



azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **ASCORBILE PALMITATO Ph.Eur.-E 304**

NOME INCI	Ascorbyl Palmitate
NOME INCI USA	Ascorbyl Palmitate
CAS	137-66-6
EINECS / ELINCS	205-305-4
FORMULA	C22 H38 O7
PESO MOLECOLARE	414.54

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Aspetto	EP	polvere	
Colore		quasi bianco o bianco-giallastro	
Identificazione IR		conforme	
Aspetto della soluzione		limpida e non più colorata di BY4	
Rotazione ottica specifica		21,00 - 24,00	°
Punto di fusione		107,0 - 117,0	° C
Identificazione		conforme	
Perdita all'essiccamento		<=1,00	%
Ceneri solforiche		<=0,10	%
Metalli pesanti		<=10	ppm
Piombo		<=2	ppm
Rame		<=25	ppm
Arsenico		<=3	ppm
Zinco		<=25	ppm
Mercurio		<=1	ppm
Titolo		98,00 - 100,50	%
Acetone		<=500	ppm
Etere di petrolio		<=290	ppm
Mesitil ossido		<=50	ppm
Revisione Capitolato		0	
Data Approvazione		09/11/2011	

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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Solubility

Ascorbyl Palmitate is practically insoluble in water. It is soluble in ethanol (approx. 10 g per 100 mL) and in peanut oil, olive oil and sunflower oil (approx. 30 mg per 100 mL)

Stability and storage

Ascorbyl Palmitate is fairly stable to air if protected from humidity, but is somewhat sensitive to light and heat. It is packed together with a drying agent. The product may be stored for 30 months from the date of manufacture in the unopened original container and at a temperature below 25 °C. The 'best used before' date is printed on the label.

Uses

In the food industry as a physiologically innocuous antioxidant for edible fats and oils. It acts as a powerful synergist when used together with α -tocopherol.

Compendial compliance

Ascorbyl Palmitate meets all requirements of the USP/NF, FCC and Ph. Eur. when tested according to these compendia.

Safety

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene.

BSE/TSE statement

We herewith confirm that TSE/BSE specified risk material or products derived thereof as defined in Annex V, 1. of Regulation (EC) No. 999/2001 laying down rules "for the prevention, control and eradication of certain transmissible spongiform encephalopathies" incl. all subsequent amendments, or materials of human origin are not present in any of our products nor used in any of our manufacturing processes. No active substance of animal origin is present in this product. We hereby confirm that this product is out of scope of the above mentioned Regulation as it is free from all known sources of possible TSE/BSE contamination.

GMO statement

We hereby confirm that the product Ascorbyl Palmitate is manufactured by conventional processes** and therefore does not contain GMO-DNA. It does not fall under the scope of the Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed. The product does not fall under the scope of Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed nor under the scope of Regulation (EC) No 1830/2003. Therefore, the product stated above does not require labelling as a GMO, as defined in Regulations above mentioned, either as a food and feed ingredient in its own right or when incorporated in the final product.

LATTEX materials

We hereby confirm that our products for human nutrition and health are free from adventitious contamination with latex. During the production of a number of our formulations and premixes protective clothing is worn. This may include the use of latex or nitril gloves when the machine operators are in contact with the raw materials or end products.

In the production facility control measures have been instigated to ensure that end products are not contaminated with latex material. Our quality management system stipulated precautionary procedures to be taken when operators are using latex material within the production facility. In addition, the powder premixes are sieved. This provides further assurance that no latex materials are in the final product.

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1i.Product allergen labeling-European Union	Yes	No	Comments
Cereals containing gluten and products thereof		X	
Crustaceans and products thereof		X	
Eggs and products thereof		X	
Fish and products thereof		X	
Peanuts and products thereof		X	
Soybeans and products thereof		X	
Milk and dairy products (incl. lactose)		X	
Nuts and products thereof		X	
Celery and products thereof		X	
Mustard and products thereof		X	
Sesame seed and products thereof		X	
Sulphur dioxide and sulphite at concentration of more than 10mg/liter expressed as SO ₂ in the product intended for the ultimate consumer		X	
Lupin and products thereof		X	
Mollusks (gastropods, bivalves, cephalopods) and products thereof		X	
1ii.Sensitizer and other constituents	Yes	No	Comments
Maize and products thereof		X	
Sugar (sucrose)		X	
Benzoates		X	
BHA/BHT		X	
Cinnamon, cocoa, vanilla, chicken, yeast, legumes (other than peanut), pulses, coriander, umbelliferae, flavor (any artificial/natural), carrot, buckwheat, glutamate (% if naturally occurring)		X	
The present declaration, prepared to the best of our knowledge, is related to the product in the original packaging			
2i.Origin of the active ingredient	Yes	No	Comments
Synthetic	X		
Fermentation		X	
Vegetable		X	
Animal		X	
2ii.Origin of carrier components	Yes	No	Comments
Synthetic		X	
Fermentation		X	
Vegetable		X	
Animal		X	
Mineral		X	
3i.Regulatory profile (for products used in food application and food supplements)	Yes	No	Comments
GMO statement	X		

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GMO labeling required		X	
Allergen labeling required		X	
Allergen declaration	X		
Allergen labeling/policy statement	X		
BSE/TSE statement (Regulation (EC) 999/2001*)	X		
Microbiology statement	X		
Mycotoxins statement	X		
Dioxin/PCB statement	X		
Ionization/irradiation statement	X		
Pesticide statement	X		
Heavy metals statement		X	See product data sheet
PAH	X		
Extraction solvents statement			n.a.
Permitted as food additive (colour) positive list (Directive 94/36/EC*) and compliance with purity criteria for colours (Directive 2008/128/EC*)	X		
Permitted as food additive (antioxidant) positive list (Directive 95/2/EC*) and compliance with purity criteria for colours (Directive 2008/84/EC*)	X		
Is a nutrient, nutrient source or a substance with nutritional or physiological effect/function	X		Listed in Reg (EC) 1925/2006, 953/2009 and Dir 2002/46/EC, 2006/125/EC, 2009/141/EC
3ii.Regulatory profile (for products used as active pharmaceutical ingredients)	Yes	No	Comments
Residual solvents ICH statement	X		
BSE/TSE statement (EMA guidance)	X		
Heavy metals specified	X		See Ph.Eur. monograph Nr 0807 and/or product data sheet
Qualitative composition sheet (compendia compliance)		X	Pure active substance
4.Product suitability	Yes	No	Comments
Vegetarians	X		
Vegans	X		
Kosher	X		
Halal	X		

n.a. = not applicable

* and subsequent amendments

** exempted from allergen labeling by Dir. 2007/68/EC

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