior to use or sampling, the product must be heated to 70 – 80 °C in the unopened container in a water bath and homogenized.

Applications
Dietary supplements:
For preparations with a lipophilic base, e.g., soft gelatin capsules.

Food products:
Used for the fortification of fats (margarine and spreads) and oils. 3 – 9 mg (10,000 – 30,000 IU) of vitamin A (calculated as retinol) is usually added per kg of margarine. The regulations governing the use of BHT must be observed.

Cosmetics:
For use in cosmetic oils, emulsions (creams, lotions, body milk, gels, etc.) and other preparations, e.g., lipstick, masks. The maximum quantities legally permitted for use in cosmetics must be observed.

Note
Vitamin A-Acetate 1.5 Mio IU/G stabilized with BHT in oil must be handled in accordance with the Safety Data Sheet.
### Chemical names of active ingredient
Retinyl palmitate, all-trans retinol palmitic acid ester

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>EINECS-No.</th>
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<tbody>
<tr>
<td>79-81-2</td>
<td>201-228-5</td>
</tr>
</tbody>
</table>

### PRD-Nos. | Articles
--- | ---
30041032* | Vitamin A-Palmitate 1.7 Mio IU/G unstab.
55857270 | 5 kg plastic can
55857164 | 25 kg plastic bucket

30041041* | Vitamin A-Palmitate 1.7 Mio IU/G stabilized with BHT
56283231 | 5 kg plastic can
56283178 | 25 kg plastic bucket

30041031* | Vitamin A-Palmitate 1.7 Mio IU/G stabilized with Tocopherol
55800295 | 5 kg plastic can
55800242 | 25 kg plastic bucket

* The product is kosher.

### Country of origin
Germany

### Units
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

### Description
Viscous, yellow oil at room temperature. At the recommended storage temperatures, some of the vitamin A-palmitate may crystallize.

### Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvent should not contain peroxides. Insoluble in water.

### Specification
**Assay**
- min. 1.7 million IU vitamin A (= 510,000 RE) per gram


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

### Monographs
The product complies with the current “Vitamin A concentrate (oily form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

### Regulations
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

### Stability
Vitamin A-Palmitate 1.7 million IU/g is unstabilized. However, it can be supplied with approx. 10 mg t-butylhydroxytoluene (BHT, E321) or with approx. 10 mg of DL-alpha-tocopherol (E307) per 1.0 million IU upon request.

Stored in its unopened original packaging in a cool (8 – 15 °C), dry place, all grades of Vitamin A-Palmitate 1.7 Mio IU/g are stable for at least 24 months.
Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, it should be stored in a cool, dark place in the unopened original packaging. Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.

Prior to use or sampling, the product must be heated to 40 °C in the unopened container in a water bath and homogenized.

Applications

**Dietary supplements:**
For preparations with a lipophilic base, e.g., soft gelatin capsules.

**Pharmaceutical products:**
Both EU Drug Master File and US Drug Master File are available. The product is particularly suitable for manufacturing aqueous solutions using solubilizing agents, such as Cremophor® EL or Cremophor RH 40 for oral administration, and Solutol® HS 15 for parenteral use. The chart shows the required quantity of Cremophor RH 40 for the solubilization of proportional quantities of vitamin A-palmitate. Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

**Food products:**
Used for the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products. Of 3 – 9 mg (10,000 – 30,000 IU) of vitamin A, calculated as retinol, are usually added per kg of margarine. The regulations governing the use of BHT must be observed.

**Cosmetics:**
For use in cosmetic oils, emulsions (creams, lotions, body milk, gels, etc.), and other preparations, e.g., lipstick, masks. A solubilizing agent is required if the product is to be used in an aqueous/alcoholic preparation. The maximum quantities legally permitted for use in cosmetics must be observed.

![Chart showing the required quantity of Cremophor RH 40 for the solubilization of proportional quantities of vitamin A-palmitate.]

**Note**
Vitamin A-Palmitate 1.7 Mio IU/G must be handled in accordance with the Safety Data Sheet.
**Vitamin A-Palmitate 1.0 Mio IU/G**

**Chemical names of active ingredient**
Retinyl palmitate, all-trans retinol palmitic acid ester

**CAS-No.** 79-81-2  
**EINECS-No.** 201-228-5

**PRD-Nos.**  
30041040* Vitamin A-Palmitate 1.0 Mio IU/G stabilized with BHT  
55799871  5 kg plastic can  
55798705  25 kg plastic bucket  

30041043* Vitamin A-Palmitate 1.0 Mio IU/G stabilized with Tocopherol  
55856899  5 kg plastic can  
55856634  25 kg plastic bucket

* The product is kosher.

**Country of origin**
Germany

**Units**  
1 International Unit (IU) = 0.550 µg vitamin A-palmitate

**Description**
Viscous, yellow oil at room temperature. At the recommended storage temperatures, some of the vitamin A-palmitate may crystallize. The assay is adjusted by adding pharmaceutical-grade sunflower oil.

**Solubility**
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvent should not contain peroxides. Insoluble in water.

**Molar mass**
\[ C_{36}H_{60}O_2 \]  
524.9 g/mol

**Specification**
Assay min. 1.0 million IU vitamin A (= 300,000 RE) per gram


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

**Monographs**
The product complies with the current “Vitamin A concentrate (oily form), synthetic” Ph. Eur. and “Vitamin A” USP monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin A source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Stability**
Vitamin A-Palmitate 1.0 Mio IU/g is stabilized with approx. 10 mg t-butylhydroxytoluene (BHT, E321) or with approx. 10 mg of DL-alpha-tocopherol (E307) per 1.0 million IU. However, it may be supplied unstabilized upon request.

Stored in its unopened original packaging in a cool (8 – 15 °C), dry place, all grades of Vitamin A-Palmitate 1.0 million IU/g are stable for at least 24 months.
Storage/Handling
As vitamin A is sensitive to atmospheric oxygen, light, moisture, and heat, it should be stored in a cool, dark place in the unopened original packaging. Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.

Prior to use or sampling, the product must be heated to 40 °C in the unopened container and homogenized.

Applications
Dietary supplements:
For preparations with a lipophilic base, e.g., soft gelatin capsules.

Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

Food products:
Used for the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products. Quantities of 3 – 9 mg (10,000 – 30,000 IU) of vitamin A, calculated as retinol, are usually added per kg of margarine. The regulations governing the use of BHT must be observed.

Cosmetics:
For use in cosmetic oils, emulsions (creams, lotions, body milk, gels, etc.), and other preparations, e.g., lipstick, masks. The maximum quantities legally permitted for use in cosmetics must be observed.

Note
Vitamin A-Palmitate 1.0 Mio IU/G in oil must be handled in accordance with the Safety Data Sheet.
# Vitamin A-Propionate

2.5 Mio IU/G stabilized with BHT

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**Chemical name of active ingredient**
Retinyl propionate, all-trans retinol propionic acid ester

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**PRD-No.**
30041062*

* The product is kosher.

**Articles**

<table>
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<td>5 kg plastic can</td>
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<tr>
<td>55796320</td>
<td>25 kg plastic bucket</td>
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</table>

**Country of origin**
Germany

**Units**
1 International Unit (IU) = 0.359 µg vitamin A-propionate

**Description**
Viscous, yellow oil at room temperature, with a mild odor.

**Solubility**
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvent should not contain peroxides. Insoluble in water.

**Specification**
Assay min. 2.5 million IU vitamin A (= 750,000 RE) per gram

For further information see separate document: "Standard Specification" (not for regulatory purposes) available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

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Unles otherwise stated, the methods of analysis can be found in the Ph. Eur.
Applications

Dietary supplements:
For use in liquid preparations (syrups, oily solutions, drops, emulsions), particularly highly concentrated aqueous solutions made with the aid of a solubilizer, such as Cremophor® EL, Cremophor RH 40, or Solutol® HS 15.
The chart shows the required quantity of Solutol HS 15 for the solubilization of proportional quantities of vitamin A esters.

The propionic acid ester is particularly recommended to counter the crystallizing tendency of vitamin A-acetate and palmitate, which causes processing problems.

Food products:
Used for the fortification of oils and fats (margarine, spreads). Quantities of 3 – 9 mg (10,000 – 30,000 IU) of vitamin A, calculated as retinol, are usually added per kg of margarine.
The regulations governing the use of BHT must be observed.

Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

Cosmetics:
For use in cosmetic oils, emulsions (creams, lotions, body milk, gels, etc.), and other preparations, e.g., lipstick, masks. The maximum quantities legally permitted for use in cosmetics must be observed.

Note
Vitamin A-Propionate must be handled in accordance with the Safety Data Sheet.
Customized oily blends

Vitamin components
- Vitamin A:
  - Vitamin A-acetate
  - Vitamin A-palmitate
  - Vitamin A-propionate
- Vitamin D₃
- Vitamin E:
  - Vitamin E-acetate
  - DL-α-tocopherol
- Vitamin K₁
- Beta-carotene

Description
Depending on their composition, the oily vitamin blends vary in viscosity and their colors range from yellow to orange. Blends containing beta-carotene tend to be orange.

If stored at low temperature, vitamin A forms crystals in the mixture. These may be redissolved by heating the mixture slowly to approximately 40 °C, which is the optimal processing temperature.

Composition
We manufacture customized blends of the above vitamins according to the needs of the customer, using vegetable oils as the carrier. The standard oil is sunflower oil, but others may be used upon request.

Solubility
Soluble in a wide range of organic solvents. Insoluble in water. The solvents should not contain peroxides.

Monographs
All vitamins used comply with the relevant monographs described in one or more of the main international pharmacopoeias, i.e., USP, Ph. Eur., and FCC.

Specification
| Assay | min. 100% of the declared content of each vitamin |

Stability
The oily vitamin blends are available both stabilized with DL-α-tocopherol (E307) or butylhydroxytoluene (BHT, E321) as well as unstabilized. Stored in their unopened original packaging at 5 °C, the products are stable for up to 24 months.

Storage/Handling
As some of the fat-soluble vitamins are sensitive to light, heat, moisture, and oxygen, the oily blends should be stored tightly sealed in a cool, dry place. Once the packaging has been opened, it is recommended to use the remaining contents as quickly as possible.

Applications
Particularly suitable for the fortification of food products with a high fat content, e.g., margarine, spreads, edible oils, mayonnaise, salad dressings, cheese spreads, etc.

Dosages for the fortification of margarine:

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>10,000 – 30,000 IU/kg (3 – 9 mg/kg)</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>1,000 – 3,000 IU/kg (25 – 75 µg/kg)</td>
</tr>
</tbody>
</table>

The vitamin blends can easily be incorporated into the fatty phase of the food product as they are miscible in all proportions with all oils and fats. By means of special technology, the vitamin blends may also be used to fortify products with little or no fat content.

Examples include:
- **Dairy products**
  The vitamin blend is emulsified in the milk.
- **Breakfast cereals**
  The vitamin blend is sprayed onto the product.
- **Vegetable oils**
  The vitamin blend is added to the vegetable oil.
- **Products based on dried milk**
  The vitamin blend is emulsified in the milk prior to drying.
Daily requirement of fat-soluble vitamins

The tables below show the Recommended Dietary Allowances (RDA).

### Recommended Dietary Allowances

#### Vitamin A

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg RAE¹,²/day</td>
<td>µg RE³,⁴/day</td>
</tr>
<tr>
<td>Men</td>
<td>900</td>
<td>1,000</td>
</tr>
<tr>
<td>Women</td>
<td>700</td>
<td>800</td>
</tr>
</tbody>
</table>

¹ Recommended Dietary Allowance (RDA)
² 1 µg RAE (Retinol Activity Equivalent) = 1 µg retinol = 2 µg supplemental beta-carotene = 12 µg dietary beta-carotene = 24 µg other dietary provitamin A carotenoids
³ Recommended Intake
⁴ 1 µg RE (Retinol Equivalent) = 1 µg retinol = 6 µg beta-carotene = 12 µg other provitamin A carotenoids = 1.15 µg retinyl acetate = 1.83 µg retinyl palmitate

#### Vitamin D

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg¹,²/day</td>
<td>µg³,⁴/day</td>
</tr>
<tr>
<td>Men</td>
<td>5 (≥ 51y)</td>
<td>10 (≥ 65y)</td>
</tr>
<tr>
<td></td>
<td>10 (&gt; 70y)</td>
<td>15 (≥ 70y)</td>
</tr>
<tr>
<td>Women</td>
<td>5 (≥ 51y)</td>
<td>10 (≥ 65y)</td>
</tr>
<tr>
<td></td>
<td>10 (&gt; 70y)</td>
<td>15 (≥ 65y)</td>
</tr>
</tbody>
</table>

¹ 1 µg = 40 IU
² Adequate Intake (AI): intake by healthy people assumed to be adequate; used when an RDA cannot be determined
³ Recommended Intake

#### Vitamin E

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>mg¹,²/day</td>
<td>mg TE³,⁴/day</td>
</tr>
<tr>
<td>Men</td>
<td>15</td>
<td>13 – 15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 (∈ 65y)</td>
</tr>
<tr>
<td>Women</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11 (∈ 65y)</td>
</tr>
</tbody>
</table>

¹ Alpha-tocopherol including RRR-alpha-tocopherol and other 2R-stereoisomeric forms of alpha-tocopherol
² Recommended Dietary Allowance
³ 1 mg TE (RRR-alpha-Tocopherol Equivalent) = 1 mg RRR-alpha-tocopherol = 2 mg RRR-beta-tocopherol = 4 mg RRR-gamma-tocopherol = 3.3 mg RRR-alpha-tocotrienol = 1.1 mg RRR-alpha-tocopheryl acetate = 1.49 mg all-rac-alpha-tocopheryl acetate = 1.49 IU
⁴ Estimated values for an adequate intake

#### Vitamin K

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg¹/day</td>
<td>µg²/day</td>
</tr>
<tr>
<td>Men</td>
<td>120</td>
<td>70 – 80</td>
</tr>
<tr>
<td>Women</td>
<td>90</td>
<td>60 – 65</td>
</tr>
</tbody>
</table>

¹ Adequate Intake (AI): intake by healthy people assumed to be adequate; used when an RDA cannot be determined
² Estimated values for an adequate intake

The Recommended Dietary Allowances (RDA) and the Adequate Intakes (AI) are part of the Dietary Reference Intakes (DRI), released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences.

They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).

The D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.
Regulations
In many countries, the use of oily vitamin blends is subject to different regulations restricting the quantities of vitamins and t-butylhydroxytoluene stabilizer, which may be added to food products.

Note
Because some of the vitamin A may have crystallized during storage, the oily vitamin blends must be heated to 40 °C in the closed container and homogenized prior to use or sampling.

The oily vitamin blends must be handled in accordance with the respective Safety Data Sheet.
Oily Vitamin Blend 02-185

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>Vitamin A</th>
<th>79-81-2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vitamin D₃</td>
<td>67-97-0</td>
</tr>
<tr>
<td>EINECS-No.</td>
<td>Vitamin A</td>
<td>201-228-5</td>
</tr>
<tr>
<td></td>
<td>Vitamin D₃</td>
<td>204-673-2</td>
</tr>
<tr>
<td>PRD-No.</td>
<td>30082219*</td>
<td></td>
</tr>
</tbody>
</table>

* The product is kosher.

Articles
56052469  5 kg plastic can
56052416  25 kg plastic bucket

Description
Viscous, yellow oil at room temperature. When stored in a cool place as recommended, some of the vitamin A-palmitate may crystallize.

Composition
Ingredients in descending order of weight: sunflower oil, vitamin A-palmitate, vitamin D₃ (cholecalciferol)

Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, ethers, fats, and oils. The solvents should not contain peroxides. Insoluble in water.

Specification
Assay at least 100% of the declared value of each component


Monographs
The vitamins contained in the oily vitamin blend comply with the current USP and Ph. Eur. monographs. Vitamin A-palmitate complies with the current “Vitamin A Concentrate (oily form), synthetic” Ph. Eur. and “Vitamin A” USP monographs. Vitamin D₃ complies with the “Cholecalciferol” Ph. Eur. and the “Cholecalciferol” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin A and D source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Stability
Stored in its unopened original packaging in a cool place (8 – 15 °C), the product is stable for at least 24 months.

Storage/Handling
As the vitamins are sensitive to atmospheric oxygen, light, and heat, the oily vitamin blend should be stored in its unopened original packaging in a cool place (8 – 15 °C). Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.

Prior to use or sampling, the product needs to be homogenized by means of heating the unopened container to 40 °C with agitation, because it may be partially crystallized.

Applications
For the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products.

Note
Oily Vitamin Blend 02-185 must be handled in accordance with the Safety Data Sheet.
**Chemical names of active ingredient**
Riboflavin, lactoflavin

**Physiological importance**
In the form of flavin mononucleotide (FMN) or flavin adenine dinucleotide (FAD), riboflavin is a coenzyme in a large number of oxidizing and reducing enzymes, which are called flavoproteins.

Some of the flavoproteins play a role in the transfer of hydrogen atoms during the energy-generating oxidation processes within the cell, known as the respiratory chain. Therefore, riboflavin—along with other B-complex vitamins—acts as a coenzyme in the protein, fat, and carbohydrate metabolisms, as well as in the generation of energy via ATP.

Due to its high concentration in the eye, medical experts are considering the possibility that it is involved in the visual process, possibly transmitting light stimuli to the visual nerves.

Furthermore, riboflavin is involved in the metabolism of other B-vitamins (folic acid, pyridoxine, and niacin) and in the production of hormones in the adrenal cortex.

**Occurrence**
Vitamin B₂ occurs in free form or as FMN and FAD in all vegetable and animal organisms. Rich sources include yeast, milk, and dairy products, as well as eggs, meat (particularly the viscera, i.e., liver, heart, and kidneys), fish, certain vegetables (green cabbage, beans, peas), as well as wholemeal products.

In grain, the vitamin is found mainly in the germ and in the aleuronic layer. Therefore, white flour contains only about one third of the riboflavin contained in the whole grain. Most types of fruit and vegetable contain little vitamin B₂.

**Recommended dosages**
Due to the importance of riboflavin for protein metabolism and energy generation, the intake recommendations depend on the protein and energy content of the diet, as well as metabolic rate and body weight.

The minimum amount of riboflavin required for an adult is 0.6 mg per 1,000 Kcal (4,200 joules). To maintain the basic metabolic rate and to ensure proper metabolism, the intake of vitamin B₂ should not be less than 1.2 mg per day, even if the daily energy intake is below 2,000 Kcal (8,400 joules/day).

**Dietary reference values for vitamins**
The tables below provide recommended intake levels as well as reference values for nutrition labeling.
Recommended intake levels

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>mg¹/day</td>
<td>mg²/day</td>
</tr>
<tr>
<td>Men</td>
<td>1.3</td>
<td>1.3 – 1.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.2 (≥ 65y)</td>
</tr>
<tr>
<td>Women</td>
<td>1.1</td>
<td>1.2</td>
</tr>
</tbody>
</table>

¹ Recommended Dietary Allowances
² Recommended Intake

The Recommended Dietary Allowances (RDA) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).

The Recommended Intakes within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

Current labeling values

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
<th>RDA (2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe</td>
</tr>
<tr>
<td>Unit</td>
<td>mg</td>
<td>mg</td>
</tr>
<tr>
<td>Nutrition Labeling</td>
<td>1.7</td>
<td>1.4</td>
</tr>
</tbody>
</table>

The Reference Daily Intake (RDI) is the value established by the FDA for use in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for nutrition labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

An increased amount of riboflavin is required during pregnancy, lactation, and adolescence. Increased riboflavin is needed after an infection, surgery and trauma, and in chronic alcohol abuse, increased thyroid activity, and for supplementing a diet containing large amounts of fat.

The amount of riboflavin required is mainly covered with the consumption of milk, dairy products, and cheese (accounting for approximately 30% of the supply), followed by meat and meat products (approximately 20%). Deficiency is most often found in persons with a low consumption of milk or dairy products.

Deficiency symptoms

Vitamin B₂ deficiency very rarely occurs on its own. It is observed only in conjunction with a diet low in riboflavin (less than 0.5 mg riboflavin/day) and occurs together with other dietary deficiency symptoms frequently associated with insufficient supply of other B-complex vitamins.

Characteristic disorders may become apparent after a delay of several weeks and include:

- changes inside the mouth such as inflammation of the buccal and nasal mucous membranes, changes on the lips, tongue, and in the gastrointestinal tract, e.g., purple tongue, glossitis, stomatitis, and cheilosis,
- changes of the skin, e.g., lesions at the corner of the mouth, seborrhoeic dermatitis in the areas of naso-labial groove and ears, as well as dystrophia of the finger nails,
- changes in the eyes, e.g., keratitis, opacification of the lens, vascularization of the cornea with a sensation of foreign bodies, cataract with vitreous opacity, and photophobia.
- neurological disorders including abnormal sensations (paresthesia) in the legs, burning sensation in the feet, ataxia and tremors, as well as changes in the hemogram (disturbed iron metabolism, erythrocyte formation, and erythrocyte life span) may be observed as well.
Riboflavin deficiency may also be caused by chronic alcohol abuse, the use of oral contraceptives, stress, diseases of the thyroid gland (overactivity), diabetes, imperforation of the bile tract, hyperbilirubinemia in babies, as well as chronic inflammation of the small intestine.

**Toxicity**
No side effects have been described for oral administration of riboflavin in humans. Vitamin B<sub>2</sub> is neither toxic nor mutagenic, teratogenic, or carcinogenic.

The ULS (Upper Level for Supplements) has been estimated at 200 mg (CRN) and the Guidance Level for Supplements at 40 mg (Expert Committee on Vitamins and Minerals, UK). FNB (US) and SCF (EC) have reviewed the safety but did not establish a Tolerable Upper Intake Level (no toxicological basis).

**Indications**
Vitamin B<sub>2</sub> is used both for the prevention and therapy of riboflavin deficiency disorders of various origins, which cannot be alleviated with a modification of the diet such as:
- unbalanced and improper diet (alcoholism in conjunction with very low intake of milk and dairy products, etc.),
- increased requirement during pregnancy and lactation, high performance sport, chronic hemodialysis, etc.,
- impaired absorption of riboflavin and chronic inflammation of the small intestine (Morbus Crohn, sprue, intestinal disorders),
- phototherapy of hyperbilirubinemia in newborns (neonatal jaundice),
- long-term use of certain drugs, such as oral contraceptives, tricyclic antidepressants, etc.

For the fortification of ingredients and food products in the food industry, vitamin B<sub>2</sub> is frequently used in combination with other vitamins. The products include flour, breakfast cereals, baked goods, baby food, dietetic products, multivitamin juices and beverages, as well as confectionery.

Riboflavin in concentrations of 10 – 50 ppm is also used as a food colorant in instant products, soup and beverage powders, custard powder, preserves, etc.

If riboflavin is used as a colorant, please note that it is sensitive to light. In milk products containing active microorganisms (e.g., lactobacilli), riboflavin may be decolorized due to a reversible reduction reaction.
Riboflavin Fine Powder

Chemical names of active ingredient
Riboflavin, lactoflavin

EU name
Riboflavin E101

CAS-No. 83-88-5
EINECS-No. 201-507-1

PRD-No. 30214973*

* The product is kosher.

Article 54402422 25 kg bag in box

Country of origin
South Korea

Description
Yellow or orange-yellow, fine powder with a slight odor and a persistent bitter taste. Riboflavin Fine Powder is produced in a fermentation process using the microorganism Ashbya Gossypii. This unique production process guarantees a product of highest quality and purity.

Solubility
Somewhat soluble in water, virtually insoluble in alcohol.

Specification
Assay 98 – 102%


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

C_{17}H_{20}N_{4}O_{6}  Molar mass 376.4 g/mol

Monographs
The product complies with the current “Riboflavin” Ph. Eur., the “Riboflavin” USP, the “Riboflavin” FCC, and the “Riboflavin” Ph.JP monographs, as well as the “E101” EU directives for food colorants.

Regulations
Riboflavin is approved for use as a food colorant and as vitamin B2 source in most countries. However, specific regulations in the respective countries and for the intended use have to be observed.

