

Antares Vitamin E TPGS

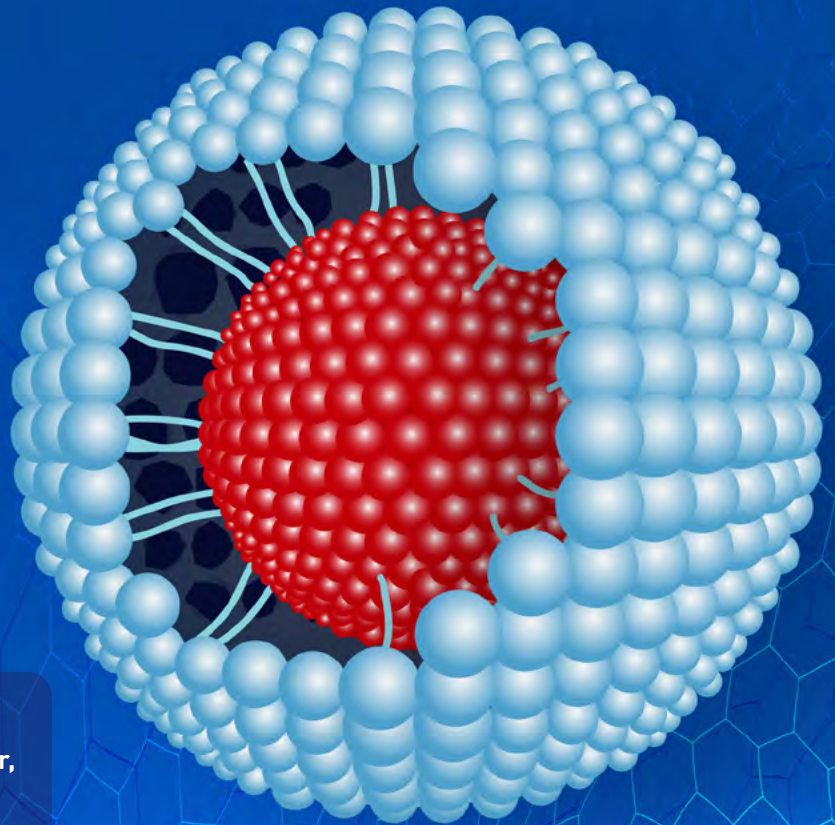
TPGS is a powerful tool in the formulation of poorly-soluble, lipophilic compounds and the enhancement of their absorption and bioavailability.

Antares TPGS

- Pharmaceutical Grade (NF)
- Food Grade (FG)

Sunflower TPGS™

- Pharmaceutical Grade (NF)
- Food Grade (FG)



Antares helps customers develop commercial success implementing custom formulations, powder, and liquid products. Contact our formulation development team for support at info@tpgs.com.

Proven Effective For Use In:

PHARMACEUTICALS

DIETARY
SUPPLEMENTS

FOOD AND
BEVERAGE

PERSONAL CARE
AND COSMETICS

ANIMAL HEALTH
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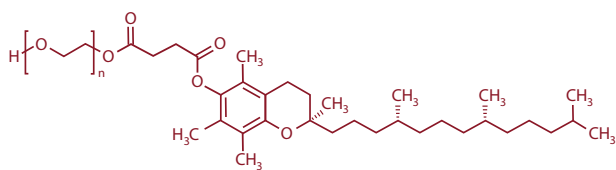
ANTARES
HEALTH PRODUCTS, INC.

Antares TPGS (d- α -tocopheryl polyethylene glycol 1000 succinate), is a water-soluble derivative of the natural form of d- α -tocopherol. TPGS has unique properties due to its dual combination of lipophilicity and hydrophilicity, similar to a surface-active agent. Its applications include formulation of lipophilic and poorly soluble compounds and significantly enhancing absorption and bioavailability. TPGS has a proven record of safety and efficacy in pharmaceuticals, dietary supplements, food and beverage, personal care and cosmetics, animal nutrition, and cannabinoids.

Chemical Properties

Antares TPGS is the polyethylene glycol 1000 ester of d- α -tocopherol succinate.

Chemical structure



Chemical Name	d- α -tocopheryl polyethylene glycol 1000 succinate
Synonyms/Acronyms	Vitamin E TPGS or TPGS, Tocophersolan (INCI and USAN)
Molecular Weight	1513 (approximately)
d- α -tocopherol	25% minimum weight basis, typical range 25-30% d- α -tocopherol
Chemical Stability	Stable when exposed to oxygen, heat, light, or oxidizing agents and under the conditions of heat sterilization.

