

## Antares Vitamin E TPGS NF Product Data Sheet

Products	<b>Antares Vitamin E TPGS Pharmaceutical Grade (NF)</b>
Chemical name	d- $\alpha$ -tocopheryl polyethylene glycol 1000 succinate
Empirical formula	$C_{33}O_5H_{54}(CH_2 CH_2O)_n$
Synonyms/Acronyms	Vitamin E TPGS or TPGS Tocophersolan (International Nomenclature of Cosmetic Ingredients – INCI and United States Adopted Names - USAN)
CAS Number	9002-96-4 (Chemical Abstracts Service registration number)

Antares vitamin E TPGS NF is a water-soluble derivative of the natural form of d-alpha-tocopherol. In addition to serving as water-soluble source of vitamin E, TPGS has unique properties due to its dual combination of lipophilicity and hydrophilicity, similar to a surface-active agent.

### Applications

Source of water-soluble vitamin E  
Emulsifier and solubilizer  
Enhancer of absorption and bioavailability  
Product applications include dietary supplements, food and beverage, personal care and cosmetics, and animal nutrition products.

### Typical Characteristics

Appearance Waxy solid; white to light yellow  
Solubility Soluble (up to 20 weight % in water)  
Melting point 38 °C approximate (range 37---41)  
Specific gravity 1.06 at 45°C, approximate  
Heat stability Differential Scanning Calorimetry indicates there is no thermal degradation at temperatures well above normal formulation processing temperatures with the lots tested as high as 199 °C showing no signs of thermal degradation

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**Specifications**

d- $\alpha$ -Tocopherol	25% minimum weight basis; (range 25---30%)
Vitamin E activity	372 to 447 IU/gram
Solubility	Soluble (up to 20 weight % in water)
Acid Value	1.5 (maximum)
Color, Gardner	Less than 10 (generally less than 5)
Optical Rotation	NLT +24 degrees

**Regulatory and safety information**

The United States Pharmacopeia (USP) published a monograph for vitamin E TPGS in the USP/NF Supplement #9 dated November 15, 1998.

The Food and Drug Administration (FDA) includes vitamin E TPGS in the list of inactive ingredients.

In Canada, vitamin E TPGS is approved as a form of vitamin E, in the European Community as an API (Active pharmaceutical Ingredient) and in Japan as a pharmaceutical excipient for oral drug formulations.

Antares vitamin E TPGS FG meets the Current Good Manufacturing Practice (cGMP) requirements in manufacturing, packaging, labeling, or holding operations for food in the Food and Drug Administration Code of Federal Regulations Title 21 Part 110 (FDA 21 CFR Part 110) and dietary supplements in FDA 21 CFR Part 111. It also meets applicable regulations for microbial limits, heavy metals and residual solvents.

**Packaging, storage and shelf---life**

Antares Vitamin E TPGS NF grade is available in 1 kg, 5kg and 15 kg in tamper-evident plastic sealed containers.

The containers are heat tolerant up to 70 °C.

It is recommended that the containers be stored in cool, dry temperatures, and opened only when necessary with extreme care to avoid contamination.

Antares Vitamin E TPGS NF is labeled with a 4 year shelf life from the date of manufacturing when stored in the original sealed unopened container.