Stability
Stored in its unopened original packaging at room temperature (max. 25 °C), protected from light and moisture, the product is stable for at least 36 months.
Because the product is hydroscopic, it is recommended to hermetically reseal the remaining product in the packaging. Riboflavin is resistant to heat in acid solutions in the absence of light. It is sensitive to alkaline substances, heavy metal salts, and light. Reducing agents convert it to colorless leuco compounds.
Storage/Handling
The product should be transported and stored in the tightly sealed original packaging at a temperature below 25 °C, protected from light and moisture.

Applications
Food products:
Riboflavin Fine Powder was developed for the fortification of powder food products and staple food, such as flour. Because of its fine particle size, it is particularly suitable for use as colorant in powder food products or powders, which must be dissolved in water or milk prior to consumption.

Pharmaceutical products:
Both an EU-Drug Master File (CTD) and a US-Drug Master File (CTD) are available.

Note
Riboflavin Fine Powder must be handled in accordance with the Safety Data Sheet.
Riboflavin High Flow 100

Chemical names of active ingredient
Riboflavin, lactoflavin

EU name
Riboflavin E101

CAS-No. 83-88-5
EINECS-No. 201-507-1

PRD-No. 30214976*

* The product is kosher.

Article
57903970 25 kg bag in box

Country of origin
South Korea

Description
Yellow or orange-yellow, free-flowing, fine granular powder with a slight odor and a persistent bitter taste. Riboflavin High Flow 100 is produced in a fermentation process using the microorganism Ashbya Gossypii. This unique production process guarantees a product of highest quality and purity.

Solubility
Somewhat soluble in water, virtually insoluble in alcohol.

Specification
Assay 98 – 102%


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “Riboflavin” Ph. Eur., the “Riboflavin” USP, the “Riboflavin” FCC, and the “Riboflavin” Ph.JP. monographs, as well as the “E101” EU directives for food colorants.

Regulations
Riboflavin is approved for use as a food colorant and as vitamin B2 source in most countries. However, specific regulations in the respective countries and for the intended use have to be observed.

Stability
Stored in its unopened original packaging at room temperature (max. 25 °C), protected from light and moisture, the product is stable for at least 36 months. Since the product is hygroscopic, it is recommended to hermetically reseal the remaining product in the packaging. Riboflavin is resistant to heat in acid solutions in the absence of light. It is sensitive to alkaline substances, heavy metal salts, and light. Reducing agents convert it to colorless leuco compounds.
Storage/Handling
The product should be transported and stored in the tightly sealed original packaging at a temperature below 25 °C, protected from light and moisture.

Applications
Dietary supplements:
The product can be used in all solid and liquid dosage forms such as tablets, hard-shell capsules, effervescent and other instant formulae. Riboflavin High Flow 100 has been developed for the direct compression of high-dosage vitamin B complex tablets. It is ideal for use in multivitamin formulations and equally suitable for low-concentrated solutions and fine powder grade. In addition, it can be used as a colorant in liquid form and powder preparations, which must be dissolved in water prior to use.

Food products:
Riboflavin High Flow 100 is recommended for the fortification of various food and beverage products, such as multivitamin juices, baby food, and instant-drink powders. It is also suitable for use as a colorant in liquid food products. Compared to the fine powder grade, it has the following advantages: due to better flowability, it is much easier to handle, produces less dust and lower static charge.

Pharmaceutical products:
Both an EU-Drug Master File (CTD) and a US-Drug Master File (CTD) are available.

Note
Riboflavin High Flow 100 must be handled in accordance with the Safety Data Sheet.
**Chemical names of active ingredient**
Vitamin B₅, D(+)−pantothenic acid or (R)-pantothenic acid, and calcium D-pantothenate or calcium (R)-pantothenate

**Units**
1 mg of calcium D-pantothenate = 0.92 mg of pantothenic acid
1 mg of pantothenic acid = 1.087 mg of calcium D-pantothenate

**Physiological importance**
Pantothenic acid is an essential component of coenzyme A as well as certain peptide coenzymes, in the form of which it is involved in various key reactions of the amino acid, fat, and carbohydrate metabolisms.

It has a special function in the synthesis and degradation of fats because the coenzyme A transfers C₂ units (activated acetic acid = acetyl-CoA) and activates long-chain fatty acids. Acetyl-CoA is required for the biosynthesis of fatty acids, phospholipids, cholesterol, and a number of steroid hormones.

Pantothenic acid plays an important role for the growth and normal function of body tissue. It protects the mucous membranes from infection and optimizes metabolic processes of the skin and epithelial tissue. It plays a role in regenerative processes of the skin, such as wound healing and epithelization. It is further involved in stimulating hair growth and pigmentation. The fundamental importance of pantothenic acid for metabolism is confirmed by the fact that coenzyme A is present in all types of tissue.

**Biological activity**
Due to its solubility in water, calcium D-pantothenate is readily absorbed and is effective in the metabolism as pantothenic acid. Both pantothenic acid and pantothenates are optically active compounds, which appear either as D(+) or L(−) forms. Only D-pantothenic acid occurs in nature.

The L-form does not provide vitamin activity to the human organism. The alcohol dexpanthenol or D-panthenol (provitamin B₅) does not occur in nature. In the body, it is rapidly oxidized to pantothenic acid, which is the active vitamin.

**Occurrence**
Pantothenic acid is contained in foods of both vegetable and animal origin, though in different concentrations. Particularly rich sources include viscera, i.e., liver and kidneys, egg yolk, muscle tissue, fish, milk, yeast, mushrooms, rice, wheat bran, vegetables with green leaves, and legumes. Whole meal products are considerably better sources of pantothenic acid compared to products made from grain with removed husks.

In nature, pantothenic acid exists mainly as a component of coenzyme A (CoA) or acetyl-CoA. Human and animal organisms cannot synthesize the vitamin; they can only convert pantothenic acid into the coenzyme A molecule, which plays an active role in metabolism.
**Recommended dosages**
So far, no minimum daily dosage requirements have been determined for pantothenic acid. As hardly any clinical deficiency symptoms attributed to the diet are known in humans, it is assumed that the quantities extracted from a balanced diet are adequate.

International recommendations on the adequate intake of pantothenic acid are based on dietary surveys. Suggested amounts vary considerably between 3 and 14 mg per day.

**Dietary reference values for vitamins**
The tables below provide recommended intake levels as well as reference values for nutrition labeling.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>mg/day</td>
<td>mg/day</td>
</tr>
<tr>
<td>Men</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Women</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

1 Adequate Intake (AI): intake by healthy people assumed to be adequate; used when an RDA cannot be determined
2 Estimated values for an adequate intake

The Adequate Intakes (AI) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).

The estimated values for a suitable intake do not take into account losses of usually approximately 30% during storage and processing.

<table>
<thead>
<tr>
<th>Current labeling values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference value</td>
</tr>
<tr>
<td>Country</td>
</tr>
<tr>
<td>Unit</td>
</tr>
<tr>
<td>Nutrition Labeling</td>
</tr>
</tbody>
</table>

The Reference Daily Intake (RDI) is the value established by the FDA for use in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for nutrition labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

Despite the lack of knowledge in terms of intake requirements, an increased need during pregnancy and lactation is generally acknowledged. Certain lifestyles and dietary habits, e.g., stress, high alcohol consumption, or certain diseases, such as diabetes mellitus, appear to require a greater intake of pantothenic acid.

The estimated values for a suitable intake do not take into account losses of usually approximately 30% during storage and processing.
Deficiency symptoms
Due to the wide occurrence of pantothenic acid, deficiency symptoms in humans are extremely rare. Vitamin B₅ deficiency is usually accompanied by a deficiency of other B-complex vitamins. Characteristic pantothenic acid deficiency symptoms can only be induced experimentally after administration of the pantothenic acid antagonist methyl pantothenic acid. Lack of pantothenic acid can manifest itself in the following symptoms:

- impaired function of the adrenal gland (insufficiency and atrophy of the adrenal cortex),
- symptoms of a dysfunctional nervous system (disturbed peripheral sensitivity, loss of coordination, degeneration of central/peripheral nerve paths),
- deterioration of skin (dermatitis), hair, and nails,
- gastrointestinal disorders (nausea, vomiting, motility disorders),
- reproductive disorders,
- stunted growth or loss of weight,
- degeneration of the liver cells (fat infiltration),
- reduced immune defense/formation of antibodies (increased susceptibility to infections).

Evidence of deficiency has also been discovered in malnourished population groups displaying the following characteristic symptoms: general exhaustion, fatigue, weakness, insomnia, depression, and paresthesia in the extremities, particularly the “burning feet syndrome” (tingling followed by pain in the toes and sole of the foot), etc.

Toxicity
No toxic effects after oral or parenteral administration of pantothenic acid or its salts (e.g., calcium pantothenate) have been observed. Even daily dosages of up to 10 g are tolerated without symptoms. Pantothenic acid can therefore be considered atoxic. It may cause mild diarrhea.

There is no evidence of teratogenic or embryotoxic effects.

The ULS (Upper Level for Supplements) has been estimated at 1,000 mg (CRN, OSL method) and the Guidance Level for Supplements at 200 mg (Expert Committee on Vitamins and Minerals, UK). FNB (US) and SCF (EC) have reviewed the safety but did not establish a Tolerable Upper Intake Level (no toxicological basis).

Indications
In medicine, pantothenic acid and D-panthenol are used both topically (local application to skin and mucous membranes) and systemically (administered orally and parenterally). While calcium D-pantothenate is mainly used in systemic dosage forms—usually in combination with other vitamins, particularly B-complex vitamins—D-panthenol is more suitable for local application to skin and mucous membranes because of its superior stability in liquid and semi-solid formulations.
Pantothenic acid and D-panthenol are used for the following indications:

- **Prevention and therapy of deficiency symptoms resulting from a poor diet or malnutrition**
  - with complete parenteral drip feeding
  - in chronic dialysis patients
  - for chronic alcoholism
- **Impaired absorption, reduced bioavailability**
  - intestinal disorders, e.g., colitis ulcerosa
  - diabetes mellitus (increased excretion with the urine)
- **Delayed healing of skin and mucous membrane lesions of almost any origin**
  (burns caused by heat, radiation, or corrosive chemicals, irritation, inflammation, and injury of the conjunctiva and cornea, etc.)

D-panthenol is being used on a trial basis to treat intestinal weakening (atony) resulting from intoxication, injury, or after surgery. High dosages of pantothenic acid appear to stimulate the peristaltic action of the intestine by an unknown mechanism.

In the food industry, calcium D-pantothenate is added to a number of foods, such as food products for babies and small children, food products for athletes, low-calorie and calorie-reduced foods, vitamin-fortified juices, etc., and for the prevention of pantothenic acid deficiency as well as meeting particular nutritional requirements.

Because of its soothing and moisturizing properties, dexpanthenol (D-panthenol) is used in a wide variety of cosmetic skin and hair products. Its soothing, anti-inflammatory effect is particularly valuable in after-sun products and emulsions for dry, cracked skin, as well as in dental rinses and mouth washes.

**Properties**
Pantothenic acid is a yellow, viscous, hygroscopic oil. It is stable in neutral solutions but rapidly decomposes in acid or alkaline solutions, particularly if exposed to heat. Therefore, pantothenic acid is sold as calcium and sodium salts. Calcium D-pantothenate is a white, slightly hygroscopic powder, readily soluble in water, somewhat soluble in ethanol, and insoluble in ether. Stored in a dry, cool place in the airtight packaging, pantothenic acid salts are stable to atmospheric oxygen and light.
Calcium D-Pantothenate

**Chemical names of active ingredient**
Calcium D-pantothenate, calcium R-pantothenate, vitamin B₅

**CAS-No.** 137-08-6  
**EINECS-No.** 205-278-9

**PRD-No.** 30041195*  
* The product is kosher.

**Article**  
50011091 25 kg bag in box

**Country of origin**  
Germany

**Description**  
White, slightly hygroscopic, almost odorless powder with a slightly bitter taste.

**Solubility**  
Readily soluble in water, soluble in glycerol, somewhat soluble in ethanol, and virtually insoluble in ether and chloroform.

**Specification**  
Assay 98.0 – 101.0%


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

**C₁₈H₃₂CaN₂O₁₀**  
Molar mass 476.6 g/mol

**Monographs**  
The product complies with the current “Calcium Pantothenate” Ph. Eur., the “Calcium Pantothenate” USP, and the “Calcium Pantothenate” FCC monographs.

**Regulations**  
The product meets the regulatory requirements for a source of pantothenic acid in most countries. However, regulations in the respective countries and for the intended use have to be observed.

**Bulk density**  
Approx. 0.6 g/ml

**Stability**  
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months. It is hydrolyzed by strong alkalis and acids and is slightly hygroscopic.

**Storage/Handling**  
The product should be stored in the tightly sealed original packaging in a dry place at temperatures below 25 °C.
Applications

Dietary supplements:
For the prevention and therapy of D-pantothenic acid deficiency, e.g., in multivitamin or B-complex preparations.
Calcium D-pantothenate is best used in solid dosage forms (tablets, sugar-coated tablets, effervescent tablets, film-coated tablets, chewable tablets, capsules). The product is hygroscopic and is suitable for direct compression.
In liquid and semi-solid dosage forms, particularly when used in combination with other vitamins, D-panthenol (= provitamin B₅) is preferable to Calcium D-Pantothenate, because it is more stable.

Food products:
In the ingredients and food industry, calcium D-pantothenate is added to a number of foods, e.g., food products for babies and small children, food products for athletes, low-calorie and calorie-reduced foods, vitamin-fortified juices, etc., and for the prevention of pantothenic acid deficiency as well as meeting particular nutritional requirements. It is also used for the fortification of fruit, vegetable and multivitamin juices, confectionery, isotonic beverages, instant-drink powders, milk and other dairy products, breakfast cereal, etc.

Cosmetic products:
D-pantothenic acid improves hair growth and pigmentation and protects the skin. As it is more stable and easier to process, D-panthenol is usually preferred to calcium D-pantothenate, e.g., in hair care products, sun care products, shaving lotions, and baby care products.

Note
Calcium D-Pantothenate must be handled in accordance with the Safety Data Sheet.
Vitamin B\textsubscript{12}

**Chemical name of active ingredient**
Cobalamin

**Physiological importance**
Vitamin B\textsubscript{12} (cobalamin) is a collective term for compounds which have a cobalt atom in the center of a porphyrin-type ring system, but different substituents. The following six cobalamin forms demonstrate vitamin B\textsubscript{12} activity in the human organism: cyanocobalamin, hydroxocobalamin, cobalamin R, cobalamin S, methylcobalamin, and adenosylcobalamin.

In the metabolic process, dietary vitamin B\textsubscript{12} is converted into its active forms, the coenzymes adenosylcobalamin and methylcobalamin. Adenosylcobalamin is responsible for the intramolecular re-arrangement of alkyl groups in the degradation of odd-numbered and branched fatty acids, as well as certain amino acids.

Methylcobalamin plays an important role for the methyl group transfer in the synthesis of amino acid methionine from plasma homocysteine, which may be dependent on the presence of folates in the mitochondria. Therefore, vitamin B\textsubscript{12} also plays an important role in converting the folic acid transport and storage forms into its active form required for hemogenesis.

By way of biosynthesis of purine and pyrimidine bases, as well as methionine, vitamin B\textsubscript{12} is indirectly involved in the synthesis of nucleic acids and proteins, respectively. Thereby it plays an important role in growth and development processes.

Gastric intrinsic factor is required for absorption with low (dietary) vitamin B\textsubscript{12} intake of up to approximately 5 µg, whereas with higher intakes, particularly supplemental, intrinsic factor is not required for absorption.

**Occurrence**
Vitamin B\textsubscript{12} is only contained in foods of animal origin, with the highest concentrations found in liver. Further rich sources of vitamin B\textsubscript{12} include meat, fish, eggs, milk, and cheese. A strict vegetarian diet is almost completely deficient of vitamin B\textsubscript{12}. Foods of vegetable origin only contain traces of the vitamin if they have been subject to bacterial fermentation, as is the case for sauerkraut and other fermented vegetables, as well as beer.

Vitamin B\textsubscript{12} is synthesized by bacteria. Although some vitamin B\textsubscript{12} is synthesized by microbes in the large intestine of humans, it cannot be utilized as it originates beyond the absorption site in the small intestine. Therefore, humans require dietary vitamin B\textsubscript{12}.
Recommended dosages
The average healthy adult requires 1 – 2 µg of absorbed vitamin B₁₂ per day. The larger the individual dosage, the smaller the degree of absorption from the diet, as intrinsic factor is required for absorption. In Central Europe, for example, the principal meals provide more than two thirds of the total supply and an average absorption loss of 50% is expected with a mixed diet.

Therefore, the required amount of vitamin B₁₂ can only be reliably met with the intake of at least 3 µg/day.

Dietary reference values for vitamins
The tables below provide recommended intake levels as well as reference values for nutrition labeling.

**Recommended intake levels**

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg¹/day</td>
<td>µg²/day</td>
</tr>
<tr>
<td>Men</td>
<td>2.4</td>
<td>3</td>
</tr>
<tr>
<td>Women</td>
<td>2.4</td>
<td>3</td>
</tr>
</tbody>
</table>

¹ Recommended Dietary Allowances  
² Recommended Intake

The Recommended Dietary Allowances (RDA) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).

The Recommended Intakes within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

Current labeling values

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
<th>RDA (2008)</th>
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</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe</td>
</tr>
<tr>
<td>Unit</td>
<td>µg</td>
<td>µg</td>
</tr>
<tr>
<td>Nutrition Labeling</td>
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</table>

The Reference Daily Intake (RDI) is the value established by the FDA for use in nutrition labeling.

The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for nutrition labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

Approximately 50 µg of vitamin B₁₂ is passed on to the fetus during pregnancy, followed by an additional 0.4 µg per day during lactation. Therefore, a supplement of 0.2 – 1 µg of vitamin B₁₂ per day is recommended during pregnancy and lactation.

As a rule, the vitamin B₁₂ intake exceeds the requirement. However, persons such as strict vegetarians who never eat meat, dairy products, or eggs over a period of many years are at risk of developing deficiencies, as the vitamin B₁₂ stored in the liver is gradually depleted. The first deficiency symptoms are expected to appear within 5 – 10 years.
The following two groups are at risk of vitamin B$_{12}$ deficiency: namely babies of strictly vegetarian (vegan) mothers who are exclusively breast-fed and therefore receive an inadequate supply of vitamin B$_{12}$, as well as the elderly. An estimated 12 – 30% of the elderly suffer from chronic changes in the gastric mucosa including lack of hydrochloric acid production and inadequate production of intrinsic factor, commonly resulting in malabsorption of vitamin B$_{12}$.

**Deficiency symptoms**

Vitamin B$_{12}$ deficiency is extremely rare and is usually caused by certain physical disorders, which seriously impair the vitamin B$_{12}$ absorption.

Vitamin B$_{12}$ deficiency manifests itself most clearly in the following symptoms:

- **Megaloblastic anemia (pernicious anemia)**
  Defective cell formation in the bone marrow leads to anemia with characteristically oversized immature erythrocytes (megaloblasts). This is either caused by disturbed cell growth resulting from blocked DNA synthesis and replication or by impaired folic acid turnover. All cells with a high rate of division, i.e., cells of the epithelium, bronchi, stomach, and the oral cavity are affected.
  
The clinical symptoms of pernicious anemia include paleness of the skin and mucous membranes, Hunter’s glossitis with burning sensation of the tongue, which may result in atrophy of the tongue’s mucous membrane, debility, fatigue, apathy, and dizziness. Changes in the epithelium of the gastro-intestinal tract mucosa can cause malabsorption.

- **Neurological disorders**
  A severe consequence of vitamin B$_{12}$ deficiency is peripheral neuropathy, characterized by peeling away of the myelin and cell necrosis of the spinal cord and cerebral cortex, accompanied by symptoms, such as tingling in the hands and feet, loss of feeling, reflex movements, memory and visual power, confusion, changes in character, hallucinations, and psychoses.

Vitamin B$_{12}$ absorption can be impaired by physical disorders such as:

- lack of hydrochloric acid (anacidity),
- reduced production of intrinsic factor (IF) as a result of atrophy of the gastric mucosa or stomach surgery,
- formation of antibodies against IF or the IF-B$_{12}$-complex,
- liver diseases, which reduce the release of stored vitamin B$_{12}$; intracellular metabolic disorders with inadequate formation of vitamin B$_{12}$ with coenzyme activity.

Megaloblastic anemia may be caused by deficiency of either vitamin B$_{12}$ or folic acid. To distinguish between the deficiencies, the methylmalonic acid content in the urinary excretion is determined, which is elevated with vitamin B$_{12}$ deficiency.
Toxicity
Vitamin B₁₂ is virtually non-toxic. No adverse effects have been associated with excess B₁₂ intake, no UL has been established, and mutagenicity as well as carcinogenicity have been excluded. After parenteral administration, isolated cases of eczema-like allergic reactions (urticaria, anaphylactic reactions) and acne have been reported. High dosages of vitamin B₁₂ may aggravate psoriasis. There is no evidence of teratogenic or fetotoxic effects. The ULS (Upper Level for Supplements) has been estimated at 3,000 µg (CRN, OSL method) and the Guidance Level for Supplements at 2,000 µg (Expert Committee on Vitamins and Minerals, UK). FNB (US) and SCF (EC) have reviewed the safety but did not establish a Tolerable Upper Intake Level (no toxicological basis).

Indications
Vitamin B₁₂ is used both for the prevention and therapy of vitamin B₁₂ deficiency symptoms resulting from inadequate intake, malabsorption, or disturbed transport, such as:
- hyperchromic macrocytic megaloblast anemia (pernicious anemia, Biermer’s anemia, Addison’s anemia),
- funicular spinal disease,
- inadequate and unbalanced diet,
- impaired absorption,
  - intrinsic factor (IF) deficiency (antibodies, atrophy of the parietal cells, gastrectomy)
  - pancreatic insufficiency
  - blind loop syndrome
  - disorders of the ileum
  - infestation with broad tapeworms
- congenital cobalamin transport disorders.

Vitamin B₁₂ is also used for treatment of trigeminal neuralgia, multiple sclerosis, and growth disorders.

In the food industry, vitamin B₁₂ is normally used in conjunction with other vitamins, particularly the B-complex vitamins. It is added to flour, baked goods, food products for babies and small children, food products for athletes, dietetic products, multivitamin juices, breakfast cereal, and confectionery.

Properties
Cyanocobalamin is crystallized into red, odorless and tasteless needles. It is somewhat soluble in water, soluble in alcohol, insoluble in ether, acetone and chloroform. It decomposes at 210 – 220 °C, without melting. The hygroscopic crystals can absorb up to 12% water from the atmosphere. The substance is stable in the hydrated form. Crystalline vitamin B₁₂ or its neutral or slightly acidic solutions are decomposed by light and UV radiation, but are relatively stable to air and heat. Alkalis, strong acids, and reducing agents rapidly decompose vitamin B₁₂. It is gradually destroyed by thiamine and nicotinamide/nicotinic acid in solutions, although this process may be prevented with the addition of small quantities of iron or thiocyanate. Aqueous solutions of cyanocobalamin are neutral; they are most stable at pH values of 4.5 – 5.0.
Vitamin $B_{12}$ 0.1% SD

Chemical names of active ingredient
Cyanocobalamin, vitamin $B_{12}$

CAS-No. 68-19-9
EINECS-No. 200-680-0

PRD-No. 30061967*

* The product is kosher.

Article
50092883 12.5 kg bag in box

Country of origin
Denmark

Description
Free-flowing, pink powder of almost spherical particles or agglomerates with a mild characteristic odor.

Composition
Ingredients in descending order of weight: maltodextrin, trisodium citrate, citric acid, vitamin $B_{12}$ (cyanocobalamin).

Solubility
The product is soluble in cold water.

Specification
Assay min. 0.10%


Monographs
The active ingredient complies with the current “Cyanocobalamin” Ph. Eur. and “Cyanocobalamin” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin $B_{12}$ source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.5 g/ml

Stability
The stability of the product in formulations is excellent even in the presence of minerals or other aggressive components. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.
Storage/Handling
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry, dark place.