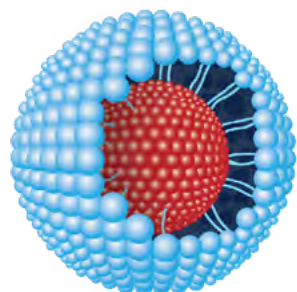
Physical Properties

Antares TPGS is a light colored, water-soluble, waxy solid with a low melting point.

Physical Form	Waxy solid
Color	White to light tan (as solid)
Specific Gravity	1.06 at 45 °C (approximate)
Melting Point	38 °C (approximate), range 37-41 °C
Solubility in Water	Soluble in water at 20 wt %. Higher concentrations will result in the formation of viscous, liquid-crystalline phases.
Heat Stability	Stable to at least 200 °C
Sterilization	Stable when exposed to approximately 125 °C for 1 hour
Viscosity	Constant and low viscosity within a wide range of concentration and temperature (10 - 20% TPGS weight basis in water, 20 - 45 °C)

Surfactant - Forms Micelles

As an amphiphile, Vitamin E TPGS emulsifies lipids and helps solubilize poorly soluble compounds. In addition, it forms micelle-like particles which increase absorption and bioavailability.



Micelles in aqueous solution sequester in their center hydrophobic tail regions and other lipophilic compounds. In the human body, formation of micelles is essential for the absorption of lipids.

Nutritional Characteristics

TPGS supplies natural d- α -tocopherol in water-soluble form. It is universally accepted that the natural form of vitamin E, d- α -tocopherol, is more potent than the synthetic form of vitamin E, dl- α -tocopherol.

TPGS supplies 372-447 IU/g from 250-300 mg d- α -tocopherol/g. Published clinical studies showed that TPGS is absorbed well by patients with liver and pancreatic diseases that lead to malabsorption of vitamin E.

A summary of the nutritional characteristics, which may be used in labeling products containing TPGS, is available at www.TPGS.com.

Applications

Antares TPGS offers unique advantages in product development.

1. Solubilizes lipophilic and poorly soluble compounds including Active Pharmaceutical Ingredients (APIs), nutrients, nutraceuticals, and cannabinoids.
2. Forms micelles and increases absorption and bioavailability.
3. Expands the use of lipophilic and poorly soluble compounds in a wide range of product formats ranging from prescription pharmaceutical and veterinary formulations to capsules, chewable tablets, nutrition bars, gummies, drops, bottled water, beverages and sports drinks, creams, lotions, sprays, and pet snacks and treats.
4. Supplies, in water-soluble form, ethanol free, natural vitamin E without affecting the taste and color of foods and especially drinks.
5. Its safety and efficacy are supported by strong clinical evidence.



Pharmaceuticals

TPGS is a powerful tool in pharmaceutical product development. In addition to its functionality as emulsifier/solubilizer resulting in the formation of micelles, it modulates the efflux pump activity by inhibition of the P-glycoprotein which increases bioavailability. TPGS serves as a vehicle for semisolid formulation and for preventing crystallization, carrier of actives, and thermal binder in developing delivery and controlled release systems.

The multifunctional capabilities of TPGS are currently being used in several innovative drug development projects with promising results. The important targets of this work include diseases such as COVID-19^a, HIV^b, various forms of cancer^{c,d}, and heart disease^e. Antares is pleased to support research into potential new treatment forms, so please contact us for more information. *See citations on next page.*



Dietary Supplements

TPGS has been used to formulate supplements in order to enhance absorption of lipophilic nutrients and nutraceuticals. Of major significance is the formulation of poorly absorbed compounds especially for people with suboptimal absorption such as the elderly and for disease conditions of the liver and the digestive tract which reduce absorption. Examples include CoQ₁₀ and carotenoids (astaxanthin, lycopene, zeaxanthin, and curcumin).

TPGS is also used as a highly bioavailable form of vitamin E in a variety of product formats including drinks and beverages. In addition, its functionality as a solubilizer and absorption enhancer enables the use of lipids and poorly soluble nutrients in liquid supplements which are important product formats especially for children and the elderly.