Applications

Dietary supplements:
The product is particularly suitable for use in tablets and hard gelatin capsules. Due to the small particle size and relatively low vitamin B₁₂ content of the dry powder, the vitamin can be distributed very homogenously even in formulations with a low active content. The product is suitable for use in powder preparations, which are dissolved in water prior to use.

Food products:
To prevent vitamin B₁₂ deficiency, the product is added to a large number of food products, such as food for babies and small children, food products for athletes, dietetic products, milk powder, multivitamin juices, drink powders, confectionery, and breakfast cereal.

The dry powder is especially suitable for use in powder food products, which are dissolved in water or milk prior to use. It can also be used in vitamin mixtures in the food ingredients industry. As it does not contain proteins, the product is very suitable for use in hypoallergenic food products.

Note
Vitamin B₁₂ 0.1% SD must be handled in accordance with the Safety Data Sheet.
**Vitamin B\textsubscript{12} 1\% SD**

**Chemical names of active ingredient**
Cyanocobalamin, vitamin B\textsubscript{12}

**CAS-No.** 68-19-9  
**EINECS-No.** 200-680-0

**PRD-No.** 30061968*  
* The product is kosher.

**Article**  
50092989  12.5 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, pink powder of almost spherical particles or agglomerates with a mild characteristic odor.

**Composition**
Ingredients in descending order of weight: maltodextrin, trisodium citrate, citric acid, vitamin B\textsubscript{12} (cyanocobalamin).

**Solubility**
The product is soluble in cold water.

**Specification**

| Assay | min. 1.0% |


**Monographs**
The active ingredient complies with the current “Cyanocobalamin” Ph. Eur. and “Cyanocobalamin” USP monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin B\textsubscript{12} source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.5 g/ml

**Stability**
The stability of the product in formulations is excellent even in the presence of minerals or other aggressive components. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.
Storage/Handling
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry, dark place.

Applications
Dietary supplements:
The product is particularly suitable for use in tablets and hard gelatin capsules. Due to the small particle size and relatively low vitamin B\textsubscript{12} content of the dry powder, the vitamin can be distributed very homogenously even in formulations with a low active content. The product is suitable for use in powder preparations, which are dissolved in water or milk prior to use.

Food products:
The product is added to a large number of ingredients and food products, such as food for babies and small children, food products for athletes, dietetic products, skimmed milk, multivitamin juices, drink powders, confectionery, and breakfast cereal.

Dry powder is especially suitable for the use in powder food products, which are dissolved in water or milk. It can also be used in vitamin mixtures in the food ingredients industry. As it does not contain proteins, the product is very suitable for use in hypoallergenic food products.

Note
Vitamin B\textsubscript{12} 1% SD must be handled in accordance with the Safety Data Sheet.
Vitamin D

**Chemical names of active ingredient**
Vitamin D$_2$ (ergocalciferol), vitamin D$_3$ (cholecalciferol)

**Units**
- 1 International Unit (IU) = 0.025 µg of vitamin D$_2$ or D$_3$
- 40 IU = 1 µg of vitamin D$_2$ or D$_3$

**Physiological importance**
Vitamin D is also known as the anti-rickets vitamin. In addition to the hormones calcitonin and parathyroid hormone, it is required for the calcium homeostasis regulation as well as the phosphate metabolism. Its active form is the vitamin D hormone calcitriol. Calcitriol also leads to incorporation of calcium and phosphorus in the skeleton, thus maintaining the mineral content of the bones. Therefore, calcitriol plays an important role in the prevention of osteoporosis, a disease prevalent in many elderly women living in industrialized countries.

In addition, results from recent scientific studies indicate that vitamin D may play an important role in heart health, immunity, and in the prevention of diabetes, autoimmune diseases, and cancer.

**Occurrence**
There are few dietary sources of vitamin D. Significant quantities are found in foods such as fish liver oils, fatty fish (herring, mackerel, sardine), liver, margarine, and egg yolk. The vitamin D content of milk and butter depends on the season: greater quantities are synthesized in cows during the summer (bright sunlight), increasing the vitamin D content in the milk.

In addition, results from recent scientific studies indicate that vitamin D may play an important role in heart health, immunity, and in the prevention of diabetes, autoimmune diseases, and cancer.

Vitamins D$_3$ (cholecalciferol) and D$_2$ (ergocalciferol) are the most important vitamin D compounds (calciferols) for the human organism. Vitamin D$_3$ occurs in foods of animal origin. It is formed from its provitamin 7-dehydrocholesterol in liver and intestinal mucosa, and is converted to vitamin D$_3$ in the skin with exposure to UV light. Foods of vegetable origin contain only a provitamin, ergosterol, which is converted into vitamin D$_2$ in the skin after ingestion. Vitamins D$_2$ and D$_3$ demonstrate approximately the same activity in the human organism.
Recommended dosages
Compared to other vitamins, vitamin D is unique: it can be synthesized by the body. With adequate sun exposure, a healthy adult can synthesize a sufficient amount of vitamin D in the skin. The amount of vitamin D₃ produced in skin upon exposure to sunlight depends on environmental (geographic, climatic, and cultural) and individual factors.

Optimum conditions for vitamin D₃ synthesis are low latitudes, summertime, solar noon, fair sky, clean air (rural) and high reflection (snow).

Skin type strongly determines a person’s effectiveness in producing vitamin D₃. The darker the skin is pigmented, the more ultraviolet radiation is absorbed by melanin and the less vitamin D₃ is produced. Age has also an influence on vitamin D₃ production. The amount of 7-dehydrocholesterol in skin decreases with age, and the body’s ability to produce vitamin D₃ declines. At the same time, vitamin D requirements rise as people grow older. Other personal factors include clothing habits, lifestyle and workplace (e.g., indoor vs. outdoor), sunscreen use, sun avoidance practices, and certain diseases (e.g., fat malabsorption).

Throughout the world, large population groups are at risk of vitamin D insufficiency due to a lack of production in skin. Most modern diets are low in vitamin D, and few countries have vitamin D food fortification programs in place.

Dietary reference values for vitamins
The tables below provide recommended intake levels as well as reference values for nutrition labeling.

Recommended intake levels

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>µg¹/day</td>
<td>µg³/day</td>
</tr>
<tr>
<td>Men</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>10 (≥ 51y)</td>
<td>10 (≥ 65y)</td>
<td></td>
</tr>
<tr>
<td>15 (&gt; 70y)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>10 (≥ 51y)</td>
<td>10 (≥ 65y)</td>
<td></td>
</tr>
<tr>
<td>15 (&gt; 70y)</td>
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</tr>
</tbody>
</table>

¹ 1 µg = 40 IU
² Adequate Intake (AI): intake by healthy people assumed to be adequate; used when an RDA cannot be determined
³ Recommended Intake

The Adequate Intakes (AI) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI). The Recommended Intakes within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

Current labeling values

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
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<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
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</tr>
<tr>
<td>Unit</td>
<td>IU¹ (µg)</td>
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<tr>
<td>Nutrition Labeling</td>
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</table>

¹ IU = International Unit

The Reference Daily Intake (RDI) is the value established by the FDA used in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for Nutrition Labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.
In some countries, vitamin D is added as a preventive measure to certain staple foods, such as margarine, due to the low vitamin D content in the average diet.

**Deficiency symptoms**
Lack of vitamin D negatively affects both calcium homeostasis and phosphorus metabolism, which may lead to rickets in babies and small children. This disease causes knock knees or bow legs, spinal column and cranium deformations, irregular teeth and other signs of impaired growth, as well as reduced muscle strength and tone due to inadequate supply of minerals to the growing bones.

In adults, D-hypovitaminosis causes osteomalacia. This disease is characterized by demineralization and structural changes in the mature bones resulting in softening, bending, and even spontaneous fracture. It is frequently accompanied by progressive muscular weakness, exaggerated startle response, and increased susceptibility to infections.

In addition to insufficient oral intake, or lack of UV exposure, other causes of vitamin D deficiency include reduced intestinal absorption due to impaired digestion or absorption of fats, severe liver and kidney disease, or underactivity of the parathyroid glands (hypoparathyroidism). Furthermore, drugs such as anti-epileptics, barbiturates, anticonvulsives, lipid lowering drugs, glucocorticoids may also indirectly cause vitamin D deficiency.

**Acute toxicity**
After consumption of more than 1.25 mg (50,000 IU) of vitamin D in adults, symptoms of acute poisoning include nausea, vomiting, headache, and anorexia. These may be followed by hypercalcemia, cardiac arrhythmia, muscular weakness and pain, polyuria, and renal calculi. Hypercalcemia can result in calcification and severe dysfunction of vital organs including lungs, heart, kidneys, and blood vessels. In children, additional symptoms include irritability, fatigue, muscular weakness, neurological abnormalities, poor weight gain, and renal failure.

**Chronic toxicity**
Long-term dosages of more than 50 µg (2,000 IU) of vitamin D per day in adults may result in the hypercalcemia syndrome. This disease is caused by an increase in calcium concentration in blood plasma leading to severe dysfunction in certain organs, including frequent micturition, excessive thirst, nausea and vomiting, endocrine psychosyndrome, kidney stones and kidney failure, calcification of heart, lung, and kidney tissue, as well as blood vessels.

In rare cases, babies may develop severe toxic symptoms caused by a moderate overdose of vitamin D. Therefore, preventive treatment of babies against rickets requires close medical supervision. Daily dosages of more than 25 µg must not be administered without clear indication and regular plasma and urine analyses.

**Safety summary**
- The Tolerable Upper Level of Intake (UL) established by FNB/Health Canada and by the SCF sub-committee of the EU is 50 µg (2,000 IU).
- The Safe Upper Level of Intake to be used as guidance for the maximum level in supplements proposed by EVM (UK Expert Group on Vitamins and Minerals) is 25 µg (1,000 IU).
- The Safe Upper Level of Intake (supplements) provided by CRN (2004) is 60 µg (2,400 IU).
- The Lowest Observed Adverse Effect Level (LOAEL) of intake in relation to the hypercalcemic effect is greater than 3,800 IU (95 µg) per day.

**Teratogenic effects**
So far, no mutagenic, carcinogenic, or teratogenic effects have been observed. However, as vitamin D and its metabolites pass through the placenta to the fetus, there is a risk of teratogenic damage if the mother is consuming an excessive amount of vitamin D.

This manifests itself in stenosis of the aortic valve, impaired physical and mental development, as well as hypoparathyroidism in the newborn child.
Applications
Treatment with vitamins D₂ and D₃ is indicated for the prevention and therapy of vitamin D deficiency symptoms, such as:
• rickets in babies and small children,
• osteomalacia,
• hypoparathyroidism (underactivity of the parathyroid glands) and pseudo hypoparathyroidism
• malabsorption, e.g., as a result of chronic, intestinal disease, cirrhosis of the liver, extensive gastrointestinal resection, and
• osteoporosis.

In dermatology, vitamin D is used in skin care products for the treatment of psoriasis, acne vulgaris, furuncles, and lupus vulgaris.

Due to the risk of overdose, the use of vitamin D in the food industry is subject to regulations in many countries and is limited to a small number of product groups. Depending on the country, these may include food products for babies and small children, dietetic products for weight reduction, balanced diets, margarine, milk, and dairy products.

In cosmetic products, vitamin D is used for its suggested ability to stimulate the keratinization, thereby enhancing the protective function of the skin.

Properties
Vitamins D₂ and D₃ are white to yellowish crystalline compounds. They dissolve readily in organic solvents such as hexane, ether, acetone, and ethanol, less well in vegetable oils, and are insoluble in water.

Both vitamins are rapidly dissociated by light, oxygen, and acid, particularly in solution or in finely powdered form. They are stable in alkaline solutions but tend to isomerize in oily solutions. The thermal stability of the crystalline compounds is reasonable.
Vitamin D₃ 1.0 Mio IU/G

Chemical name of active ingredient
Cholecalciferol

CAS-No. 67-97-0
EINECS-No. 204-673-2

PRD-No. 30070969*

* The product is kosher.

Article
56283443 4 x 5 kg plastic can

Country of origin
Germany

Units
1 International Unit (IU) = 0.025 µg vitamin D₃

Description
Clear, colorless to slightly yellowish oil at room temperature with a mild odor.

Composition
Ingredients in descending order of weight: medium-chain triglycerides, vitamin D₃ (cholecalciferol), DL-alpha-tocopherol.

Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, ether, fats, and oils.
Note: Due to degradation of vitamin D₃ by peroxides, it is important that the solvent is free of peroxides. The product can be dispersed in water using a standard food surfactant, to form a milky emulsion.

C₂₇H₄₄O Molar mass 384.7 g/mol

Specification
Assay min. 1.0 million IU vitamin D₃ per gram (= 25,000 µg cholecalciferol per gram)


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “Cholecalciferol concentrate (oily form)” Ph. Eur. monograph. The active ingredient vitamin D₃ complies with the “Cholecalciferol” Ph. Eur. and the “Cholecalciferol” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin D source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Stability
The product is stabilized with DL-alpha-tocopherol (E307). It is sensitive to oxygen, light, and heat. Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.
Storage/Handling
The product should be stored in its unopened original packaging at room temperature (max. 25 °C), in a dry place. It is recommended to flush the packaging with an inert gas once they have been opened and to use the remaining contents as quickly as possible.

Applications
Dietary supplements:
The product is suitable for preparations with a lipophilic base, e.g., soft gelatin capsules, oily solutions, drops, ointments, and creams.

Food products:
Used for the fortification of fatty foods, such as margarine, spreads, oils, milk, and dairy products. 25 – 75 µg (1,000 – 3,000 IU) of vitamin D₃, calculated as cholecalciferol, are usually added to every kg of margarine.

Note
Vitamin D₃ 1.0 million IU/g must be handled in accordance with the Safety Data Sheet.
Dry Vitamin D₃ 100

Chemical name of active ingredient
Cholecalciferol

CAS-No. 67-97-0
EINECS-No. 200-673-2

PRD-No. 30067769

Article
50144186 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.025 µg vitamin D₃

Description
Free-flowing, off-white powder, consisting of fine spherical particles.

Composition
Ingredients in descending order of weight: sucrose, gelatin, medium-chain triglycerides, modified starch, t-butyl hydroxytoluene (BHT), sodium aluminum silicate, vitamin D₃ (cholecalciferol).

Solubility
The product can be dispersed in warm water (35 – 40 °C), to form a milky emulsion. Virtually no vitamin D can be extracted from the powder with ether.

Specification
Assay min. 100,000 IU vitamin D₃/g (= 2,500 µg cholecalciferol/g)

Monographs
The product complies with the current “Cholecalciferol concentrate (powder form)” Ph. Eur. monograph. The active ingredient vitamin D₃ complies with the current “Cholecalciferol” Ph. Eur. and “Cholecalciferol” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin D source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with BHT (E321). The stability of vitamin D₃ in the dry powder is excellent even in the presence of minerals. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry place.

Applications

Dietary supplements:
The product is particularly suitable for use in multi-vitamin/mineral tablets and hard-shell capsules. The small particle size and relatively low vitamin D₃ content of the dry powder provide homogenous distribution even in product formulations with a low active content. Dry vitamin D₃ is also very suitable for the direct compression of vitamin D tablets with a high active content.

Note
Dry Vitamin D₃ 100 must be handled in accordance with the Safety Data Sheet.
Dry Vitamin D₃ 100 GFP

Chemical name of active ingredient
Cholecalciferol

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>67-97-0</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS-No.</td>
<td>200-673-2</td>
</tr>
<tr>
<td>PRD-No.*</td>
<td>30053529*</td>
</tr>
</tbody>
</table>

* The product is kosher.

Article
50051636 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 0.025 µg vitamin D₃

Description
Free-flowing, white powder, consisting of spherical particles.

Composition

Solubility
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion. Virtually no vitamin D can be extracted from the powder with ether.

Specification
Assay min. 100,000 IU vitamin D₃/g (= 2,500 µg cholecalciferol/g)


Monographs
The active ingredient complies with the current “Cholecalciferol” Ph. Eur. and “Cholecalciferol” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin D source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with DL-alpha-tocopherol (E307). Vitamin D₃ contained in both the original container as well as in food products to which it has been added, is very stable. Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.

Storage/Handling
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry place.
Applications

Dietary supplements:
For use in multivitamin preparations.

Food products:
The product is particularly suitable for the fortification of foods including food for babies and children, dietetic products, milk powder, and vitamin mixtures. Regulatory provisions for the use of tricalcium phosphate in the different product categories have to be considered. In the EU, the application in infant foods is limited to fortification with DHA and calcium. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Note
Dry Vitamin D₃ 100 GFP must be handled in accordance with the Safety Data Sheet.
Dry Vitamin D$_3$ 100 HP

**Chemical name of active ingredient**
Cholecalciferol

**CAS-No.** 67-97-0
**EINECS-No.** 200-673-2

**PRD-No.** 30204226*

* Sold in North America only.

**Article**
53151552 25 kg bag in box

**Country of origin**
Denmark

**Units**
1 International Unit (IU) = 0.025 µg vitamin D$_3$

**Description**
Free-flowing, off-white powder, consisting of fine spherical particles.

**Composition**
Ingredients in descending order of weight: sucrose, gelatin, medium-chain triglycerides, modified starch, t-butyl hydroxytoluene (BHT), sodium aluminum silicate, vitamin D$_3$ (cholecalciferol).

**Solubility**
The product can be dispersed in warm water (35 – 40 °C), to form a milky emulsion. Virtually no vitamin D can be extracted from the powder with ether.

**Specification**
Assay min. 100,000 IU vitamin D$_3$/g (= 2,500 µg cholecalciferol/g)


**Monographs**
The active ingredient complies with the current “Cholecalciferol” Ph. Eur. and “Cholecalciferol” USP monographs.

**Regulations**
The product is conditionally approved as vitamin D source in certain regions. Therefore, national regulations in the respective countries have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with BHT (E321). The stability of vitamin D$_3$ in the dry powder is excellent even in the presence of minerals. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

**Storage/Handling**
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry place.
Applications

Dietary supplements:
The product is particularly suitable for use in multi-vitamin/mineral tablets and hard-shell capsules. The small particle size and relatively low vitamin D₃ content of the dry powder provide homogenous distribution even in product formulations with a low active content. Dry vitamin D₃ is also very suitable for the direct compression of vitamin D tablets with a high active content.

Note
Dry Vitamin D₃ 100 HP must be handled in accordance with the Safety Data Sheet.
**Chemical name of active ingredient**
Cholecalciferol

**CAS-No.** 67-97-0
**EINECS-No.** 204-844-2

**PRD-No.** 30208576*

* The product is kosher.
  Sold in North America only.

**Article**
53763345  25 kg bag in box

**Country of origin**
Denmark

**Units**
1 International Unit (IU) = 0.025 µg vitamin D₃

**Description**
Free-flowing, white powder, consisting of spherical particles.

**Composition**
Ingredients in descending order of weight:
sucrose, corn starch, gum arabic, medium-chain triglycerides, tricalcium phosphate, vitamin D₃ (cholecalciferol), DL-alpha-tocopherol.

**Solubility**
The product can be dispersed in cold water with temperatures as low as 10 °C, to form a stable milky emulsion. Virtually no vitamin D can be extracted from the powder with ether.

**Specification**
Assay  min. 100,000 IU vitamin D₃/g
      (= 2,500 µg cholecalciferol/g)


**Monographs**
The active ingredient complies with the current “Cholecalciferol” Ph. Eur. and “Cholecalciferol” USP monographs.

**Regulations**
The product is conditionally approved as vitamin D source in certain regions. Therefore, national regulations in the respective countries have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with DL-alpha-tocopherol (E307). Vitamin D₃ contained in both the original container as well as in food products to which it has been added, is very stable. Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.

**Storage/Handling**
The product should be stored in the original packaging at room temperature (max. 25 °C), in a dry place.
Applications

Dietary supplements:
For use in multivitamin preparations.

Food products:
The product is particularly suitable for the fortification of foods including food for babies and children, dietetic products, milk powder, and vitamin mixtures. Regulatory provisions for the use of tricalcium phosphate in the different product categories have to be considered. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Note
Dry Vitamin $D_3$ 100 GFP/HP must be handled in accordance with the Safety Data Sheet.
Dry Vitamin D₃ 50 GFP

**Chemical name of active ingredient**
Cholecalciferol

**CAS-No.** 67-97-0  
**EINECS-No.** 200-673-2

**PRD-No.** 30235889*  
* The product is kosher.

**Article**
56682956 25 kg bag in box

**Country of origin**
Denmark

**Units**
1 International Unit (IU) = 0.025 µg vitamin D₃

**Description**
Free-flowing, white powder, consisting of spherical particles.

**Composition**

**Solubility**
The product can be dispersed even in cold water with temperatures as low as 10 °C, to form a stable milky emulsion. Practically no vitamin D can be extracted from the powder with ether.

**Specification**
Assay  
min. 50,000 I.U. vitamin D₃/g  
(= 1,250 µg cholecalciferol/g)

Applications

Food products:
The product is particularly suitable for the fortification of foods including food for babies and children, dietetic products, milk powder, and vitamin mixtures. Regulatory provisions for the use of tricalcium phosphate in the different product categories have to be considered. In the EU, the application in infant foods is limited to fortification with DHA and calcium. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Dietary supplements:
This dry powder has been developed in order to provide an improved content uniformity of vitamin D₃ in tablets.

Note
Dry Vitamin D₃ 50 GFP must be handled in accordance with the Safety Data Sheet.
Vitamin E

Chemical names of active ingredient
Tocopherols, tocotrienols, and their esters

Units
1 mg of RRR-\(\alpha\)-tocopherol = 1 mg \(\alpha\)-Tocopherol (D-\(\alpha\)-tocopherol) = 1.49 USP units
1 mg of all-rac-\(\alpha\)-tocopheryl acetate (DL-\(\alpha\)-tocopheryl acetate) = 1 former IU of vitamin E = 1 USP unit

Physiological importance
Vitamin E was originally discovered as an essential micronutrient involved in reproduction and is now widely recognized as a major lipophilic antioxidant in virtually all cells of the human body. In combination with vitamin C and antioxidant enzymes such as glutathione peroxidase, vitamin E forms an integral part of the so-called antioxidant network. Antioxidants have the ability to counteract many types of oxidative stress resulting from exercise, exposure to the environment (ultraviolet light, cigarette smoke, pollutants, and chemicals), as well as metabolic processes like ageing. In addition, vitamin E has non-antioxidant effects in cell signaling and gene expression. In recent years, its properties—positively influencing human health and disease prevention—have been discovered.

Vitamin E plays an important role as an antioxidant for the protection of lipids and vitamin A from being oxidized. Vitamin E has the ability to deactivate products formed in the radical chain reaction, which can damage cell membranes, have mutagenic and potentially carcinogenic effects by damaging the DNA. Moreover, vitamin E has repeatedly been shown to prevent LDL-cholesterol oxidation, thus preventing atherosclerotic changes. In addition, vitamin E (specifically tocopherol) is believed to indirectly prevent thrombotic disease and inflammation reactions, as it has an effect on prostacyclin synthesis and eicosanoids metabolism.

Occurrence
Vitamin E consists of a group of eight closely related chemical substances: four tocopherols (\(\alpha\), \(\beta\), \(\gamma\), and \(\delta\)) and four tocotrienols, which differ greatly in terms of their vitamin E activity. The most effective of these substances is the naturally occurring RRR-\(\alpha\)-tocopherol (formerly D-\(\alpha\)-tocopherol).

Foods of animal and vegetable origin contain different amounts of tocopherols. However, they can only be synthesized in plants. Vegetable oils, especially seed oil such as wheat germ oil, contain particularly high amounts of vitamin E.

The vitamin E content in these oils correlates with the proportion of unsaturated fatty acids, providing natural protection against oxidation. The vitamin E concentrations are lower in nuts, seedlings, grain and grain products, green vegetables, and legumes.

Synthetic tocopherol is a mixture of eight enantiomers and is referred to as all-rac-\(\alpha\)-tocopherol or DL-\(\alpha\)-tocopherol.
Vitamin E activities of the tocopherols and their esters (according to USP)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Conversion Factor</th>
<th>USP Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mg D-(\alpha)-tocopherol</td>
<td>1.00 mg D-(\alpha)-TE</td>
<td>1.49</td>
</tr>
<tr>
<td>1 mg D-(\alpha)-tocopheryl acetate</td>
<td>0.91 mg D-(\alpha)-TE</td>
<td>1.36</td>
</tr>
<tr>
<td>1 mg DL-(\alpha)-tocopherol</td>
<td>0.74 mg D-(\alpha)-TE</td>
<td>1.10</td>
</tr>
<tr>
<td>1 mg DL-(\alpha)-tocopheryl acetate</td>
<td>0.67 mg D-(\alpha)-TE</td>
<td>1.00</td>
</tr>
<tr>
<td>1 mg DL-(\alpha)-tocopheryl succinate</td>
<td>0.60 mg D-(\alpha)-TE</td>
<td>0.89</td>
</tr>
</tbody>
</table>

\* = D-\(\alpha\)-Tocopherol Equivalents

**Recommended dosages**
The required amount of vitamin E depends on the intake of polyunsaturated fatty acids. With a moderate intake of polyunsaturated fatty acids (up to 7 g of linoleic acid/day), adults require a minimum of 4 – 6 mg of \(\alpha\)-tocopherol/day to prevent peroxidation of lipids in the tissue. Higher intakes of polyunsaturated fatty acids increase the amount of vitamin E required. An estimated additional amount of 0.4 – 0.6 mg of \(\alpha\)-tocopherol is required for every gram of absorbed polyunsaturated fatty acid.

**Dietary reference values for vitamins**
The tables below provide recommended intake levels as well as reference values for nutrition labeling.

**Recommended intake levels**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td>Unit</td>
<td>mg(^{1,2}/)day</td>
<td>mg TE(^{3,4}/)day</td>
</tr>
<tr>
<td>Men</td>
<td>15</td>
<td>13 – 15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 ((\geq) 65y)</td>
</tr>
<tr>
<td>Women</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11((\geq) 65y)</td>
</tr>
</tbody>
</table>

1 Alpha-tocopherol including RRR-alpha-tocopherol and other 2R-stereoisomeric forms of alpha-tocopherol
2 Recommended Dietary Allowance
3 1 mg TE (RRR-A-Tocopherol Equivalent) = 1 mg
   RRR-alpha-tocopherol = 2 mg RRR-beta-tocopherol
   = 4 mg RRR-gamma-tocopherol = 3.3 mg RRR-alpha-tocotrienol = 1.1 mg RRR-alpha-tocopheryl acetate
   = 1.49 mg all-rac-alpha-tocopheryl acetate = 1.49 IU
4 Estimated values for an adequate intake

The Recommended Dietary Allowances (RDA) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI). The estimated values for an adequate intake within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

**Current labeling values**

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
<th>RDA (2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>US, CAN</td>
<td>Europe</td>
</tr>
<tr>
<td>Unit</td>
<td>IU(^5) (mg)</td>
<td>mg</td>
</tr>
<tr>
<td>Nutrition Labeling</td>
<td>30 (20)</td>
<td>12</td>
</tr>
</tbody>
</table>

5 1 IU= 0.67 mg RRR-alpha-tocopherol
   = 1 mg all-rac-alpha-tocopheryl acetate
The Reference Daily Intake (RDI) is the value established by the FDA used in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for Nutrition Labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

Higher amounts of vitamin E are required during pregnancy and lactation, impaired digestion and absorption, after long-term use of certain drugs, for supplementing unbalanced diets (e.g., a high consumption of fish), and cholesterol-reduced diets rich in polyunsaturated fatty acids.

An increased intake of vitamin E may be required in certain situations, during which the metabolism is stimulated to produce higher quantities of free radicals, such as stress after an accident, surgery under anesthesia, smoking, exposure to carcinogens at work, physical exertion, etc.

**Deficiency symptoms**

Overt clinical deficiency is very rare. It occurs only in individuals with an inborn error of lipoprotein metabolism (abetalipoproteinemia) and in individuals with malabsorption of lipids due to the loss of pancreatic exocrine secretion and bile deficiency (chronic cholestatic liver disease, cystic fibrosis and short-bowel syndrome). The primary clinical deficiency symptom is peripheral neuropathy caused by the degeneration of sensory nerves.

**Toxicity**

Vitamin E (α-tocopherol or α-tocopheryl acetate) is characterized by very low toxicity. No case of E-hypervitaminosis has ever been reported. Daily oral dosages of up to 100 mg are considered as being within the normal physiological range. However, daily dosages of 200 – 1,000 mg over several weeks are non-toxic for adults. In some cases, gastrointestinal symptoms such as nausea, stomach ache, vomiting, and diarrhea, as well as fatigue and dermatitis have been observed. No mutagenic, teratogenic, or carcinogenic effects have been reported.

The following table contains a comparison of safety values for vitamin E.

<table>
<thead>
<tr>
<th>Safety Level</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Level for Supplements (CRN, OSL method)</td>
<td>1,000 mg (1,600 IU)</td>
</tr>
<tr>
<td>Tolerable Upper Intake Level (UL, FNB)</td>
<td>1,000 mg</td>
</tr>
<tr>
<td>Expert Committee (SCF)</td>
<td>300 mg</td>
</tr>
<tr>
<td>Safe Upper Limit for Supplements (EVM, UK)</td>
<td>540 mg (800 IU)</td>
</tr>
</tbody>
</table>

**Applications**

Established medical indications for intake of vitamin E are the prevention and therapy of vitamin E deficiency and circumstances in which an inadequate intake or conversion is expected, e.g.:

- impaired absorption and transport (abetalipoproteinemia, intestinal resection, cholestasis, cystic fibrosis),
- hemolytic or anemic metabolic anomalies, e.g., sickle-cell anemia, glutathione synthetase deficiency.

In the **food industry**, vitamin E (α-tocopherol) is used both as an antioxidant in oxidation-sensitive fats, oils, and fatty products and for the fortification of food products (α-tocopheryl acetate), such as children’s food, dietetic products, milk powder, breakfast cereals, beverages, etc.

In **cosmetic products**, vitamin E is used to moisturize the upper scaly layer of the skin. Due to its anti-inflammatory action when applied externally and its ability to bind free radicals and, therefore, to counter photoaging of the skin, it is frequently added to sun care products.

Tocopherol also acts as an antioxidant in cosmetic preparations by protecting sensitive vegetable fats and oils from oxidation.
**Properties**

Tocopherols are light-yellow oils at room temperature. They are insoluble in water and readily soluble in organic solvents. While free tocopherols oxidize quickly, turning dark, their esters are more stable when exposed to atmospheric oxygen. Tocopherols are unaffected by temperatures up to approximately 200 °C. They are relatively insensitive to acids and alkalis.
DL-alpha-Tocopherol

Chemical names of active ingredient
Vitamin E, DL-α-tocopherol, all-rac-alpha-tocopherol, racemic 5,7,8-trimethyltocol

EU name
DL-α-tocopherol E307

CAS-No. 10191-41-0
EINECS-No. 233-466-0

PRD-No. 30054571*
* The product is kosher.

Articles
55434701  5 kg plastic can
55434224  25 kg plastic bucket

Country of origin
Germany

Units
1 International Unit (IU) = 0.91 mg DL-α-tocopherol

Description
Viscous, yellow to brown oil

Solubility
Soluble in hydrocarbons, chlorinated hydrocarbons, alcohol, fats, and oils; insoluble in water.

Specification
Assay (Ph. Eur. / USP/FCC) min. 96% max. 102%


Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

Monographs
The product complies with the current “All-rac-α-tocopherol” Ph. Eur., “Vitamin E” USP, “All-rac-alpha-tocopherol” FCC monographs, as well as the “E307” EC directives on food additives.

Regulations
DL-alpha-Tocopherol is approved for use as an antioxidant and as a vitamin E source in most countries. However, specific regulations on the product in the respective countries and for its intended use have to be observed.

Stability
DL-alpha-Tocopherol is sensitive to oxidizing agents, turning dark when exposed to air and light.
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for up to 36 months.

Storage/Handling
The product should be stored tightly sealed in a dry place, protected from light at max. 25 °C.
Once opened, it is recommended to flush the packaging with an inert gas and to use the remaining contents as quickly as possible.
Applications

Dietary supplements:
DL-alpha-Tocopherol is used mainly as an antioxidant in preparations containing fat (ointments, creams, and oils). The vitamin E acetate is more stable and therefore preferred as an active ingredient.

Pharmaceutical products:
CEP (No. 2005-39) is available.
Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

Food products:
DL-alpha-Tocopherol is used as an antioxidant to increase the stability of fats (oils, margarine, baking and frying fats, fish oil), fatty products (ready-made desserts containing cream, soup powders, cocoa, dietetic and frozen products, potato crisps, essences, and chewing gum), and to protect vitamin A and carotene in oils and other food products. Regular quantities are between 200 and 500 mg/kg of fat and up to 1,000 mg/kg is used in essences and chewing gum. By adding tocopherol, the shelf life of meat products sensitive to oxidation (particularly pork and turkey) can be improved. The acetate is more stable and therefore preferred for the fortification of food products with vitamin E.

Cosmetics:
The product is used as an antioxidant and active ingredient in cosmetic preparations containing fat, e.g., creams, ointments, emulsions, body and face oils, and decorative cosmetics, such as lipstick, etc.

Note
DL-alpha-Tocopherol must be handled in accordance with the Safety Data Sheet.
Vitamin E-Acetate (DL-alpha-tocopheryl acetate)

Chemical names of active ingredient
DL-α-tocopheryl acetate, DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

- **CAS-No.** 7695-91-2
- **EINECS-No.** 231-710-0
- **PRD-No.** 30041054*

* The product is kosher.

**Articles**
- 55434595 4 x 5 kg plastic can
- 55434171 25 kg plastic bucket

**Country of origin**
Germany

**Units**
1 International Unit (IU) = 1 mg vitamin E-acetate

**Description**
Light-yellow, viscous, virtually odorless oil.

**Solubility**
Soluble in hydrocarbons, alcohols, fats, and oils; insoluble in water.

**Specification**

Unless otherwise stated, the methods of analysis can be found in the Ph. Eur.

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**Monographs**
The product complies with the current “All-rac-α-tocopheryl acetate” Ph. Eur., “Vitamin E” USP, and “All-rac-alpha-tocopheryl acetate” FCC monographs. A grade complying with the requirements of the JP. Ph. may be supplied upon request.

**Regulations**
The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the product in the respective countries and for its intended use have to be observed.

**Stability**
In contrast to vitamin E alcohol, vitamin E-acetate is resistant to heat and oxygen. It is not resistant to strong oxidizing agents or to alkalis because it undergoes saponification. Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.
Storage/Handling
The product should be stored tightly sealed in a cool, dry place.

Applications
Dietary supplements:
For use in dietary supplements with a lipophilic base, e.g., ointments, creams, oils, soft gelatin capsules, as well as aqueous preparations, e.g., syrups, drops, tonics, solubilizates, and injectables in conjunction with a solubilizing agent, such as Cremophor EL, Cremophor RH 40, or Solutol HS 15.

Pharmaceutical products:
CEP (No. 2005-40) is available. Sterilization of the final product is required for parenteral use. Further information can be found in the book “Functions and Applications of BASF Pharmaceutical Excipients.”

Food products:
Used for the fortification of fats, e.g., regular and low-fat margarine as well as oils and fat-containing foods, such as cakes, biscuits, and dairy products.

Cosmetics:
For use in cosmetic emulsions such as suncare products, body lotions, face, hand and body creams, hair care products, as well as skin oils and other preparations including decorative cosmetics, e.g., anti-chap lipsticks, mascara, eye shadow, rouge, face powder, and foundation cream. A solubilizing agent, e.g., Cremophor RH 40 is required in aqueous and aqueous/alcoholic preparations, such as face water and gels.

Note
Vitamin E-Acetate must be handled in accordance with the Safety Data Sheet.
Vitamin E-Acetate SD 50

Chemical names of active ingredient
DL-α-tocopheryl acetate,
DL-alpha-tocopherol acetate, all-rac-
alpha-tocopherol acetic acid ester, racemic
5,7,8-trimethyltocol acetate

CAS-No. 52225-20-4
EINECS-No. 231-710-0

PRD-No. 30041058*

* The product is kosher.

Article 50047396 25 kg bag in box

Country of origin
Germany

Units
1 International Unit (IU) = 1 mg vitamin E-acetate

Description
White to creamy-white powder with a
characteristic mild odor.

Composition
Ingredients in descending order of weight:
vitamin E-acetate, lactose, sodium caseinate,
glycerin monostearate, tricalcium phosphate.

Solubility
The product can be dissolved both in cold (10 °C)
and warm (35 – 40 °C) water, to form a stable milky
emulsion. It is virtually insoluble in organic solvents.

C_{31}H_{52}O_{3}  Molar mass 472.8 g/mol

Specification
Assay min. 50% DL-α-tocopheryl acetate
 (= 500 former IU of vitamin E =
336 α-TE per gram)

For further information see separate document:
“Standard Specification” (not for regulatory
purposes) available via BASF’s WorldAccount:
https://worldaccount.basf.com (registered access).

Monographs
The active ingredient complies with the current
“All-rac-α-tocopheryl acetate” Ph. Eur., “Vitamin E”
USP, and “All-rac-alpha-tocopherol acetate” FCC
monographs.

Regulations
The product meets the regulatory requirements
for a vitamin E source in most countries. How-
ever, regulations on the ingredients used in the
respective countries and for the intended use
have to be observed.

Bulk density
0.4 – 0.55 g/ml

Stability
Stored in its unopened original packaging at room
temperature (max. 25 °C), the product is stable
for at least 36 months.
**Storage/Handling**
The product should be stored tightly sealed in the original packaging at max. 25 °C, in a dry place.

**Applications**

*Dietary supplements:*
The product is suitable for the direct compression of chewable tablets, sugar- and film-coated tablets, as well as hard gelatin capsules. Due to its excellent dispersibility in cold water, it is also ideal for use in preparations, which need to be dissolved or dispersed in water prior to use, such as low-acid or acid-free instant-drink granules.

*Food products:*
Food products, e.g., childrens food, except for non-cereal-based Infant Food formulations in the EU, dietetic products, food products for athletes, dried milk, milk shake and cocoa powder, as well as vitamin mixtures for the food industry. The content of milk protein in the product may trigger a reaction with acid resulting in undesirable precipitates. Therefore, it is not suitable for the production of acidic juices, effervescent tablets, and instant-drink granules.

**Note**
Vitamin E-Acetate SD 50 must be handled in accordance with the Safety Data Sheet.
Dry Vitamin E-Acetate 50% CWD

Chemical names of active ingredient
DL-α-tocopheryl acetate,
DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

CAS-No. 52225-20-4
EINECS-No. 231-710-0

PRD-No. 30065483*
* The product is kosher.

Article 50023134 25 kg bag in box

Country of origin Denmark

Units 1 International Unit (IU) = 1 mg vitamin E-acetate

Description Free-flowing, creamy-white, virtually odorless powder, consisting of spherical particles. Some white starch particles may be visible.

Composition Ingredients in descending order of weight:
DL-alpha-tocopheryl acetate, corn starch, fish gelatin, sucrose, silicon dioxide.

Solubility Dispersible in cold water (10 °C), to form a milky emulsion.

C_{31}H_{52}O_{3} Molar mass 472.8 g/mol

Specification Assay min. 50% DL-α-tocopheryl acetate (= 500 former IU of vitamin E = 336 α-TE per gram)


Monographs The product complies with the current “α-tocopheryl acetate concentrate (powder form)” Ph. Eur. and “Vitamin E preparation” USP monographs.

Regulations The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density Approx. 0.6 g/ml

Stability Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling The product should be stored tightly sealed in the original packaging in a dry place at max. 25 °C.
Applications

Food products:
The product has been developed for the enrichment of soft drinks. It may also be used in effervescent tablets and dry food products, such as dietetic products and milk powder.

Note
Dry Vitamin E-Acetate 50% CWD must be handled in accordance with the Safety Data Sheet.
Chemical names of active ingredient
DL-α-tocopheryl acetate,
DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

CAS-No. 52225-20-4
EINECS-No. 231-710-0

PRD-No. 30041051

Article 50051053 25 kg bag in box

Country of origin
Denmark

Units
1 International Unit (IU) = 1 mg vitamin E-acetate

Description
Dry, almost white, virtually odorless, free-flowing powder, consisting of spherical particles.

Composition
Ingredients in descending order of weight:
DL-alpha-tocopherol acetate, corn starch, gelatin, sucrose, sodium aluminum silicate.

Solubility
Dispersible in warm water (35 – 40 °C), to form a milky emulsion. Insoluble particles may be visible.

Specification
Assay min. 50% DL-α-tocopheryl acetate
(= 500 former IU of vitamin E = 336 α-TE per gram)


Monographs
The product complies with the current “α-tocopheryl acetate concentrate (powder form)” Ph. Eur. and “Vitamin E preparation” USP monographs.

Regulations
The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.5 g/ml

Stability
The stability of Dry Vitamin E-Acetate 50% DC is excellent even in the presence of minerals. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling
The product should be stored in the original packaging in a dry place at room temperature (max. 25 °C).
Applications

Dietary supplements:
The product has been developed for the direct compression of high-dosage chewable tablets and for sugar- or film-coated vitamin E tablets. It is also very suitable for multivitamin/mineral tablets as well as hard gelatin capsules.

Note
Dry Vitamin E-Acetate 50% DC must be handled in accordance with the Safety Data Sheet.
Dry Vitamin E-Acetate
50% DC/GFP

Chemical names of active ingredient
DL-α-tocopheryl acetate, DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

CAS-No. 52225-20-4
EINECS-No. 231-710-0

PRD-No. 30253144*
* The product is kosher.

Article 50486886 25 kg bag in box

Country of origin Denmark

Units 1 International Unit (IU) = 1 mg vitamin E-acetate

Description Free-flowing, high-density, almost white, virtually odorless powder, consisting of spherical particles, with a uniform particle size.

Composition Ingredients in descending order of weight: DL-alpha-tocopheryl acetate, sucrose, modified starch, corn starch, sodium aluminum silicate.

Solubility Dispersible in cold water (10 °C), to form a stable milky emulsion. Insoluble starch particles may be visible.

C₃₁H₅₂O₃ Molar mass 472.8 g/mol

Specification
Assay min. 50% DL-α-tocopheryl acetate (= 500 former IU of vitamin E = 336 α-TE per gram)


Monographs The product complies with the current “α-tocopheryl acetate concentrate (powder form)” Ph. Eur. and “Vitamin E preparation” USP monographs.

Regulations The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density Approx. 0.6 g/ml

Stabilization/Stability Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage The product should be stored in the original packaging in a dry place at room temperature (max. 25 °C).
Applications

Dietary supplements
The product has been designed for the direct compression of multivitamin mineral tablets as well as hard-shell capsules. It is also suitable for both chewable and effervescent tablets and sugar- or film-coated tablets.

Food products
The product does not contain protein and is suitable for use in many different food products including hypoallergenic products.

Note
Dry Vitamin E Acetate 50% DC/GFP must be handled in accordance with the Safety Data Sheet.
Vitamin E 500 BG

**Chemical names of active ingredient**
DL-α-tocopheryl acetate, DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

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<tbody>
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<th>PRD-No.</th>
<th>30176617*</th>
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</table>

* The product is kosher.

<table>
<thead>
<tr>
<th><strong>Article</strong></th>
<th>57311006 25 kg bag in box</th>
</tr>
</thead>
</table>

**Country of origin**
USA

**Units**
1 International Unit (IU) = 0.91 mg DL-α-tocopherol

**Description**
White to creamy-white powder with a characteristic mild odor.

**Composition**
Ingredients in descending order of weight: 
DL-alpha-tocopheryl acetate, modified starch, silicon dioxide.

**Solubility**
The product readily disperses in either cold (10 °C) or warm water, to form a stable cloudy dispersion.

C<sub>31</sub>H<sub>52</sub>O<sub>3</sub> 
Molar mass 472.8 g/mol

**Specification**
Assay min. 50% DL-α-tocopheryl acetate (= 500 former IU of vitamin E = 336 α-TE per gram)


**Monographs**
The active ingredient complies with the current “Vitamin E” USP, “All-rac-α-tocopheryl acetate” Ph. Eur., and “All-rac-alpha-tocopheryl acetate” FCC monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
0.4 – 0.5 g/ml

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.

**Storage/Handling**
The product should be stored tightly sealed in the original packaging in a dry place at room temperature (max. 25 °C).
Applications

Food products:
The product is designed for use in food applications, dry premixes, and products requiring rapid and complete water dispersibility, such as instant beverages.

Note
Vitamin E 500 BG must be handled in accordance with the Safety Data Sheet.
**Chemical names of active ingredient**
DL-α-tocopheryl acetate, DL-alpha-tocopherol acetate, all-rac-alpha-tocopherol acetic acid ester, racemic 5,7,8-trimethyltocol acetate

<table>
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<tr>
<th>CAS-No.</th>
<th>7695-91-2</th>
</tr>
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<tbody>
<tr>
<td>EINECS-No.</td>
<td>231-710-0</td>
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</table>

**PRD-No.**
30079657*

* The product is kosher.

**Article**
5280749 25 kg bag in box

**Country of origin**
USA

**Units**
1 International Unit (IU) = 0.91 mg DL-α-tocopherol

**Description**
White to creamy-white powder with a characteristic mild odor.

**Composition**
Ingredients in descending order of weight:
DL-alpha-tocopheryl acetate, modified starch, silicon dioxide.

**Solubility**
The product readily disperses in either cold (10 °C) or warm water, to form a stable cloudy dispersion.

**Specification**
Assay min. 50% DL-α-tocopheryl acetate (= 500 former IU of vitamin E = 336 α-TE per gram)


**Monographs**
The active ingredient complies with the current “Vitamin E” USP, “All-rac-α-tocopheryl acetate” Ph. Eur., and “All-rac-alpha-tocopheryl acetate” FCC monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin E source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
0.4 – 0.5 g/ml

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.
**Storage/Handling**
The product should be stored tightly sealed in the original packaging in a dry place at room temperature (max. 25 °C).

**Applications**

*Food products:*
The product is designed for use in food applications, dry premixes, and products requiring rapid and complete water dispersibility, such as instant beverages.

**Note**
Vitamin E 500 FG must be handled in accordance with the Safety Data Sheet.
Vitamin K

**Chemical names of active ingredient**
Vitamin K₁: Phytomenadione, phylloquinone, phytonadione, 2-methyl-3-phytyl-1,4-naphthoquinone
Vitamin K₂: Menaquinone
Vitamin K₃: Menadione

**Physiological importance**
Vitamin K is vital for the development of bones and teeth. Furthermore, it plays a crucial role in blood clotting as it activates blood clotting factors II (prothrombin), VII, IX, and X, as well as the coagulation-inhibiting factors. Vitamin K is essential for the synthesis of osteocalcin, which helps to incorporate calcium phosphate into the bones. The osteocalcin synthesis is stimulated by vitamin D and inhibited by warfarin. Osteocalcin, and consequently vitamin K, are necessary for regular bone growth.

**Occurrence**
Vitamin K is found in both animal and plant foods. Green plants and algae are important sources of vitamin K₁ (phylloquinone), where it is involved in photosynthesis. Other rich sources of vitamin K include green vegetables such as spinach, brussels sprouts, broccoli, and lettuce, as well as cauliflower, kohlrabi, and cabbage (e.g., sauerkraut).

Foods of animal origin contain vitamin K₂ (menaquinone), which is produced by bacteria in the intestine of the animal. Particularly high levels can be found in chicken. Cow liver and butter only contain moderate amounts. The bacterial flora within the large intestine of humans is also a source of vitamin K₂.

The structural differences between vitamins K₁, K₂, and K₃ are slight. However, vitamin K₃ (menadione) does not occur in nature, unlike vitamins K₁ and K₂. Due to its many side-effects, it should no longer be used for therapeutic purposes in humans.

**Recommended dosages**
There are no exact figures for vitamin K requirement in humans. However, it is thought that the requirement is covered by the intake of vitamins K₁ and K₂ with the food and the vitamin K₂ synthesized in the intestine.