Food and Beverage

TPGS is used to fortify foods and formulate nutrients and nutraceuticals especially into beverages, sports drinks, juices, and water. Major applications include:

- Beverages, sports drinks, juices, and water fortified with vitamin E or multivitamin/mineral and nutraceuticals. Being water soluble and ethanol free, with neutral taste, TPGS is preferable over other products, especially in water and clear drinks.
- Foods such as bars, puddings, yogurt, and others which aim to supply highly absorbable vitamin E and other lipophilic nutrients and nutraceuticals.



Personal Care & Cosmetics

The properties of TPGS as emulsifier, solubilizer, and formulation excipient, coupled with its safety profile make it a strong formulation tool for topical applications including cosmetics. Major applications include:

- Creams, lotions, and other products for topical application of vitamin E and other formulated actives.
- Eye drops, nasal sprays, syrups, and others primarily in formulating active compounds.



Animal Health & Nutrition

TPGS supplies highly absorbable and bioavailable vitamin E for animals which do not absorb efficiently the traditional oil and solid forms.

These include zoo animals, especially elephants and black rhinoceros, horses, and other animals and pets that require highly absorbable and bioavailable vitamin E.

Major applications include:

- High vitamin E supplements in the form of liquid, powder, gel, tablet, and others.
- Premixes, concentrates, and other forms that can be used in feed fortification.
- Formulation of veterinary, nutrition, and topical compounds for solubility and increased absorption and functionality.



Cannabinoids

Significant scientific evidence indicates that oral absorption of cannabinoids including CBD is very low (below 20%). Emerging research indicates that formulation of cannabinoids with TPGS significantly increases absorption and bioavailability.

In addition, its functionality as a solubilizer and absorption enhancer expands the applications of cannabinoids in a wide range of market segments and product formats. These includes prescription pharmaceutical formulations, capsules, chewable tablets, nutrition bars, gummies, drops, bottled water, beverages, sports drinks, creams, lotions, sprays, and pet treats.

Safety and Regulatory Status

TPGS has a record of safety based on decades of use in animals and humans and on reported toxicology studies. Studies in humans included dosing of cholestatic children at 3 grams of TPGS per day for over two years. It is safe for transportation, storage, and handling. TPGS has a self-affirmed Generally Recognized as Safe (GRAS) status when used as an oral dietary supplement of vitamin E. The United States Pharmacopeia published a monograph for TPGS in the USP/NF Supplement #9 dated of November 15, 1998.

In Canada, TPGS is approved as a form of vitamin E. In the European Community it is approved as an Active Pharmaceutical Ingredient (API) for the treatment of vitamin E deficiency due to digestive malabsorption in pediatric patients and for use in foods for special medical purposes. In Japan it is approved as a pharmaceutical excipient for oral drug formulations.

Products and Packaging

Antares supplies Vitamin E TPGS in multiple grades, Pharmaceutical Grade (NF), Food Grade (FG), and Sunflower TPGS™ (non-GMO) in both NF and FG grades. All products are available in 500 g, 1 kg, 5 kg, and 15 kg tamper-evident, plastic-sealed containers. The containers are heat tolerant to 65 °C. The containers may be stored in room temperature and should be opened only when necessary. Antares TPGS is labeled with a 4 year shelf life from the date of manufacture when stored in the original sealed unopened container.

Selected Publications

1. TPGS in food for special medical purposes. EFSA Journal. 2007;490:18-19.
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12. Papas, AM. Major engine of growth in the cannabis industry: State of the art formulation technology for product innovation and expanded applications. Cannabis Science and Technology. 2018;1(4), 56-59.
13. Knaub K, et al. A Novel Self-Emulsifying Drug Delivery System (SEDDS) Based on VESIsorb® Formulation Technology Improving the Oral Bioavailability of Cannabidiol in Healthy Subjects. Molecules. 2019;24(16), 2967.

Pharma Citations

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- b. SalehaRehman, BushraNabi, Mohammad Fazil, Saba Khan, NaimatKalimBari, RomiSingh, ShavejAhmad, VarinderKumar, SanjulaBaboota, and JavedAli, Role of P-Glycoprotein Inhibitors in the Bioavailability Enhancement of Solid Dispersion of Darunavir, Biomed Res Int. 2017: 8274927
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Our website provides additional information and access to documents including:

- GMO Statement
- Residual Solvents Statement
- Nutrient Data Sheet
- BSE/TSE Statement
- Safety Data Sheet
- Product Data Sheet
- cGMP Statement
- Kosher Certificate
- Certificate of Analysis
- GRAS Statement
- Halal Certificate
- SDS Certificate