**Dietary reference values for vitamins**
The tables below provide recommended intake levels as well as reference values for nutrition labeling.

**Recommended intake levels**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Country</strong></td>
<td>US, CAN</td>
<td>Europe (D, A, CH)</td>
</tr>
<tr>
<td><strong>Unit</strong></td>
<td>µg¹/day</td>
<td>µg²/day</td>
</tr>
<tr>
<td><strong>Men</strong></td>
<td>120</td>
<td>70 – 80</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td>90</td>
<td>60 – 65</td>
</tr>
</tbody>
</table>

¹ Adequate Intake (AI): intake by healthy people assumed to be adequate; used when an RDA cannot be determined
² Estimated values for an adequate intake

The Adequate Intakes (AI) are part of the Dietary Reference Intakes (DRI) released by the Institute of Medicine of the Food and Nutrition Board of the US Academy of Sciences. They are intended to be used for planning and assessing the diet of an apparently healthy population in the US and Canada. These values may eventually be used for updating the Reference Daily Intakes (RDI).
The estimated values for an adequate intake within the D-A-CH reference values were established by the National Nutrition Societies of Germany (D), Austria (A), and Switzerland (CH), and serve as guidelines for nutrient intakes of an apparently healthy population.

**Current labeling values**

<table>
<thead>
<tr>
<th>Reference value</th>
<th>RDI (1968)</th>
<th>RDA (2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country</strong></td>
<td>US, CAN</td>
<td>Europe</td>
</tr>
<tr>
<td><strong>Unit</strong></td>
<td>µg</td>
<td>µg</td>
</tr>
<tr>
<td><strong>Nutrition Labeling</strong></td>
<td>80</td>
<td>75</td>
</tr>
</tbody>
</table>

The Reference Daily Intake (RDI) is the value established by the FDA for use in nutrition labeling. The Recommended Daily Allowances (RDA) were established by the Council of the European Communities for nutrition labeling (90/496/EEC), and amended by Commission Directive 2008/100/EC.

Green vegetables as well as meat, milk, and dairy products are important sources of approximately equal proportions of vitamins K₁ and K₂. Because vitamin K is insensitive to oxygen and heat, losses during processing or preparation are negligible. When suffering from chronic gastrointestinal disease, impaired bile production, diseases of the liver, or cystic fibrosis, the intake of vitamin K should be increased, as these diseases can reduce the effectiveness of vitamin K.

The intake of vitamin K should be increased during long-term treatment with certain drugs, such as antibiotics, sulfonamides, coumarin, tuberculostatics, laxatives containing mineral oil, lipid-reducing drugs, antirheumatics, anticonvulsives, or hypnotics.

**Deficiency symptoms**

Vitamin K hypovitaminosis is rarely observed in healthy adults. It is characterized by hemorrhage and is caused by chronic diseases of the liver and severely impaired fat absorption. It is further observed during the course of combined therapy with antibiotics and vitamin K antagonists. These situations primarily lead to a reduced prothrombin content of the blood, resulting in impaired coagulation. Even minor internal and external injuries of a wide range of tissue and organs can cause severe bleeding (hemorrhage).

Hemorrhages in adults most frequently occur in the nose, the urogenital and gastrointestinal tracts, muscles, and subcutaneous tissue. After trauma or surgery, bleeding is more severe and duration of bleeding prolonged.

Vitamin K deficiency is particularly common in newborns and babies fed exclusively with breast milk, because breast milk contains little vitamin K, the ability of the child’s liver to store vitamin K is limited, and intestinal synthesis is not yet fully developed. Intestinal hemorrhage causing the passage of tarry stools (melena) is a characteristic symptom. Cerebral hemorrhage can also occur, especially if the mother is undergoing treatment with anti-epileptics, tuberculostatics, and coumarin during pregnancy. These types of bleeding can be avoided with a preventive dosage of vitamin K immediately after birth.
Toxicity

Vitamins K₁ and K₂ are virtually non-toxic even at high dosage levels. In rare cases, they can cause allergic skin reactions. Neither of the vitamin K forms have been found to cause hemotoxic effects, nor is there any evidence of mutagenic, teratogenic, or carcinogenic risks to humans.

Vitamin K₃ is no longer used for therapeutic purposes, due to its toxicity, particularly after parenteral application.

The ULS (Upper Level for Supplements) has been estimated at 10 mg (CRN, OSL method) and the Guidance Level for Supplements at 1 mg (Expert Committee on Vitamins and Minerals, UK). These values do not apply to persons being treated with anticoagulant drugs. FNB (US) and SCF (EC) have reviewed the safety but did not establish a Tolerable Upper Intake Level (no toxicological basis).

Applications

Vitamin K is used for prevention and treatment of hemorrhages resulting from vitamin K deficiency, which cannot be alleviated by modifying the diet, particularly in the following situations:

• preventive administration of vitamin K to newborns immediately after birth,
• preventive administration of vitamin K, prior to giving birth, to mothers who had been treated with anticonvulsives, tuberculostatics, or coumarin derivatives during pregnancy, for the benefit of the baby,
• preventive administration of vitamin K to patients at risk of developing a vitamin K deficiency, e.g., Morbus Crohn patients,
• vitamin K therapy for treatment of hemorrhages resulting from vitamin K deficiency.

In adults, vitamin K therapy is required only in special cases, e.g., for the therapy of thrombotic conditions and an acute increased need for vitamin K due to severe loss of blood and for the treatment of post-surgical bleeding.

Special recommendations have been established for treatment of whooping cough, heart muscle disease after diphtheria, hypertension, toxidermia, caries, and treatment of tumors with radiation.

In the food industry, vitamin K is mainly used for the enrichment of food products for babies and small children, dietetic products, and dried milk.

Properties

Vitamin K₁ is a light-yellow oily liquid that is decomposed by light and alkaline substances. Vitamin K₂ is a crystalline substance with a melting point between 35 °C and 60 °C. The K vitamins are relatively resistant to heat and oxygen. They are insoluble in water, slightly soluble in alcohol, and readily soluble in ether, chloroform, fats, and oils.
Dry Vitamin K$_1$ 1% GFP

**Chemical names of active ingredient**
Phytomenadione, phylloquinone, phytonadione, 2-methyl-3-phytyl-1,4-naphthoquinone

**CAS-No.** 84-80-0  
**EINECS-No.** 201-564-2

**PRD-No.** 30041016*

* The product is kosher.

**Article**
50052166  25 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, light-yellow powder, consisting of almost spherical particles or agglomerates.

**Composition**
Ingredients in descending order of weight: glucose syrup, gum arabic, vitamin K1 (phytonadione), tricalcium phosphate.

**Solubility**
The product can be dispersed in cold water at 10 °C, to form a stable milky emulsion.

**Specification**
Assay  min. 1.00% vitamin K$_1$


**Monographs**
The active ingredient complies with the current “Phytomenadione” Ph. Eur. and “Phytonadione” USP monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin K source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

**Storage/Handling**
The product should be stored in the tightly sealed packaging at room temperature (max. 25 °C), in a dry place. It is essential to protect the product from light.

**Applications**
* Dietary supplements:*
For use in solid products containing vitamin K$_1$ as the sole active ingredient, as well as multivitamin and mineral preparations, such as tablets, sugar-coated tablets, instant-drink granules, effervescent tablets, and hard gelatin capsules.
Food products:
Food products for babies and children, except for non-cereal-based Infant Food formulations in the EU, dietetic products, instant-drink powders, dried milk, and vitamin mixtures for the food and ingredients industry. Dry vitamin K₁ 1% GFP can also be used in multivitamin fruit juices and confectionery, e.g., multivitamin sweets. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

Note
Dry Vitamin K₁ 1% GFP must be handled in accordance with the Safety Data Sheet.
Dry Vitamin K$_1$ 5% GFP

**Chemical names of active ingredient**
Phytomenadione, phylloquinone, phytonadione, 2-methyl-3-phytyl-1,4-naphthoquinone

<table>
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<th>CAS-No.</th>
<th>84-80-0</th>
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<td>EINECS-No.</td>
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**PRD-No.**
30041002*

* The product is kosher.

**Article**
56283231  25 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, light-yellow powder, consisting of almost spherical particles or agglomerates.

**Composition**
Ingredients in descending order of weight: glucose syrup, gum arabic, vitamin K1 (phytonadione), tricalcium phosphate.

**Solubility**
The product can be dispersed in cold water at 10 °C, to form a stable milky emulsion.

**Specification**
Assay  min. 5.00% vitamin K$_1$


**Monographs**
The active ingredient complies with the current “Phytomenadione” Ph. Eur. and “Phytonadione” USP monographs.

**Regulations**
The product meets the regulatory requirements for a vitamin K source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

**Storage/Handling**
The product should be stored in the tightly closed packaging at room temperature (max. 25 °C). It is essential to protect the product from light.

**Applications**
*Dietary supplements:*
For the manufacture of solid products with vitamin K$_1$ as the sole active ingredient, as well as multivitamin and mineral preparations, e.g., tablets, sugar-coated tablets, instant-drink granules, effervescent tablets, and hard gelatin capsules.
**Food products:**
Food products for babies and small children, except for non-cereal-based Infant Food formulations in the EU, dietetic products, instant-drink powders, dried milk and for vitamin mixtures for the food and ingredients industry. Dry vitamin K, 5% can also be used in multivitamin fruit juices and confectionery, e.g., multivitamin sweets. Furthermore, the maximum level of acacia gum in the final infant nutrient preparation has to be considered. The product is gelatin-free and particularly suitable for vegetarian foods.

**Note**
Dry Vitamin K, 5% GFP must be handled in accordance with the Safety Data Sheet.
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Carotenoids

Carotenoids occur in virtually all plants and animals, but particularly in organisms exposed to the sun, as most carotenoids selectively absorb light.

More than 500 different types of carotenoids, excluding their various cis- and trans-isomers have been described. The main carotenoids and polyenes include:

- α- and β-carotene
- lycopene
- lutein
- zeaxanthin
- astaxanthin
- β-cryptoxanthin
- β-apo-8′-carotenoids
- phytoene and phytofluene
- neoxanthin
- violaxanthin
- canthaxanthin
- citranaxanthin

Carotenoids are divided into carotenes (hydrocarbons) and xanthophylls (oxygenated derivatives of these hydrocarbons). Xanthophylls (Greek: xanthos = yellow, phyllon = leaf) are usually yellow in color. They are responsible for the yellow coloration of leaves in autumn. Lutein and zeaxanthin are the most important types of xanthophylls. The group of hydrocarbon carotenoids includes the best known of all, beta-carotene. The carotenoid distribution in plant and animal tissue varies greatly.

Naturally occurring carotenoids are completely insoluble in water. They are associated with lipids, to which they impart their color, e.g., milk fat, red palm oil, tomatoes, and carrots. Some of the carotenoids absorbed are not metabolized in the intestinal mucosa. Instead they are incorporated into the chylomicrons, which transport them unchanged into the blood stream via the lymphatic system. Based on the vitamin A requirement of the organism, carotenoids with provitamin A character such as β-carotene, α-carotene, β-cryptoxanthin, as well as the two β-apo-8′-carotenoids, β-apo-8′-carotenal, and β-apo-8′-carotenoic acid ethyl ester can be converted to retinal in the mucosa, followed by reduction to retinol (= vitamin A alcohol). LDL particles usually transport lycopene and β-carotene in the blood stream. Tissue containing more LDL receptors such as the testes, adrenals, and prostate therefore absorb more lycopene. According to Bendich and Olson (1989), the biological activity of the carotenoids can be subdivided into function, effects, and association. Association includes the relationship between beta-carotene status or absorption and development of certain chronic diseases.

**Functions**

- α-, β-, and γ-carotene, β-apo-8′-carotenal, β-cryptoxanthin, 3-keto-beta-carotene, and β-apo-8′-carotenoids have a proven provitamin A activity in humans.

- They protect against light and oxidation in plants.

**Effects**

- antioxidant effect, particularly at low oxygen tension (lycopene shows the highest antioxidant potential)
- singlet oxygen quenching
- inhibition of mutagenicity
- increased in vivo immune response
- improved cell-to-cell communication
- reduction of precancerous changes, e.g., leukoplakia and dysplasia
- reduction of light-induced neoplasias in animals
- reduction of skin reactions in light dermatoses
- macula protection from UV light.

Other potential effects are being examined.
Associations

- Low plasma beta-carotene concentration is associated with an increased risk of various precancerous diseases, e.g., cervical dysplasia and various forms of cancer including prostate cancer.
- Low plasma beta-carotene concentration is associated with an increased risk of cardiovascular disease.
- High plasma lycopene concentration is believed to reduce the risk of prostate cancer.

Some carotenoids are used in the food industry mainly as colorants in lemonades, margarine, butter, edible oils, soup powders, pastry and baked goods, confectionery, ice cream, custard, cheese, yoghurt, and other dairy products.

In addition to the coloring effect, carotenoids play an important role in metabolic functions. As it is not teratogenic, beta-carotene (provitamin A) in particular is added to many vitamin-fortified food products as a safe source of vitamin A.
**Chemical names of active ingredient**
β-Apo-8’-carotenal and β-apo-8’-carotenoic acid ethyl ester, or beta-apo-8’-carotenal and ethyl beta-apo-8’-carotenoate

**Units**
1 mg retinol = 12 mg of β-apo-8’-carotenoids

**Physiological importance**
β-Apo-8’-carotenal and β-apo-8’-carotenoic acid ethyl ester belong to the provitamin A group, which is partially converted to vitamin A compounds in the intestinal mucosa. These structural intermediates are formed when the carotenes are metabolized to vitamin A compounds.

**Occurrence**
Provitamin A is synthesized in plants only. Traces of β-apo-8’-carotenal are formed during the decomposition of C_{40} provitamins (i.e., beta-carotene) and are distributed all over the biological tissue. Traces can be found in citrus fruits, alfalfa, spinach, and a number of other green vegetables. β-Apo-8’-carotenoic acid ethyl ester is found both in traces as an intermediate in the decomposition of C_{40} provitamins and in the apocarotenal metabolism.

**Biological activity**
In contrast to beta-carotene, β-apo-8’-carotenal and β-apo-8’-carotenoic acid ethyl ester demonstrated a vitamin A activity of 72% and 25 – 78% respectively in a curative growth test in rats. Calculated on a molar basis, the activity of β-apo-carotenoids is 40 – 80% compared to beta-carotene.

Based on an average mixed diet, the activity ratio for humans is 12:1, i.e., the effect of 12 mg of β-apo-8’-carotenoid is equivalent to 1 mg of retinol.

**Toxicity**
β-Apo-8’-carotenal and β-apo-8’-carotenoic acid ethyl ester are considered non toxic. Properly handled and used as intended, these substances have no harmful effects on human health.

**Applications**
The β-apo-8’-carotenoids are primarily used as physiologically safe food colorants in fats, oils, margarine, mayonnaise, cheese, and other fat-containing products.

**Properties**
β-Apo-8’-carotenal and β-apo-8’-carotenoic acid ethyl ester are deep-violet and rust-red powders respectively. Their characteristic luminous color is attributed to conjugated double bonds and a carbonyl group.

β-Apo-8’-carotenoids are insoluble in water and glycerol, almost insoluble in alcohol, fats, and oils, somewhat soluble in ether and acetone, and relatively readily soluble in chloroform and benzene. Their solubility is higher compared to beta-carotene. Similar to vitamin A, they are sensitive to light, air, and acids. They are readily oxidized by air to form colorless products.
### Chemical name of active ingredient

β-Apo-8′-carotenal, mainly in the form of the trans isomer

### CAS-No.
1107-26-2

### EINECS-No.
214-171-6

### PRD-No.
30078425*

* The product is kosher. Sold in Japan.

### Article

| 51294498 | 4 x 5 kg aluminum bottle |

### Country of origin

Germany

### Description

Dark-brown, oily, odorless dispersion of liquid consistency.

### Composition

Apocarotenal (food colorant), medium-chain triglycerides, DL-alpha-tocopherol (E307).

### Specification

| Assay | min. 20% |


### Monographs

No monographs exist for the apocarotenal dispersion.

### Regulations

Apocarotenal is approved for use as a food colorant in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

### Stability

The apocarotenal dispersion is stabilized with approximately 1% DL-α-tocopherol (E307). Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months.

### Storage/Handling

The product is sensitive to atmospheric oxygen, light, heat, and moisture and should therefore be stored under nitrogen in a cool place, in the tightly sealed, original packaging.

### Applications

**Food products:** Apocarotenal dispersions are used as colorants in fats, oils, margarine, and other fat-containing foods.
The following quantities are recommended:

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheese</td>
<td>30 – 60 mg apocarotenal/kg</td>
</tr>
<tr>
<td>Salad dressings</td>
<td>50 – 120 mg apocarotenal/kg</td>
</tr>
<tr>
<td>Sauces</td>
<td>20 – 100 mg apocarotenal/kg</td>
</tr>
</tbody>
</table>

**Note**

Apocarotinal Dispersion 20 MCT must be handled in accordance with the Safety Data Sheet.
**Beta-carotene**

**Chemical names of active ingredient**
Beta-carotene, provitamin A

**Units**
1 µg Retinol Activity Equivalent (RAE) (US)
- = 1 µg all-trans-retinol
- = 2 µg β-carotene in supplements
- = 12 µg β-carotene in foods
- = 24 µg α-carotene in foods
- = 24 µg β-cryptoxanthin in foods

1 µg Retinol Equivalent (RE) (Europe)
- = 1 µg all-trans-retinol
- = 6 µg β-carotene
- = 12 µg other provitamin A carotenoids

**Physiological importance**
Beta-carotene has two independent effects in humans: it is a source of vitamin A and it prevents the harmful effects of free radicals.

In its role as provitamin A, it can enzymatically be converted into retinol on demand. The rate of conversion of beta-carotene to retinol is dependent on the source. 2 µg of beta-carotene dissolved in oil supply 1 µg of retinol. More than 12 µg beta-carotene is required to produce 1 µg of retinol from mixed vegetables and fruits.

As an antioxidant, beta-carotene is able to scavenge aggressive free radicals and quench singlet oxygen, thereby reducing cell damage resulting from the oxidation of lipids, proteins, hormones, vitamins, nucleic acids, and polysaccharides. Free radicals may be involved directly in the development of malignant neoplasias, carcinogenesis, arteriogenesis, and coronary heart disease. Epidemiological studies show that low plasma beta-carotene and carotenoid concentrations correlate with an increased risk of developing different types of cancer, such as esophageal, stomach and skin cancers, as well as cardiovascular disease.

**Occurrence**
Only higher plants and microorganisms synthesize carotenoids. Due to its broad occurrence and the fact that it has the highest vitamin A activity, beta-carotene is the most important among the 50 – 60 compounds with provitamin A activity.

Intensively yellow and orange colored vegetables, such as carrots, various types of potato, apricots, mangoes, some types of melon, pumpkins, etc., contain more than 80% of their provitamin A in the form of beta-carotene. Other rich sources are intensively colored green vegetables, such as spinach, green cabbage, broccoli, lamb’s lettuce, and fennel.

**Recommended dosages**
No RDA for beta-carotene has been established in any country to date.

The degree to which beta-carotene in vegetables is utilized is dependent on their mechanical preparation, i.e., whether the cell walls are broken open or not. As the absorption of beta-carotene is linked to the presence of lipids, it is only readily absorbed if the diet contains adequate quantities of fat. The additional presence of proteins or bile acid further supports absorption.
Based on the scientific data currently available, the American Heart Association and the National Cancer Institute in the US recommend a diet rich in carotenoids.

The National Nutrition Societies of Germany, Austria, and Switzerland (DACH 2000) recommend a daily beta-carotene intake of 2 – 4 mg.

Metabolic situations in which radicals are formed at a higher rate, such as stress after an accident, surgery under anesthetic, smoking, alcoholism, handling of carcinogens at work, physical exertion, intensive sun exposure, etc., greatly reduce the concentration of beta-carotene in plasma, indicating the need for increased beta-carotene intake in these situations.

Deficiency symptoms
So far, no deficiency symptoms have been attributed to an inadequate intake of beta-carotene. However, epidemiological studies indicate that an inadequate intake of beta-carotene (and other carotenoids) is associated with an increased risk of cancer, as well as degenerative diseases, such as atherosclerosis and coronary heart disease.

Safety
In toxicity and mutagenicity tests, no effects of beta-carotene were observed. Oral dosages are well tolerated and interactions with drugs have not been observed. At high dosages, the skin may turn yellow (carotinodermia). This is a nuisance, but not a hazard and reversible when supplementation is terminated. No toxic effects have been reported from the treatment of erythropoietic protoporphyria with very high dosages (about 180 mg/d). Two intervention studies on beta-carotene showed an increased lung cancer risk in chronic heavy smokers treated with high-dose supplements of beta-carotene (20 mg/day or more). Other studies have shown no adverse effects of beta-carotene.

There is no evidence of teratogenic or embryotoxic effects and no malformations have ever been reported even after long-term intake of high dosages or during pregnancy.

FNB and SCF reviewed but did not establish a UL for beta-carotene. EVM has established a Safe Upper Limit of 7 mg per day (supplemental intake). According to CRN, the Upper Level for Supplements for non-smokers is 25 mg per day. Smokers usually are discouraged from taking supplemental beta-carotene.

Indications
Established clinical indications for beta-carotene include:
- prevention of vitamin A deficiencies
- therapy of light dermatoses
  - erythropoietic porphyria (protoporphyria, porphyria erythropoetica congenita)
  - polymorphous light dermatosis
  - light urticaria
  - UVA intolerance

Good cosmetic effects can also be achieved in the treatment of both hypopigmentation (vitiligo, albinism) and hyperpigmentation.

Based on the possible preventive effect of beta-carotene on the development of atherosclerosis, coronary heart disease, hyperlipidemia, and cancer, a balanced supply of antioxidants, including adequate beta-carotene supply appears to be beneficial.

In the food industry, beta-carotene is mainly used as a colorant in lemonades, margarine, butter, edible oils, soup powders, pasta, baked goods, confectionery, ice cream, custard, cheese, yoghurt, and other dairy products.

As provitamin A, beta-carotene is increasingly being used for the fortification of multivitamin juices, beverages for athletes, food supplement preparations, health foods, etc.
**Properties**

Beta-carotene forms red-brown to deep-violet crystals, which are very sensitive to heat and oxidation. It is insoluble in water and glycerol, somewhat soluble in ether and acetone, hardly soluble in alcohol, fats, and oils, but readily soluble in chlorinated hydrocarbons (chloroform), benzene, n-hexane, and carbon disulfide. The pattern of conjugated double bonds in the beta-carotene molecule imparts a fluorescent yellow color to the solutions. Upon heating in solution, particularly in the presence of light, isomerization occurs, resulting in decreased amounts of all-trans beta-carotene and increased amounts of cis isomers, until the thermodynamic equilibrium is reached.
Beta-Carotene 10% DC

**Chemical names of active ingredient**
Beta-carotene, provitamin A

**CAS-No.** 7235-40-7

**EINECS-No.** 230-636-6

**PRD-No.** 30061834

**Article**
50097700 25 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, dark-red powder with a mild characteristic odor, consisting of spherical particles, with a uniform particle size. Some white starch particles may be visible.

**Composition**
Ingredients in descending order of weight: gelatin, sucrose, corn starch, beta-carotene, tocopherol (E306), sodium ascorbate, tricalcium phosphate, ascorbyl palmitate.

**Solubility**
Dispersible in warm water (35 – 40 °C), to form a stable orange dispersion.

**Specification**
Assay min. 10%


**Monographs**
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

**Regulations**
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with tocopherol (E306), sodium ascorbate (E301), and ascorbyl palmitate (E304). The stability of Beta-Carotene 10% DC is excellent even in the presence of minerals. The product has a high mechanical integrity and little or none of the beta-carotene is expressed during tabletting, resulting in good stability of the tablets. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

**Storage/Handling**
The product is sensitive to oxygen, light, heat, and moisture and should therefore be stored in the tightly sealed original packaging at room temperature (max. 25 °C), in a dry and dark place.
Applications

Dietary supplements:
Beta-carotene dry powders are used as provitamin A in solid multivitamin preparations, because no Upper Safe Level for the use of beta-carotene as provitamin A has been established unlike for vitamin A. Beta-Carotene 10% DC is used both as provitamin A and as an active ingredient. It is particularly suitable for use in multivitamin/mineral tablets and beta-carotene tablets, as well as hard gelatin capsules due to its excellent flow properties.

Food products:
Due to its composition, Beta-Carotene 10% DC is especially suitable for use in food supplement preparations such as plain tablets, effervescent tablets, and sugar-coated tablets.

Note
Beta-Carotene 10% DC must be handled in accordance with the Safety Data Sheet.
Beta-Carotene 10% DC/GFP

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-No. 30255882*
* The product is kosher.

Article 50802978 25 kg bag in box

Country of origin
Denmark

Description
Free-flowing, dark-red powder with a mild characteristic odor, consisting of spherical particles, with a uniform particle size. Some white starch particles may be visible.

Composition

Solubility
Dispersible in cold water (10 °C), to form a stable orange dispersion.

Specification
Assay min. 10%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.7 g/ml

Stability
The product is stabilized with tocopherol (E307), sodium ascorbate (E301), and ascorbic acid (E300). Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling
The product is sensitive to oxygen, light, heat, and moisture and should therefore be stored in the tightly sealed original packaging at room temperature (max. 25 °C), in a dry and dark place.
Applications

Dietary supplements
The product has been designed for the direct compression of multivitamin mineral tablets as well as hard-shell capsules. It is also suitable for both chewable and effervescent tablets, and sugar- or film-coated tablets.

Food products
The product does not contain protein and is suitable for use in many different food products including hypoallergenic products.

Note
Beta-Carotene 10% DC/GFP must be handled in accordance with the Safety Data Sheet.
Beta-Carotene 20% DC

**Chemical names of active ingredient**
Beta-carotene, provitamin A

**CAS-No.** 7235-40-7

**EINECS-No.** 230-636-6

**PRD-No.** 30061292

**Article**
50094891 25 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, dark-red powder with a mild characteristic odor, consisting of spherical particles with a uniform particle size. Some white starch particles may be visible.

**Composition**

**Solubility**
Dispersible in warm water (35 – 40 °C), to form a stable orange dispersion.

**Specification**

<table>
<thead>
<tr>
<th>Assay</th>
<th>min. 20%</th>
</tr>
</thead>
</table>


**Monographs**
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

**Regulations**
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with tocopherol (E306) and sodium ascorbate (E301). The stability of Beta-Carotene 20% DC is excellent even in the presence of minerals. The product has a high mechanical integrity and little or none of the beta-carotene is expressed during tabletting, resulting in good stability of the tablets. Stored in its original packaging at room temperature (max. 25 °C), it is stable for at least 36 months.

**Storage/Handling**
The product is sensitive to oxygen, light, heat, and moisture and should therefore be stored in the tightly closed original packaging at room temperature (max. 25 °C), in a dry and dark place.
Applications

Dietary supplements:
Beta-carotene dry powders are used as provitamin A in solid multivitamin preparations. Unlike vitamin A, no Upper Safe Level for use of beta-carotene as provitamin A has been established to date.
Beta-Carotene 20% DC is used both as a provitamin A and as an active ingredient. Due to its excellent flow properties, it is particularly suitable for use in multivitamin/mineral tablets and beta-carotene tablets, as well as hard gelatin capsules.

Food products:
Due to its composition, Beta-Carotene 20% DC is especially suitable for use in food supplement preparations, such as plain, effervescent, and sugar-coated tablets.

Note
Beta-Carotene 20% DC must be handled in accordance with the Safety Data Sheet.
Lucarotin® 1 CWD/Y

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-No. 30249105*
* The product is kosher.

Article 52574132 20 kg bag in box

Country of origin
Germany

Description
Free-flowing, low-dust, red-orange powder with a mild characteristic odor.

Composition

Solubility
The product can be scattered into stirred cold water, to obtain a fine dispersion (CWD = cold-water dispersible) with a yellow color (Y = yellow).

Specification
Assay min. 1%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
0.5 – 0.65 g/ml

Stability
The product is stabilized with DL-α-tocopherol (E307) and sodium ascorbate (E301). Stored in its unopened original packaging at room temperature (max. 25 °C), it is stable for at least 24 months.

Storage/Handling
The product is sensitive to atmospheric oxygen, light, heat, and moisture. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.
**Applications**

*Dietary supplements:* Lucarotin 1 CWD/Y is excellent for use as a colorant in sugar-coated tablets, syrups, and emulsions. It can be included in instant-drink granules as provitamin A.

*Food products:* Lucarotin 1 CWD/Y is particularly suitable as a colorant in instant-drink powders, confectionery, candied fruit, biscuits, chewing gum, ice cream, custard powder, soup powders, pickle liquor, fermented milk products, etc., as well as fruit beverages and lemonades.

**Note**

Lucarotin 1 CWD/Y must be handled in accordance with the Safety Data Sheet.
Lucarotin® 10 CWD S/Y

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-No. 30041166*
* The product is kosher.

Article 50046711 2 x 5 kg bag in box

Country of origin
Germany

Description
Fine, free-flowing, brown-red powder with a mild characteristic odor.

Composition

Solubility
The product can be scattered into stirred cold water (CWD = cold-water dispersible), to obtain a fine dispersion with an orange-yellow color, which is slightly more yellow than the F/O formulation.

Specification
Assay min. 10%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
0.40 – 0.55 g/ml

Stability
The product is stabilized with DL-α-tocopherol (E307) and ascorbyl palmitate (E304). Stored in its unopened original packaging at room temperature (max. 25 °C), it is stable for at least 24 months.

Storage/Handling
The product is sensitive to atmospheric oxygen, light, heat, and moisture. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.
Applications

Food products:
One of the advantages of Lucarotin 10 CWD S/Y is its excellent dispersibility in cold water, thereby saving time and energy otherwise required for heating the product. The powder disperses very readily at room temperature in aqueous media to form a fine dispersion of beta-carotene particles.

The powder can be added directly during the production process or as a 1% stock dispersion. Stock dispersions are prepared by slowly scattering the product into stirred water in the required proportions. They should always be prepared for immediate use only.

Lucarotin 10 CWD S/Y is particularly suitable as a colorant in fruit juices, fruit beverages, lemonades, and other products based on fruit juice concentrates potentially containing ascorbic acid.

In addition, it can be used as a colorant in instant-drink powders, confectionery, candied fruit, biscuits, chewing gum, ice cream, custard powder, soup powders, fermented milk products, pasta, cheese, etc., as long as the use of beta-carotene as colorant in any of these products is not prohibited by law.

Due to its excellent dispersibility in cold media, the product is suitable for use in vitamin mixtures for the fortification of foods with provitamin A.

Note
Lucarotin 10 CWD S/Y must be handled in accordance with the Safety Data Sheet.
## Chemical names of active ingredient

Beta-carotene, provitamin A

<table>
<thead>
<tr>
<th><strong>CAS-No.</strong></th>
<th>7235-40-7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EINECS-No.</strong></td>
<td>230-636-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PRD-No.</strong></th>
<th>30218536*</th>
</tr>
</thead>
</table>

* The product is kosher.

### Article

| 52338653 | 20 kg bag in box |

### Country of origin

Germany

### Description

Fine, free-flowing, brown-red powder with a mild characteristic odor.

### Composition

Ingredients in descending order of weight:
modified food starch, glucose syrup, beta-carotene, medium-chain triglycerides, DL-alpha-tocopherol, tricalcium phosphate.

### Solubility

The product can be scattered into stirred cold water (CWD = cold-water dispersible), to obtain a fine dispersion with an orange-yellow color (O = orange).

### Specification

**Assay**

min. 10%

For further information see separate document:

### Monographs

The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

### Regulations

Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

### Bulk density

0.40 – 0.55 g/ml

### Stability

The product is stabilized with DL-α-tocopherol (E307). Stored in its unopened original packaging at room temperature (max. 25 °C), it is stable for at least 24 months.

### Storage/Handling

The product is sensitive to oxygen, light, heat, and moisture. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.
Applications

Food products:
One of the advantages of Lucarotin 10 CWD/O is its excellent dispersibility in cold water, thereby saving time and energy otherwise required for heating the product. The powder disperses very readily at room temperature in aqueous media to form a fine dispersion of beta-carotene particles. The powder can either be added directly during the production process or added slowly to 20 – 100 times its weight of water. Stock dispersions are prepared by slowly scattering the product into stirred water in the required proportions. They should always be prepared for immediate use only.

Lucarotin 10 CWD/O is particularly suitable for use as a colorant in fruit juices, fruit beverages, lemonades, and other products based on fruit juice concentrates, which may also contain ascorbic acid.

In addition, it can be used as a colorant in instant-drink powders, confectionery, candied fruits, biscuits, chewing gum, ice cream, custard powder, soup powders, milk shakes, fermented milk products, pasta, cheese, etc., as long as the use of beta-carotene as a colorant in any of these products is not forbidden by law.

Due to its excellent dispersibility in cold media, the product is suitable for use in vitamin mixtures for the fortification of foods with provitamin A.

Note
Lucarotin 10 CWD/O must be handled in accordance with the Safety Data Sheet.
**Chemical names of active ingredient**
Beta-carotene, provitamin A

**CAS-No.** 7235-40-7  
**EINECS-No.** 230-636-6

**PRD-No.** 30153296*  
* The product is kosher.

**Article**  
56976893 2 x 5 kg bag in box

**Country of origin**  
Germany

**Description**  
Fine, free-flowing, brown-red powder with a mild characteristic odor.

**Composition**  

**Solubility**  
The product can be scattered into stirred cold water (CWD = cold-water dispersible), to obtain a fine dispersion with an orange-yellow color, which is slightly more orange than the S/Y formulation.

**Specification**  
Assay min. 10%


**Monographs**
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

**Regulations**
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**  
0.40 – 0.55 g/ml

**Stability**
The product is stabilized with DL-α-tocopherol (E307) and ascorbyl palmitate (E304). Stored in its unopened original packaging at room temperature (max. 25 °C), it is stable for at least 24 months.

**Storage/Handling**
The product is sensitive to oxygen, light, heat, and moisture. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.
Applications

Food products:
One of the main advantages of Lucarotin 10 CWD F/O is its excellent dispersibility in cold water, thereby saving time and energy otherwise required for heating the product. The powder disperses very readily at room temperature in aqueous media to form a fine dispersion of beta-carotene particles. The powder can either be added directly during the production process or added slowly to 20 – 100 times its weight of water. Stock dispersions are prepared by slowly scattering the product into stirred water in the required proportions. They should always be prepared for immediate use only.

Lucarotin CWD F/O is particularly suitable as a colorant in fruit juices, fruit beverages, lemonades, and other products based on fruit juice concentrates, which may also contain ascorbic acid. In addition, it can be used as a colorant in instant-drink powders, confectionery, candied fruits, biscuits, chewing gum, ice cream, custard powder, soup powders, milk shakes, fermented milk products, pasta, cheese, etc., as long as the use of beta-carotene as a colorant in any of these products is not forbidden by law.

Due to its excellent dispersibility in cold media, the product is suitable for use in vitamin mixtures for the fortification of foods with provitamin A.

Note
Lucarotin 10 CWD F/O must be handled in accordance with the Safety Data Sheet.
Lucarotin® 10 CWD F/R

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-No. 30167279*
* The product is kosher.

Article 50573434 25 kg bag in box

Country of origin
Denmark

Description
Free-flowing, dark-red powder with a mild characteristic odor, consisting of spherical particles with a uniform particle size. Some white starch particles may be visible.

Composition
Ingredients in descending order of weight: fish gelatin, sucrose, corn starch, beta-carotene, sodium ascorbate, tricalcium phosphate.

Solubility
The product can be dissolved in cold water (10 °C), to obtain an orange-red dispersion, which remains uniform for a long time (F/R = fish gelatin/red).

Specifications
Assay min. 10%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with sodium ascorbate (E301). It is sensitive to humidity. Stored in its original packaging at room temperature (max. 25 °C), it is stable for at least 36 months.

Storage/Handling
In the original packaging at room temperature (max. 25 °C), in a dry place, protected from daylight.

Applications
Used in effervescent tablets, beverages, and other food and dietary supplement products.

Note
Lucarotin 10 CWD F/R must be handled in accordance with the Safety Data Sheet.
Beta-Carotene 20% CWD/R

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-No. 30283190*
* The product is kosher.

Article 53387788 25 kg bag in box

Country of origin
Denmark

Description
Free-flowing, dark-red powder with a mild characteristic odor, consisting of spherical particles with a uniform particle size. Some white starch particles may be visible.

Composition
Ingredients in descending order of weight: modified starch, isomalt, beta-carotene, corn starch, sodium ascorbate, ascorbic acid, tricalcium phosphate.

Solubility
The product can be dissolved in cold water (10 °C) to obtain an orange-red dispersion which remains uniform for a long time (R = red).

Specification
Assay min. 20%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is stabilized with sodium ascorbate (E301) and ascorbic acid (E300). It is sensitive to humidity. Stored in its original packaging at room temperature (max. 25 °C), it is stable for at least 36 months.

Storage/Handling
In the original packaging at room temperature (max. 25 °C), in a dry place, protected from daylight.

Applications
Used in effervescent tablets, beverages, and other food and dietary supplement products.

Note
Beta-Carotene 20% CWD/R must be handled in accordance with the Safety Data Sheet.
**Lucarotin® Emulsion 10**

**Chemical names of active ingredient**
Beta-carotene, provitamin A

<table>
<thead>
<tr>
<th>Chemical No.</th>
<th>CAS-No.</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient</td>
<td>7235-40-7</td>
<td>230-636-6</td>
</tr>
</tbody>
</table>

**PRD-No.**
30041144*

* This product is kosher.

**Article**
50003146 4 x 5 kg aluminum bottle

**Country of origin**
Germany

**Description**
Red-brown emulsion. Stabilized beta-carotene dispersed in vegetable oil and emulsified in a mixture of glycerol and water. It contains ascorbyl palmitate (E304) and DL-alpha-tocopherol (E307) as antioxidants. The emulsion has a characteristic odor.

**Composition**

**Solubility**
Homogeneously miscible even in cold water.

**Specification**
Assay min. 10%

For further information see separate document: "Standard Specification" (not for regulatory purposes) available via BASF’s WorldAccount: https://worldaccount.basf.com (registered access).

**Monographs**
The active ingredient complies with the current "Beta-carotene" Ph. Eur. and "β-Carotene" FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

**Regulations**
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Stability**
The product is stabilized with ascorbyl palmitate (E304) and DL-α-tocopherol (E307).

Stored in its unopened original packaging at 5 – 10 °C, the product is stable for at least 12 months.

**Storage/Handling**
The product is sensitive to atmospheric oxygen, light, heat, and moisture. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place (5 – 10 °C). Once opened, it is recommended to use the remaining contents as quickly as possible.

C_{40}H_{56} Molar mass 536.9 g/mol
Applications

*Food products:* Lucarotin Emulsion 10 is particularly suitable as a colorant in fruit beverages, carbonated lemonades, and other products made with fruit juice concentrates, potentially containing ascorbic acid. Moreover, it can also be used as a colorant in confectionery, candied fruits, biscuits, chewing gum, ice cream, milk-based drinks, fermented milk products, pasta, cheese, etc.

It is recommended to dilute Lucarotin Emulsion 10 to a concentration of 2% with soft water before use.

**Note**

Lucarotin Emulsion 10 must be handled in accordance with the Safety Data Sheet.
Lucarotin® Dispersions

Chemical names of active ingredient
Beta-carotene, provitamin A

CAS-No. 7235-40-7
EINECS-No. 230-636-6

PRD-Nos. Articles
30041157* Lucarotin 30 M
50082735 4 x 5 kg aluminum bottle
30085626* Lucarotin 30 SUN
51988215 4 x 5 kg aluminum bottle

* The product is kosher.

Country of origin
Germany

Description
Brick-red, oily dispersions with a neutral flavor containing beta-carotene in microcrystalline form in vegetable oils.

Composition
Lucarotin 30 M corn oil
Lucarotin 30 SUN sunflower oil

Specifications
Assay Lucarotin 30 M min. 30%
Lucarotin 30 SUN min. 30%


Monographs
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

Regulations
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Stability
The Lucarotin dispersions do not contain a stabilizer. Stored in their unopened original packaging at room temperature (max. 25 °C), the products are stable for at least 36 months. As beta-carotene may sink to the bottom of the container, the dispersions should always be stirred prior to use.

Storage/Handling
The products are sensitive to atmospheric oxygen, light, heat, and moisture. Lucarotin dispersions should therefore be stored under nitrogen in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.

Applications
Dietary supplements:
The Lucarotin dispersions are used in soft capsules as provitamin A, as an active ingredient, and as a colorant.

Food products:
Used as both yellow-orange colorant and provitamin A. Even at low concentrations, beta-carotene dispersions have a high tintorial strength. They are suitable for coloring as well as for standardizing the color of oils, fats, margarine, butter, processed
cheese, cheese spreads, milk replacement products, ice cream, soups, sauces, fillings of baked goods, and egg products. They are added to the oily phase.

**Important: Beta-carotene dispersions should be stirred briefly prior to use.**

The Lucarotin dispersions are usually processed as stock solution in a suitable quantity of oil, prepared by careful heating to 40 °C. This stock solution is then added to the food product.

The table below provides approximate of 100% beta-carotene, which are added to 1 kg of various food products. The quantity is dependent on the required shade and should be determined in small scale tests.

<table>
<thead>
<tr>
<th>Product</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butter</td>
<td>14 – 16 mg/kg</td>
</tr>
<tr>
<td>Cream fillings</td>
<td>1 – 10 mg/kg</td>
</tr>
<tr>
<td>Egg products</td>
<td>2 – 5 mg/kg</td>
</tr>
<tr>
<td>Fats, oils</td>
<td>7 – 10 mg/kg</td>
</tr>
<tr>
<td>Replacement products</td>
<td>2 – 5 mg/kg</td>
</tr>
<tr>
<td>based on vegetable oils</td>
<td></td>
</tr>
<tr>
<td>Cheese preparations</td>
<td>1 – 2 mg/kg</td>
</tr>
<tr>
<td>Margarine</td>
<td>6 – 12 mg/kg</td>
</tr>
<tr>
<td>Salad dressings</td>
<td>3 – 9 mg/kg</td>
</tr>
<tr>
<td>Processed cheese</td>
<td>10 – 25 mg/kg</td>
</tr>
<tr>
<td>Sauces</td>
<td>4 – 20 mg/kg</td>
</tr>
<tr>
<td>Ice cream</td>
<td>2 – 6 mg/kg</td>
</tr>
<tr>
<td>Soups</td>
<td>0.2 – 1 mg/kg</td>
</tr>
</tbody>
</table>

1 The Lucarotin dry powders can also be used to color these food products.

- **Butter:**
  The stock solution is heated to 45 °C and added to the cream.

- **Pasta products containing egg:**
  A stock solution containing about 0.5% beta-carotene in oil is evenly mixed with a defined quantity of flour; the colored premix is added to the flour prior to production.

- **Imitation cheese:**
  The beta-carotene stock solution in vegetable oil is heated to 50 – 60 °C and added during production.

- **Margarine:**
  The beta-carotene dispersion is completely dissolved in the oily phase prior to emulsification.

- **Salad dressings:**
  The vegetable oil is heated to 45 – 50 °C before adding the beta-carotene dispersion.

- **Processed cheese:**
  A beta-carotene stock solution is prepared in melted butter and added to the cheese mixture prior to the melting process.

- **Ice cream:**
  The required quantity of beta-carotene is stirred into fat or oil until it is completely dissolved; the temperature of the oil should be at least 20 °C, preferably 37 – 50 °C.

- **Soups:**
  The oil for the soup is heated and the beta-carotene dispersion dissolved in it.

**Note**

The Lucarotin Dispersions must be handled in accordance with the Safety Data Sheet.
Beta-Carotene 22% HS-HP

**Chemical names of active ingredient**  
Beta-carotene, provitamin A

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>7235-40-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS-No.</td>
<td>230-636-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRD-No.</th>
<th>30206583*</th>
</tr>
</thead>
</table>

* The product is kosher.

**Article**  
50534110 20 kg plastic bucket

**Country of origin**  
Germany

**Description**  
Brick-red oily, dispersion containing 22% beta-carotene, citric acid, and DL-alpha-tocopherol in corn oil.

**Composition**  
Ingredients in descending order of weight: corn oil, beta-carotene, citric acid, DL-alpha-tocopherol.

**Solubility**  
Soluble in oils and fats. Insoluble in water.

**Specification**  
Assay  
min. 22% of β-carotene  
(min. 367,400 IU/gram of vitamin A)


**Monographs**  
The active ingredient complies with the current “Beta-carotene” Ph. Eur. and “β-Carotene” FCC monographs, as well as the purity requirements of Directive 2008/128/EC (E160 a).

**Regulations**  
Beta-carotene is approved for use as a food colorant and as a provitamin A source in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Stability**  
The product is stabilized with tocopherol (E307). Stored in their unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 24 months. As beta-carotene may sink to the bottom of the container, the product should always be stirred prior to use.

**Storage/Handling**  
The products is sensitive to atmospheric oxygen, light, heat, and moisture. Beta-Carotene 22% HS-HP should therefore be stored under nitrogen in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible or at least pad with nitrogen until reuse.

**Applications**  
* Dietary supplements:  
Beta-Carotene 22% HS-HP is used in soft capsules as provitamin A, as an active ingredient, and as a colorant.
**Food products:**
Used as both yellow-orange colorant and pro-vitamin A. Even at low concentrations, the product has a high tinctorial strength. It is suitable for coloring as well as for standardizing the color of oils, fats, margarine, butter, processed cheese, cheese spreads, milk replacement products, ice cream, soups, sauces, fillings of baked goods, and egg products that are processed at high temperatures. The product is added to the oily phase.

**Important: Beta-Carotene 22% HS-HP should be stirred briefly prior to use.**

Beta-Carotene 22% HS-HP is usually processed as stock solution in a suitable quantity of oil, prepared by heating to 40 – 60 °C. This stock solution is then added to the food product.

The table below provides approximate of 100% beta-carotene, which are added to 1 kg of various food products. The quantity is dependent on the required shade and should be determined in small scale tests.

<table>
<thead>
<tr>
<th>Food Product</th>
<th>Beta-Carotene Range (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butter</td>
<td>14 – 16 mg/kg</td>
</tr>
<tr>
<td>Cream fillings</td>
<td>1 – 10 mg/kg</td>
</tr>
<tr>
<td>Egg products</td>
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<td>Fats, oils</td>
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<tr>
<td>Soups</td>
<td>0.2 – 1 mg/kg</td>
</tr>
</tbody>
</table>

1 Beta-Carotene 22% HS-HP can also be used to color these food products.

- **Butter:**
  The stock solution is heated to 45 °C and added to the cream.
- **Pasta products containing egg:**
  A stock solution containing about 0.5% beta-carotene in oil is evenly mixed with a defined quantity of flour; the colored premix is added to the flour prior to production.
- **Imitation cheese:**
  The stock solution in vegetable oil is heated to 50 – 60 °C and added during production.
- **Margarine:**
  The product is completely dissolved in the oily phase prior to emulsification.
- **Salad dressings:**
  The vegetable oil is heated to 45 – 50 °C before adding the product.
- **Processed cheese:**
  A stock solution is prepared in melted butter and added to the cheese mixture prior to the melting process.
- **Ice cream:**
  The required quantity of beta-carotene is stirred into fat or oil until it is completely dissolved; the temperature of the oil should be at least 20 °C, preferably 37 – 50 °C.
- **Soups:**
  The oil for the soup is heated and the product dissolved in it.

**Note**
Beta-Carotene 22% HS-HP must be handled in accordance with the Safety Data Sheet.
Lycopene

**Chemical name of active ingredient**
Lycopene

**Physiological importance**
Lycopene complements the antioxidant network, which helps prevent oxidative stress. *In vitro* studies have shown that lycopene has the highest singlet oxygen quenching activity of all commonly consumed carotenoids.

**Cardiovascular health**
Reactive oxygen species and the resulting radical-induced changes appear to be one cause for the development of cardiovascular disease (CVD). Due to its antioxidant potential, lycopene may play a role in the prevention of CVD. Based on a prospective study including approximately 40,000 middle-aged women, a positive association was found between high intake of tomatoes or high plasma lycopene concentration and a lower risk of cardiovascular disease, including myocardial infarction, stroke, revascularization, and death from cardiovascular disease.

**Lung health**
Being permanently exposed to oxidative and ozone stress, the lungs are particularly vulnerable to oxidative damage. Antioxidants in the respiratory epithelium and the alveolar lining may provide protection. The addition of lycopene (LycoVit® 10%) to the diet substantially reduced smoke-induced squamous metaplasia, a precancerous alteration of the cells in ferrets exposed to cigarette smoke. According to an analysis of several case-controlled studies, there is some evidence of a protective association between increased consumption of tomatoes and lung cancer.

**Prostate health**
Epidemiological evidence suggests that high intake of tomato products or high plasma lycopene concentrations reduce the risk of prostate cancer. This association persists even if fruit and vegetable consumption are controlled. In an animal experiment involving nude mice carrying orthotopic transplants of a human prostate cancer line (cancer cells injected into the prostate gland of the mice), the effects of lycopene (LycoVit) and vitamin E supplements to the diet were analyzed. The clinical course was monitored with a miniature transrectal ultrasound probe. Lycopene and lycopene plus vitamin E delayed the progression of prostate cancer and lowered the serum prostate specific antigen (PSA). A randomized, double-blind, placebo-controlled pilot study was conducted, aiming to investigate the effects of lycopene supplementation in elderly men diagnosed with benign prostate hyperplasia. The intake of 15 mg lycopene (from LycoVit) per day over a period of 6 months significantly decreased serum PSA levels and inhibited the progression of prostate enlargement.

**Protection from UV radiation**
Studies in humans exposed to ultraviolet radiation showed that lycopene supplementation mitigates oxidative damage to the skin. Although oral intake of lycopene provides less sun protection than topical sunscreens with a high protection factor, dietary intervention may confer a basic protection, which remains effective when topical sunscreen is absent or has faded. Lycopene may be considered a moderately active oral sun protection. In conjunction with topical sunscreens, it contributes to the body’s defense against sun-induced skin damage.

![Lycopene Structural Formula](image_url)
Occurrence
Lycopene is most commonly found in tomatoes. Other dietary sources of lycopene are pink grapefruit, watermelon and papaya.

Trans- and cis-isomers
In raw tomatoes, approximately 95% of lycopene occurs in the trans-lycopene form. Upon heating during food processing and cooking, the isomeric composition changes with the proportion of trans-lycopene diminishing and the proportion of cis-isomers increasing up to approximately 30% of the total lycopene content. In blood, cis- and trans-lycopene account for approximately 50% each. Hence, the cis vs. trans ratio in the blood is independent of the ratio in the food.

Bioavailability
The bioavailability of LycoVit 10%, in parallel with a natural preparation based on tomato-lycopene, was tested in a clinical study. A daily dosage of 10 mg lycopene was ingested for 28 days. Both the synthetic and the natural source resulted in significant and almost identical increases of plasma lycopene concentrations, indicating that the bioavailability is equal for both sources.

Safety and recommendation
Lycopene-containing fruits and vegetables have been considered safe for human consumption for a long time. Synthetic lycopene preparations have been tested in toxicological studies to determine their safety. In a preclinical study, rats were fed LycoVit 10% and LycoVit 10 CWD powders at standardized dietary levels of up to 3,000 mg/kg body weight per day for 13 weeks.

Neither preparation was shown to have an effect on body weight, appetite, urinalysis, hematology, or post mortem results. The NOAEL was 3,000 mg/kg body weight per day. Developmental toxicity studies in pregnant rats and rabbits were carried out in order to determine embryotoxicity and teratogenicity of LycoVit 10%. The results of this study showed no developmental toxicity at maximum dosages of 3,000 mg/kg body weight per day in rats and 2,000 mg/kg body weight per day in rabbits. Likewise, no teratogenic effects were observed in a study on rats spanning two generations. Lycopene preparations are neither genotoxic nor mutagenic.

Based on the available safety data JECFA and EFSA established an ADI for lycopene ("not specified" and "0.5 mg/kg body weight" respectively). No RDA for lycopene has been established in any country to date. BASF recommends an intake of up to 15 mg lycopene from LycoVit products per day.

Properties
Lycopene forms dark-red to dark-violet crystals that are very sensitive to oxidation and heat. It is insoluble in water, acids, and alkalis, and nearly insoluble in methanol and ethanol, but it is soluble in chloroform and in tetrahydrofuran. It is sparingly soluble in ether, hexane, and in vegetable oils.
**Chemical name of active ingredient**

Lycopene

**CAS-No.** 502-65-8  
**EINECS-No.** 207-949-1

**PRD-No.** 30276090*  
* The product is kosher.

**Article**  
52753643 2 x 5 kg alu bag in box

**Country of origin**  
Germany

**Description**  
Fine, free-flowing, red-violet powder.

**Composition**  
Ingredients in descending order of weight: glucose sirup, modified starch (E1450), lycopene, and DL-α-tocopherol.

**Solubility**  
The product can be scattered into stirred cold water (CWD = cold-water dispersible), to obtain a fine dispersion with a red color. (20 – 25 ppm results in a clear, red dispersion).

**Specification**  
Assay min. 10.0%


**Chemical structure**  
\[ \text{C}_{40}\text{H}_{56} \]  
Molar mass 536.9 g/mol

**Monographs**  
The active ingredient complies with the current “Lycopene” USP, FCC, and JECFA monographs.

**Regulations**  
Lycopene is a conditionally approved food colorant and nutritional ingredient. Therefore, national regulations in the respective countries have to be observed.

**Bulk density**  
0.4 – 0.6 g/ml

**Stability**  
The product is stabilized with DL-α-tocopherol (E307). Stored in its unopened original packaging at room temperature (max. 25 °C), it is stable for at least 24 months.

**Storage/Handling**  
The product is sensitive to oxygen, light, heat, and moisture, and should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.

**Applications**  
Fortification of processed food, especially beverages, confectionery, and dairy products.

**Note**  
LycoVit 10 CWD/S must be handled in accordance with the Safety Data Sheet.
### LycoVit® 10% DC

**Chemical name of active ingredient**
Lycopene

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>502-65-8</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS-No.</td>
<td>207-949-1</td>
</tr>
<tr>
<td>PRD-No.</td>
<td>30075276</td>
</tr>
</tbody>
</table>

**Article**
50825236 25 kg bag in box

**Country of origin**
Denmark

**Description**
Free-flowing, dark-red powder, consisting of spherical particles with a uniform particle size. Some white starch particles may be visible.

**Composition**
Ingredients in descending order of weight:

**Solubility**
Dispersible in warm water (35 – 40°C), to form a stable red dispersion.

**Specification**
Assay min. 10% lycopene


**Monographs**
The product complies with the current “Lycopene preparation” USP monograph. The active ingredient complies with the current “Lycopene” USP, FCC, and JECFA monographs.

**Regulations**
Lycopene is a conditionally approved food colorant and nutritional ingredient. Therefore, national regulations in the respective countries have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is stabilized with tocopherol (E307), sodium ascorbate (E301), and ascorbyl palmitate (E304).
The stability of LycoVit 10% DC is excellent even in the presence of minerals. The product has a high mechanical integrity and little or none of the lycopene is expressed during tabletting, resulting in good stability in the tablets. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

**Storage/Handling**
The product is sensitive to oxygen, light, heat, and moisture, and should therefore be stored in the tightly sealed original packaging at room temperature (max. 25 °C), in a dry place, protected from daylight.
Applications

Dietary supplements:
Due to its excellent flow properties, LycoVit 10% DC is particularly suitable for use in multivitamin/mineral tablets, single-entity lycopene tablets, as well as hard gelatin capsules.

Food products:
Due to its composition, LycoVit 10% DC is especially suitable for use in food supplement preparations such as plain, effervescent, and sugar-coated tablets.

Note
LycoVit 10% DC must be handled in accordance with the Safety Data Sheet.
LycoVit® Dispersion 10%

**Chemical name of active ingredient**
Lycopene

**CAS-No.**
502-65-8

**EINECS-No.**
207-949-1

**PRD-No.**
30264388*

* The product is kosher.

**Article**
51588597 25 kg steel drum

**Country of origin**
Germany

**Description**
LycoVit Dispersion 10% is a red-violet, oily dispersion containing microcrystalline lycopene in sunflower oil. No additional stabilizers are used in the production of the dispersion.

**Composition**
Ingredients in descending order of weight: sunflower oil, lycopene.

**Specification**
Assay min. 10% lycopene


**Regulations**
Lycopene is a conditionally approved food colorant and nutritional ingredient. Therefore, national regulations in the respective countries have to be observed.

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months. As microcrystalline lycopene may sink to the bottom of the packaging during storage, the dispersion should always be stirred prior to use.

**Storage/Handling**
The product is sensitive to atmospheric oxygen, light, heat, and moisture, and should therefore be stored under nitrogen in the tightly sealed original packaging in a cool place (8 – 15 °C). Once opened, it is recommended to use the remaining content as quickly as possible.

**Applications**
In dietary supplements, the lycopene dispersion is used as an active ingredient in soft gelatin capsules.

Furthermore, it is suitable for the fortification of food and supplements, especially within oily preparations.

**Note**
LycoVit Dispersion 10% must be handled in accordance with the Safety Data Sheet.
Lutein

Chemical name of active ingredient
Lutein

Physiological importance
Lutein is—like other carotenoids—a powerful antioxidant and helps to prevent oxidative stress. Lutein does not have provitamin A activity.

Eye health
Lutein is the major carotenoid found in the human eye and plays an important role in eye health. It selectively accumulates in eye tissues and is, along with zeaxanthin and some metabolites, the only carotenoid found in lens and retina of the human eye. The highest concentration of lutein in the human body is found in the macular region of the retina in the back of the human eye, particularly in the center (fovea, “yellow spot”). Lutein, zeaxanthin, and mesozeaxanthin—a lutein metabolite—comprise the so-called “macular pigment.” The density of macular pigment is considered a marker for macular health. It strongly correlates with lutein intake and is inversely related to the risk of age-related eye diseases.

As a natural filter of blue light and antioxidant, lutein may protect eye tissues such as the retina and lens from light damage as well as from other sources of oxidative stress (“free radicals”) resulting from exposure to cigarette smoke, pollution, and other environmental hazards.

Age-related macular degeneration (AMD) and cataract are common eye diseases and worldwide an increasing threat to older individuals causing vision loss and eventually blindness. Both diseases may be prevented by lutein. Clinical studies with patients suffering already from these eye diseases suggest that lutein supplements can help improve vision.

AMD is an increasingly common eye disease among older individuals (age > 65 years) and the leading cause of age-related blindness in the Western world. Progressive loss of photoreceptors and degradation of the macula impair central and sharp vision, which are indispensable for activities like reading or driving, eventually lead to total blindness.

While the lens absorbs UV light, the macula at the back of the human eye is the target tissue for incoming blue light and thus highly susceptible to light damage. In the center of the retina, where a maximum of protection is required, lutein is accumulated to protect photoreceptors.

Epidemiological studies revealed that individuals with low intake and low blood levels of lutein/zeaxanthin, and (consequently) a low macular pigment density, are at increased risk of AMD. A beneficial role of these xanthophylls in preventing AMD is further supported from investigations using donor eyes from persons with AMD. Lower amounts of lutein/zeaxanthin were found in the macula as compared to eyes from healthy control subjects.

Lutein may also be important in the prevention of cataract, which is an opacification of the lens due to oxidative damage. Cataract manifests as progressive visual impairment and may lead to blindness. Cataracts are increasingly common with older age, and cataract extraction is one of the most frequent surgeries in the elderly. Prospective large-scale epidemiological studies, like the Health Professionals Study in US men (n=36,644) or the Nurses’ Health Study in US women, showed that high intake of lutein-rich food is associated with a reduced risk of cataract extraction (approximately by 20% comparing highest vs. lowest quintiles of intake), whereas other carotenoids were not found to be related to disease risk.

Regular intake of lutein supplements has been shown to increase blood lutein levels and subsequently macular pigment density. In clinical trials, an improvement of visual in patients with AMD or cataract has been demonstrated.
Heart disease and cancer
Like other carotenoids, lutein may also have a number of other health benefits preventing chronic diseases such as heart disease and some cancers (such as lung, breast, and colon cancer). This has been suggested by a number of epidemiological and experimental studies, which associated high lutein intake with a decreased risk of chronic disease.

Occurrence
Lutein is most commonly found in green leafy vegetables, such as spinach, collard greens, kale, endive, celery, and lettuce. Other important dietary sources of lutein are green legumes, orange-red tubers, and fresh herbs as well as egg yolk.

Bioavailability
The bioavailability of the direct-compressible lutein formulation was demonstrated in healthy women aged 50 – 70. A daily dose of 12 mg lutein was consumed for 2 months and resulted in a 5-fold increase in blood levels of lutein. Blood levels of beta-carotene and lycopene were not affected. In the same study, consumption of 4 mg lutein per day in combination with 4 mg beta-carotene and 4 mg lycopene also gave rise to significant increases in plasma lutein (2.3-fold). All lutein containing supplements were well tolerated.

Safety and recommendation
There is a long history of safe consumption of lutein-containing fruits and vegetables in humans. A lutein formulation based on free lutein derived from Tagetes erecta was tested in toxicological studies to determine safety. This lutein formulation was not mutagenic and did not show genotoxicity in vivo.

Repeated dose oral toxicity was tested in rats and dogs and it was demonstrated that the lutein formulation did not show any signs of maternal and developmental toxicity in doses up to 200 mg lutein/kg body weight per day. Based on a high safety margin, BASF recommends an intake of up to 15 mg lutein per day. No RDA for lutein has been established in any country to date. However, the JECFA (Joint FAO/WHO Expert Committee on Food Additives) extrapolated animal data to set an ADI (acceptable daily intake) of 2 mg/kg body weight (equivalent to 120 mg/day for a 60 kg person) for lutein and zeaxanthin derived from Tagetes erecta.

Lutein supplements may serve as a beneficial adjunct to food intake and may provide a considerable health benefit for the public. Lutein 5% DC contains free lutein derived from marigold flowers.

Properties
Lutein forms dark-orange crystals that are very sensitive to oxidation and degradation by light or heat. It is a lipophilic molecule and generally insoluble in water, and is chemically unstable in acid.
Lutein 5% DC

Chemical names of active ingredient
Lutein, β-ε-carotene-3,3’-diol (3R, 3’R, 6’R)

CAS-No. 127-40-2
EINECS-No. 204-840-0

PRD-No. 30267108

Article 51843209 25 kg bag in box

Country of origin Denmark

Description Free-flowing, dark-orange powder, consisting of spherical particles with a uniform particle size. Some white to yellow starch particles may be visible.

Composition Ingredients in descending order of weight: corn starch, gelatin, sucrose, lutein, tricalcium phosphate, DL-alpha-tocopherol, sodium ascorbate, ascorbyl palmitate.

Solubility Dispersible in warm water (35 – 40 °C), to form a stable yellow-to-orange dispersion. Insoluble starch particles may be visible.

Specification
Lutein Assay min. 5%
Zeaxanthin Assay min. 0.25%


Monographs
The active ingredient complies with the current “Lutein” USP monograph.

Regulations
Lutein is approved for use as a food colorant and as a nutritional ingredient in most countries. However, specific regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density Approx. 0.6 g/ml

Stability The product is stabilized with tocopherol (E307), sodium ascorbate (E301), and ascorbyl palmitate. Stored in its original packaging at room temperature (max. 25 °C), the product is stable for at least 36 months.

Storage/Handling The product is sensitive to oxygen, light, heat, and moisture, and should therefore be stored in the tightly sealed original packaging at room temperature (max. 25 °C), in a dry place, protected from daylight.

Applications Dietary supplements
The product has been designed for the direct compression of multivitamin mineral tablets as well as hard-shell capsules. It is also suitable for single entities and sugar- or film-coated tablets.

Note Lutein 5% DC must be handled in accordance with the Safety Data Sheet.
Omega-3s
<table>
<thead>
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<tr>
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<tr>
<td>Omega-3 fatty acids</td>
<td>161</td>
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<td>Dry n-3 18:12</td>
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<tr>
<td>Dry n-3 5:25 C</td>
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<tr>
<td>Dry n-3 DHA 11</td>
<td>170</td>
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</tbody>
</table>
Polyunsaturated fatty acids (PUFAs) are chains of 18, 20, or 22 carbon atoms with 2 – 6 double bonds in cis-configuration. The following two types of PUFAs with different biological functions are known: those with the first double bond at the 3rd carbon atom (n-3 or omega-3 fatty acids) and those with the first double bond at the 6th carbon atom (n-6 or omega-6 fatty acids), counting from the methyl or omega end. The fatty acids containing 18 carbon atoms are considered essential for growth and functioning of the body. They cannot be synthesized via the metabolic route (they can only undergo chain elongation with the introduction of additional double bonds) and must be supplied with the diet. Absence or chronically inadequate supply of polyunsaturated fatty acids may result in characteristic deficiency symptoms.

**n-6 fatty acids**
- Linoleic acid (C18:2)
- γ-Linolenic acid (C18:3)
- Arachidonic acid (C20:4)

**n-3 fatty acids**
- α-Linolenic acid (C18:3)
- Eicosapentaenoic acid (C20:5)
- Docosahexaenoic acid (C22:6)

Linoleic acid, which occurs in a large number of vegetable oils (e.g., sunflower, corn, soy, thistle, and linseed oil), is the best known n-6 fatty acid. Evening primrose and borage seeds are rich sources of γ-linolenic acid.

High concentrations of α-linolenic acid, the best known of the n-3 fatty acids, are only found in linseed and soy oil.

Long-chain n-3 fatty acids (eicosapentaenoic acid, docosahexaenoic acid) do not occur in vegetable oils. They are present only in fish oil (herring, mackerel, salmon, sardine, tuna) and marine mammals. Therefore, fish oil is considered the most important source of n-3 fatty acids.

The human organism requires both n-6 fatty acids and n-3 fatty acids as an energy source. Moreover, they are essential for the formation of structural lipids, which have important function within the membranes. As a component of the cell membranes, docosahexaenoic acid is vital for the formation of retina and the brain, particularly in newborns and infants. Polyunsaturated fatty acids also act as precursors for eicosanoids, hormone-like substances, which have a regulatory effect on tissue, i.e., the prostaglandins, thromboxanes, and leukotrienes.

n-3 and n-6 fatty acids cannot be converted into each other nor can one replace the other. In fact, they compete as building blocks in the cell membranes for the same enzyme system, one displacing the other. It is therefore possible to reduce the level of n-6 fatty acids in the body with a high intake of n-3 fatty acids and vice versa. A balanced intake of n-3 and n-6 fatty acids with the diet is therefore necessary to maintain a normal body function.

An imbalance between n-3 and n-6 fatty acids in the diet can seriously interfere with the composition of growing tissue and the equilibrium of antagonistic eicosanoids. Various health problems, such as thrombosis, inflammations, tumor growth, and psoriasis are associated with excessive intake of n-6 fatty acids.

High intake of long-chain n-3 fatty acids has the opposite effect, i.e., it prevents the development of thromboses and resulting cardiovascular disease, such as arteriosclerosis, heart attack, and stroke. In addition, long-chain n-3 fatty acids from fish oil seem to have a positive effect on the immune system and alleviate symptoms such as arthritis and psoriasis.
Research is currently being carried out in order to determine the most favorable association between n-6 and n-3 fatty acids within the human organism. According to current knowledge, a ratio of 5:1 to 10:1 appears to be desirable. However, the average diet contains a much higher proportion of n-6 fatty acids, particularly linoleic acid. To improve the intake of long-chain n-3 fatty acids from 0.1 g per day to the desirable 0.3 – 0.4 g per day, it is recommended to either include fish in 2 – 3 meals per week, eat 30 g of fish per day, or supplement the daily diet with fish oil.

Fortification of food products with n-3 fatty acids from fish oil could play an important role for improving the average diet in the future. BASF offers a free-flowing powder with a high PUFA content, which is not only resistant to oxidation, but also completely tasteless and odorless, thanks to a special microencapsulation process. The original flavor, quality, and stability of the final product will no longer be affected by the addition of n-fatty acids from fish oil. This in turn means that the dietary value of a wide range of food products can be improved and as such make important contribution toward improving the general health of the population.
**Omega-3 fatty acids**

**Chemical name of active ingredient**

n-3 fatty acids or omega-3 fatty acids, i.e., α-linolenic acid, eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA)

**Physiological importance**

The essential n-3 fatty acid α-linolenic acid (C18:3) serves as an energy carrier and precursor for the synthesis of EPA (C20:5) and DHA (C22:6) into which it is converted by chain elongation and introduction of extra double bonds. EPA is an important component of the phospholipids of cell membranes and lipoproteins. It also serves as a precursor in the synthesis of eicosanoids, which have a regulatory function on tissue hormones. These include 3-series prostaglandins (PGA₃, PGB₃, PGD₃, PGE₃, PGJ₃) with a mainly vasodilatory and coagulation-inhibiting action as well as thromboxane A₃ and 5-series leukotrienes (LTA₅, LTB₅, LTC₅, LTD₅, LTE₅).

DHA (C22:6) can be synthesized from EPA in the body with additional chain elongation and desaturation. DHA is a structural component in the cell membranes, particularly the nervous tissue of the brain, and plays an important role both for the synapses and the cells of the retina.

The conversion of α-linolenic acid to its long-chain derivatives EPA and DHA may not be sufficient to maintain optimal body functions. The limited conversion is mainly due to a dramatic change in eating habits during the past 150 years, resulting in increased n-6 PUFA intake and concomitant decrease in n-3 LCPUFA consumption in most industrialized countries. Therefore, the n-6 to n-3 ratio in our diet has changed from 2:1 to about 10 – 20:1. This change accounts for the inadequate biosynthesis of the biologically active n-3 PUFA, EPA, and DHA, as n-6 and n-3 PUFA compete for the same desaturase and elongase enzyme systems.

n-3 fatty acids have a preventive effect on the development of cardiovascular disease by significantly reducing serum triglyceride concentrations, blood pressure, and platelet aggregation, and by increasing HDL-cholesterol levels.

EPA-derived eicosanoids affect immunological processes and fulfill anti-inflammatory functions.

In addition, n-3 fatty acids have “noneicosanoid” functions attributed to their physical properties. They are able to modify the membrane fluidity, which is of particular relevance in terms of erythrocytes.
Occurrence

α-Linolenic acid is synthesized in the chloroplasts of plants, which contain the necessary enzyme system for introducing an additional double bond, allowing linoleic acid (C18:2, n-6) to be converted to α-linolenic acid (C18:3, n-3).

α-Linolenic acid occurs in wheat germ, soy oil (approx. 10%), and linseed oil (50 – 65%).

Algae, plankton as well as the fish feeding on them, contain long-chain n-3 fatty acids such as EPA and DHA. A particularly rich source of EPA and DHA is fish oil from fish that have their natural habitat in the sea (mackerel, herring, salmon, sardine, tuna, cod) and marine mammals. They do not occur in vegetable oils.

Recommended dosages

As n-3 and n-6 fatty acids compete for the same desaturase and elongase enzyme system, recommended dosages also depend on the intake of other unsaturated fatty acids. According to current scientific knowledge, the ratio of n-6 to n-3 fatty acids should be between 5:1 and 10:1.

An intake of 0.9 – 1.0 g per day is considered optimal with respect to α-linolenic acid. Estimates for the most favorable intake of long-chain n-3 fatty acids (EPA/DHA) range from 0.2 – 1.0 g per day. These quantities have been recognized as a healthy diet and a prevention of cardiovascular disease by many scientific associations.

The National Food Agency in Denmark recommends a diet containing at least 30 g of fish from different species per day (equivalent to approx. 350 mg of n-3 fatty acids) or 2 – 3 meals consisting of fish per week.

The Committee on Medical Aspects (COMA) (UK) recommends a long-chain n-3 polyunsaturated fatty acid intake of 1500 mg per week.

Recently, the American Heart Association recommended an intake of 1 g EPA and DHA per day for patients with a high risk of cardiovascular disease.

An adequate intake of the long-chain n-3 fatty acid DHA with the diet is particularly important for risk groups, such as premature babies, babies who are not breast-fed, pregnant women, malnourished persons, athletes, and individuals who cannot or do not want to eat fish or who are subject to a strict or unbalanced diet.

DHA is of particular importance for newborns as it plays a key role in the development of the central nervous system and the retina. As the metabolism of a newborn does not have the ability yet to extend the chains of fatty acids, α-linolenic acid cannot be converted into the essential DHA. Thus newborns need an adequate DHA supply either via breast milk or infant formula.

Deficiency symptoms

Due to the relatively high requirement during growth and the limited supply, the risk of developing n-3 fatty acid deficiency is higher in babies and children than in adults. No specific clinical symptoms have yet been established in adults. Visible signs of deficiency have only been observed in seriously ill patients on a special fat-free diet for several months. The patients were seen to develop extensive inflammation of the skin, ulcers, reduced visual acuity, disturbed superficial and depth sensibility, muscular weakness, and trembling.

Biochemical parameters such as EPA and DHA concentrations in the blood fats and blood cells were significantly reduced, whereas the long-chain n-6 fatty acid concentrations were elevated.
The main risk groups for essential fatty acid deficiency are premature babies, babies who are not breast-fed, persons with disturbed fat absorption, and alcoholics.

**Toxicity**

n-3 fatty acids contained in fish oils are considered nutrients. Properly handled and used as intended, these substances have no toxic effect on human health.

Side-effects associated with very high fish oil intake (> 20 g/day) include a feeling of satiation accompanied by diarrhea in rare cases. No side-effects are expected at the recommended dosages (between 0.2 and 6 g/day).

**Indications**

*Infant nutrition*

- Human breast milk contains DHA (approximately 0.3% of total fatty acids).
- Preterm and term infants require DHA for the development of visual and cognitive functions.
- In many countries, the supplementation of infant formula with DHA has been approved at dosages reflecting the intake of breast-fed infants (20 – 30 mg/kg body weight and day).

**Health effects — cardiovascular**

DHA/EPA reduce the risk of contracting cardiovascular disease. Epidemiological studies have shown that Greenland Inuits have a low incidence of CVD, which correlates with the high dietary intake of n-3 LCPUFA. A recent secondary intervention analysis involving 11,324 patients demonstrated that DHA/EPA (1 g DHA/EPA per day: ratio 1:2) reduced mortality and incidence rates of myocardial infarction.

Furthermore, n-3 long-chain PUFAs may reduce the cardiovascular risk through prevention of ventricular arrhythmia and cardiac arrest due to:
- antithrombogenic effects: inhibition of thromboxane A2 synthesis,
- hypolipidemic effects: mainly lowering of plasma VLDL and triglyceride concentrations,
- antihypertensive effects,
- retardation of atherosclerotic plaque growth,
- reduction of platelet-derived growth factor,
- inhibition of interleukin-1a and other cytokines,
- promotion of nitric oxide-induced endothelial relaxation.

**Other health effects:**

DHA/EPA improve the symptoms of both atopic and rheumatoid arthritis. As only EPA can participate in the synthesis of anti-inflammatory eicosanoids, it may play a more important role than DHA. DHA/EPA concentrations in the brain are reduced in the blood of depressive patients. A recent double-blind placebo-controlled study involving 30 patients with bipolar disorder demonstrated that patients supplemented with 9.6 g DHA/EPA per day (1:2 ratio) had a significantly longer period of remission compared to the placebo group.

In the ingredients and food industry, n-3 fatty acids in the form of oily or microencapsulated powders are used for the fortification of food products, such as infant formula, maternal nutrition products, food for children, baked goods, pasta, breakfast cereals, ready-made meals, soups, fruit and cereal bars, and frozen food (pizza etc.).

**Properties**

Fish oil quickly becomes rancid at room temperature, because the highly unsaturated fatty acids are readily oxidized. They are converted into unpalatable peroxides spoiling odor, taste, and stability of the product.
Commercial fish oil preparations are therefore sold in the form of gelatin capsules, as they provide a good oxygen barrier. Vitamin E (DL-α-tocopherol) is frequently added as an antioxidant. The highly sensitive fatty acids may also be effectively protected by incorporation into a matrix of gelatin, caseinate and carbohydrates, and micro-encapsulation. The addition of tocopherol as an antioxidant provides further protection, resulting in an easy-to-process powder. Furthermore, it is easily incorporated into foods, has no odor, or taste and provides good long-term stability.
Dry n-3® 18:12
Microencapsulated fish oil rich in EPA and DHA

**Chemical name of active ingredient**
Fish oil with a high content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)

**PRD-No.**
30040353

**Article**
50052590 25 kg bag in box

**Country of origin**
Denmark

**Description**
Light-yellow to light-beige, free-flowing, dry powder, consisting of spherical particles. The particles contain microencapsulated fish oil rich in EPA and DHA.

**Composition**
Ingredients in descending order of weight: fish oil, corn starch, gelatin, sucrose, sodium ascorbate, ascorbic acid, tricalcium phosphate, tocopherol.

**Solubility**
Dispersible in warm water (approx. 35 °C), to form a milky emulsion with good long-term stability.

**Specification**

<table>
<thead>
<tr>
<th>Assay</th>
<th>EPA: min. 4.1 weight-%*</th>
<th>DHA: min. 2.7 weight-%*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>* calculated as triglycerides</td>
<td></td>
</tr>
</tbody>
</table>


**Monographs**
No monographs exist for Dry n-3 18:12.

**Regulations**
The product meets the regulatory requirements for an omega-3 fatty acid source in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is sensitive to air, heat, and light. Stored in its unopened original packaging in a dry place at room temperature (25 °C), the product is stable for at least 24 months. Once opened, it is recommended to use the remaining contents as quickly as possible.
**Storage/Handling**
The product should be stored in the tightly sealed original packaging at room temperature (max. 25 °C) in a dry place.

**Food products:**
The product is suitable for the fortification of most food products.

**Note**
Dry n-3 18:12 must be handled in accordance with the Safety Data Sheet.
Dry n-3® 5:25 C
Microencapsulated fish oil rich in DHA

Chemical name of active ingredient
Fish oil with a high content of docosahexaenoic acid (DHA)

PRD-No.
30056967

Article
50050099  25 kg bag in box

Country of origin
Denmark

Description
Light-yellow to light-beige, free-flowing, dry powder, consisting of spherical particles. The particles contain microencapsulated fish oil rich in DHA.

Composition
Ingredients in descending order of weight:
- fish oil
- sucrose
- corn starch
- caseinate
- sodium ascorbate
- tricalcium phosphate
- tocopherol
- lecithin
- ascorbyl palmitate.

Solubility
Dispensible in cold water (approx. 10 – 15 °C), to form a milky emulsion with good long-term stability.

Specification

<table>
<thead>
<tr>
<th>Assay</th>
<th>DHA: min. 6.7 weight-%*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA: max. 2.5 weight-%</td>
<td></td>
</tr>
</tbody>
</table>

* calculated as triglycerides


Regulations

The product meets the regulatory requirements for an omega-3 fatty acid source, especially DHA, in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

Bulk density
Approx. 0.6 g/ml

Stability
The product is sensitive to air, heat, and light. Stored in its unopened original packaging at room temperature (max. 25 °C) in a dry place, the product is stable for at least 24 months. Once opened, it is recommended to use the remaining contents as quickly as possible.

Storage/Handling
The product should be stored in the tightly sealed original packaging at room temperature (max. 25 °C) in a dry place.
Food products:
The product is suitable for the fortification of basic food products, especially dairy-based powder products.

Dietetic products:
The product is particularly suitable for the fortification of baby foods and maternal nutrition products due to the specific need for DHA supplementation. Regulatory provisions for the use of tricalcium phosphate in the different product categories have to be considered. In the EU, the application in infant foods is limited to fortification with DHA and calcium. Further on in the application, maximum levels of sodium ascorbate have to be considered.

Note
Dry n-3 5:25 C must be handled in accordance with the Safety Data Sheet.
Dry n-3® DHA 11
Microencapsulated fish oil rich in DHA

**Chemical name of active ingredient**
Fish oil with a high content of docosahexaenoic acid (DHA)

**PRD-No.**
30471884

**Article**
54710829 25 kg bag in box

**Country of origin**
Denmark

**Description**
Light-yellow to light-beige, free-flowing, dry powder, consisting of spherical particles. The particles contain microencapsulated fish oil rich in DHA.

**Composition**
Ingredients in descending order of weight: fish oil, corn starch, sucrose, caseinate, sodium ascorbate, tricalcium phosphate, tocopherol, lecithin, ascorbyl palmitate.

**Solubility**
Dispersible in cold water (approx. 15 – 20 °C), to form a milky emulsion with good long-term stability.

**Specification**
<table>
<thead>
<tr>
<th>Assay</th>
<th>DHA: min.10.5 weight-%*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EPA: max. 4.0 weight-%</td>
</tr>
</tbody>
</table>

* calculated as triglycerides


**Regulations**
The product meets the regulatory requirements for an omega-3 fatty acid source, especially DHA, in most countries. However, regulations on the ingredients used in the respective countries and for the intended use have to be observed.

**Bulk density**
Approx. 0.6 g/ml

**Stability**
The product is sensitive to air, heat, and light. Stored in its unopened original packaging at room temperature (max. 25 °C) in a dry place, the product is stable for at least 24 months. Once opened, it is recommended to use the remaining contents as quickly as possible.

**Storage/Handling**
The product should be stored in the tightly sealed original packaging at room temperature (max. 25 °C) in a dry place.
**Food products:**
The product is suitable for the fortification of basic food products, especially dairy-based powder products.

**Dietetic products:**
The product is particularly suitable for the fortification of baby foods and maternal nutrition products due to the specific need for DHA supplementation. Regulatory provisions for the use of tricalcium phosphate in the different product categories have to be considered. In the EU, the application in infant foods is limited to fortification with DHA and calcium. Further on in the application, maximum levels of sodium ascorbate have to be considered.

**Note**
Dry n-3 DHA 11 must be handled in accordance with the Safety Data Sheet.
<table>
<thead>
<tr>
<th>Product</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine</td>
<td>175</td>
</tr>
<tr>
<td>Caffeine Anhydrous Granular</td>
<td>176</td>
</tr>
<tr>
<td>Caffeine Anhydrous Granular S</td>
<td>177</td>
</tr>
</tbody>
</table>
Caffeine

Chemical name of active ingredient
1,3,7-Trimethylxanthine

Caffeine is a methylxanthine and belongs to the group of purine-alkaloids. In its pure form, it is a white, crystalline substance or granules. It is an odorless, bitter-tasting substance, which is freely soluble in boiling water, somewhat soluble in water (20 °C), and slightly soluble in ethanol.

Occurrence
Caffeine is a natural substance and is found in coffee, tea, cola nuts, mate leaves, or guarana plants.

Synthetic caffeine is manufactured in a multi-step process, based on the starting materials cyanacetic acid, dimethyl urea, and acetic anhydride.

Effects
Caffeine acts as a central nervous system stimulant. It is acceptably used for the treatment of fatigue or drowsiness, to help restore mental alertness or wakefulness, as well as to increase the ability to concentrate. It is mood-enhancing and speeds up reaction time. In low concentration it decreases, in high concentration it increases the heart rate. Caffeine is applied in a variety of products and applications, for example, in energy bars, alertness aids (caffeine pills), caffeinated soft drinks, and sports beverages.
Caffeine Anhydrous Granular

**Chemical name of active ingredient**
1,3,7-Trimethylxanthine

**CAS-No.** 58-08-2

**EINECS-No.** 200-362-1

**PRD-No.** 30266245

* The product is kosher.

**Articles**
- 51763391  50 kg drum
- 53575461  500 kg big plastic bag

**Country of origin**
Germany

**Description**
White, crystalline powder, practically odorless, with a bitter taste.

**Solubility**
Somewhat soluble in water, slightly soluble in ethanol and ether.

**Specification**

**Monographs**
The product complies with the current “Caffeine” Ph. Eur, the “Caffeine” USP, and the "Anhydrous Caffeine" JP monographs.

**Stability**
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 48 months.

**Storage/Handling**
The product should be stored in the tightly sealed packaging, protected from light.

**Applications**
**Beverages:**
Caffeine acts as flavor enhancer. Because of its good solubility, the product is very suitable for all beverage applications.

**Note**
Caffeine Anhydrous Granular must be handled in accordance with the Safety Data Sheet.
### Chemical name of active ingredient
1,3,7-Trimethylxanthine

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>58-08-2</th>
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**PRD-No.**
30234997

* The product is kosher.

### Articles
<table>
<thead>
<tr>
<th>Article Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>56603668</td>
<td>50 kg drum</td>
</tr>
<tr>
<td>53724444</td>
<td>500 kg big plastic bag</td>
</tr>
</tbody>
</table>

### Country of origin
Germany

### Description
White, crystalline powder, practically odorless, with a bitter taste.

### Solubility
Somewhat soluble in water, slightly soluble in ethanol and ether.

### Specification
**Assay**
99.5 – 100.5%

(Titration)


### Monographs
The product complies with the current "Caffeine" Ph. Eur, the "Caffeine" USP, and the "Anhydrous Caffeine" JP monographs.

### Stability
Stored in its unopened original packaging at room temperature (max. 25 °C), the product is stable for at least 48 months.

### Storage/Handling
The product should be stored in the tightly sealed packaging, protected from light.

### Applications
**Beverages:**
Caffeine acts as flavor enhancer. Because of its good solubility, the product is very suitable for all beverage applications.

### Note
Caffeine Anhydrous Granular S must be handled in accordance with the Safety Data Sheet.

\[
C_8H_{10}N_4O_2 \quad \text{Molar mass 194.19 g/mol}
\]
Beverage clarifiers/stabilizers
<table>
<thead>
<tr>
<th>Product</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divergan</td>
<td>181</td>
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<tr>
<td>Divergan F</td>
<td>182</td>
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<tr>
<td>Divergan RS</td>
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<tr>
<td>Crosspure</td>
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<tr>
<td>Crosspure F</td>
<td>186</td>
</tr>
<tr>
<td>Crosspure XF</td>
<td>187</td>
</tr>
</tbody>
</table>
Divergan®

Divergan is a cross-linked, insoluble polyvinylpyrrolidone, also known as PVPP. The specific adsorption of polyphenols makes PVPP unique by removing the polyphenols responsible for clouding, without altering the character of the beer.

Different grades provide the brewers with the opportunity to use the product both in regeneration systems and as “single-use” or “single-shot” products, which are discarded after use.

Mechanisms of clouding
After filtration, every clear beer still contains dissolved phenolic compounds and proteins resulting from the raw materials. After a relatively short time, these compounds form complexes which later cause clouding. The main cause for this phenomenon are anthocyanogens, which have a particularly high clouding potential. Specially developed types of Divergan are available for use in both recycling and single-use processes.

Divergan is used in the brewing industry mainly for the following purposes:

Extended shelf life: Adequate stability is especially important for export beers due to long travel and storage times. In this context, a long shelf-life provides decisive competitive advantages.

Consistent quality: International breweries use Divergan as a stabilizer in order to ensure the same taste and consistent quality of their beer throughout the world.

No labeling requirement: Divergan is completely separated from the beer during filtration. Therefore, it is not an additive and does not need to be declared on the label.

Colloidal stability of beer under extreme climatic conditions: The use of Divergan guarantees a constant colloidal stability of the beer especially in regions subject to extreme weather such as tropical countries or very cold regions.

\[(C_6H_9NO)_n\] Molar mass cannot be determined as it is insoluble in all common solvents
Divergan® F

Chemical name of active ingredient
Poly-1-(2-oxo-1-pyrrolidinyl)ethylene

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>9003-39-8</th>
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</thead>
<tbody>
<tr>
<td>PRD-No.</td>
<td>30034969*</td>
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<tr>
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<td>* The product is kosher.</td>
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Articles

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<tr>
<th>Article No.</th>
<th>Description</th>
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<tr>
<td>50579104</td>
<td>30 kg bag in plastic drum</td>
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** This article will replace article no. 50579104 in Q1/2010.

Country of origin
Germany

Description
White, hygroscopic powder with a faint characteristic odor. Divergan F is cross-linked polyvinyl pyrrolidone (PVPP) that has been manufactured by means of a patented polymerization process (DP 2437629). It is insoluble in water and all the usual organic solvents.

Specification

Storage/Handling
In order to maintain its effectiveness, Divergan F should be kept in its closed packaging, in a dry place. Stored in its unopened original packaging, the product is stable for 3 years without loss of activity.

Application in beer
Divergan F is added to the beer as an aqueous suspension prior to filtration. To be fully effective, it must be in contact with the beer for at least 3 minutes before it is completely removed again by filtration together with the adsorbed polyphenols.

Divergan F can also be used at an earlier stage in the production of beer, e.g., during wort treatment or in the storage tank.

However, best results are obtained if the beer has already been largely clarified, e.g., by centrifugation, as the active surface can then no longer be blocked by material in suspension.

A low oxygen content is required for good stabilization results.

Application in wine
Divergan F can be used both preventively and remedially. It is best added as a 10% suspension in a portion of the medium to be treated, i.e., the must or wine, or in water.
The polymer suspension must be allowed to swell for 1–2 hours, preferably with constant stirring, after which it can be added to the fining tank and homogeneously distributed with a stirrer. Within a few minutes (approximately 5–10 minutes), it has almost completed its work.

If, however, Divergan F is added dry, it must be thoroughly mixed-in and allowed at least 30 minutes to act.

To save time, the wine or juice can be filtered before the PVPP has completely settled out, though there is no harm in waiting until it has.

**Note**

Divergan F must be handled in accordance with the Safety Data Sheet.
Divergan® RS

Chemical name of active ingredient
Cross-linked poly-1-(2-oxo-1-pyrrolidinyl)ethylene

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>9003-39-8</th>
</tr>
</thead>
<tbody>
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<td>PRD-No.</td>
<td>30034968*</td>
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* The product is kosher.

Articles

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<tr>
<th>Article</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>50116236</td>
<td>20 kg cardboard drum**</td>
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<tr>
<td>50098705</td>
<td>25 kg bag in plastic drum</td>
</tr>
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</table>

** This article will replace article no. 50098705 in Q1/2010.

Country of origin
Germany

Description
White, hygroscopic powder with a faint characteristic odor. Divergan RS is cross-linked polyvinyl pyrrolidone (PVPP) that has been manufactured by means of a patented polymerization process (DP 2437629). It is insoluble in water and all the usual organic solvents.

Specification

Storage/Handling
In order to maintain its effectiveness, Divergan RS should be kept in its closed packaging in a dry place. Stored in its unopened original packaging, the product is stable for 3 years without loss of activity.

Application
Divergan RS is intended for reuse and therefore requires special filtration and regeneration equipment consisting of a metering device and a filter unit installed downstream of the kieselguhr filters (see Fig. 1).

Fig. 1: Diagram of a filtration line with regenerable PVPP. The PVPP is in a separate filtration/stabilization unit.

Compared with the Divergan F grade, which is designed for single use, Divergan RS is coarser-grained (average particle size 80 – 100 µm) and mechanically stronger. These properties ensure that it can be used again and again without causing blockages or other problems.

Note
Divergan RS must be handled in accordance with the Safety Data Sheet.
Crosspure®

Crosspure is a new, innovative filter aid, developed by BASF for optimum filtration and stabilization of beer. Filtration with Crosspure is a cake filtration method: a purely physical separation that is complemented by adsorptive mechanisms. Compared with conventional products, the filter aid provides other advantages: Crosspure is regenerable, safe, and easy to handle.

BASF produces Crosspure by compounding poly styrene and cross-linked PVP. The special compounding process creates mechanically and chemically particularly stable particles. The product is available as Crosspure F and Crosspure XF, having the same composition but different particle sizes.

Mechanisms of clouding
After maturing, beer still contains not only yeast cells but also protein-tannin complexes, oxalate crystals, and hops resins. After a short time, dissolved proteins and polyphenols form new visible protein-tannin complexes. The particles not only cloud the beer, but also affect its taste considerably. Filtration clarifies the beer, removes particles that can compromise its quality, and provides physio-chemical stability.

Crosspure is used in the brewing industry mainly for the following reasons:

Regenerability:
The Crosspure filtration and regeneration cycle can be repeated almost endlessly. Regeneration losses are less than 1 percent, which is extremely economical and particularly environmentally friendly.

One filter for two effects:
Crosspure is a 2-in-1 solution. Filtration and stabilization occur in one step.

\((\text{C}_6\text{H}_g\text{NO})_n\) Molar mass cannot be determined as it is insoluble in all common solvents

User-friendly:
The filter cake can be easily removed from the filter candles/filter elements.

Reliable and safe:
Crosspure is an insoluble polymer. No abrasion occurs.

No labeling requirement:
Crosspure is completely separated from the beer during filtration. Therefore, it is not an additive and does not need to be declared on the label.
Crosspure F

Chemical names of active ingredients
Poly-(1-phenylethylene); cross-linked poly-(1-(2-oxo-1-pyrrolidinyl)ethylen)

PRD-No.
30369409

Article
51404158 25 kg bag in plastic drum

Country of origin
Germany

Description
White, hygroscopic powder with a weak characteristic odor. Crosspure F is a filter aid that has been manufactured by means of a patented compounding process. It is insoluble in water, alcohol, and all the other common solvents.

Solubility
Insoluble in water, alcohol, and all the other common solvents.

Specification

Stability
Stored in its unopened original packaging, the product is stable for 3 years without loss of activity.

Storage/Handling
In order to maintain its effectiveness, Crosspure F should be kept in its closed packaging in a dry place.

Applications
Beer filtration aid.

Note
Crosspure is approved in EU as a processing aid. Under the prerequisite that Crosspure F is removed from the treated food, that only technically inevitable and technologically ineffective residuels are present, which are unobjectionable in sense of sanitary, smell, and odor, the use doesn’t need to be approved. It is the responsibility of the processor (compare LFBG, §2 (3); Directive 89/107/EWG, Art. 1 (3a)). Crosspure is FDA approved in USA as food contact material. Other approvals or registrations can be requested from the local sales representative. Crosspure is not harmful to health if it is properly handled and used for the purpose intended. The usual precautions against dust should be taken. Transport and storage present no hazard to humans or the environment.

Note
Crosspure F must be handled in accordance with the Safety Data Sheet.
Crosspure XF

Chemical names of active ingredients
Poly-(1-phenylethylen); cross-linked poly-(1-(2-oxo-1-pyrrolidinyl)ethylen)

PRD-No. 30369425

Article 51407179 25 kg bag in plastic drum

Country of origin
Germany

Description
White, hygroscopic powder with a weak characteristic odor. Crosspure XF is a filter aid that has been manufactured by means of a patented compounding process. It is insoluble in water, alcohol, and all the other common solvents.

Solubility
Insoluble in water, alcohol, and all the other common solvents.

Specification

Stability
Stored in its unopened original packaging, the product is stable for 3 years without loss of activity.

Storage/Handling
In order to maintain its effectiveness, Crosspure XF should be kept in its closed packaging in a dry place.

Applications
Beer filtration aid.

Note
Crosspure is approved in EU as a processing aid. Under the prerequisite that Crosspure XF is removed from the treated food, that only technically inevitable and technologically ineffective residues are present, which are unobjectionable in sense of sanitary, smell, and odor, the use doesn’t need to be approved. It is the responsibility of the processor (compare LFBG, §2 (3); Directive 89/107/EWG, Art. 1 (3)a)). Crosspure is FDA approved in USA as food contact material. Other approvals or registrations can be requested from the local sales representative.

Crosspure is not harmful to health if it is properly handled and used for the purpose intended. The usual precautions against dust should be taken. Transport and storage present no hazard to humans or the environment.

Note
Crosspure XF must be handled in accordance with the Safety Data Sheet.
IMPRINT:
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November 2009
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e-mail: nutrition-south-america@basf.com

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