



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

17.05.2023

Version:

5.0

74907-SODIUM ASCORBYL PHOSPHATE (STABLE VIT. C)

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Sodium ascorbyl phosphate (Stable vitamin C)

Bulk code: 74907

Internal code: 405159

1.2 Synonyms

Sodium ascorbyl phosphate; Vitamin C phosphate; L-ascorbic acid monophosphate sodium salt; L-ascorbic acid phosphate sodium salt.

2. DESCRIPTION

Appearance: Powder

Colour: White or almost white

Odour: Odourless

Origin :

- Synthetic : Chemical synthesis of sodium ketogluconate to ketogluconic acid sodium ascorbyl phosphate).
- Biotechnological: Bioconversion of sorbitol obtained from corn, Zea mays, to sodium ketogluconate.

Geographic origin: China

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_6H_6O_9Na_3P \cdot 2H_2O$

CAS: 66170-10-3

ELINCS: 425-180-1

Molecular weight: 358.08 g/mol

INCI: Sodium ascorbyl phosphate

Components: Consists of a stabilised (phosphorylated) sodium salt of L-ascorbic acid

Method of production: The esterification of ascorbic acid in position 2 protects vitamin C from destruction by oxidation. The L-ascorbate molar activity of the phosphorylated ester of vitamin C is equivalent to that of L-ascorbic acid.

The calcium sodium salt of L-ascorbyl phosphate is purified with cation and ion exchange resins. After neutralisation with sodium hydroxide, the product is crystallised and dried.



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4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Readily soluble in water. Insoluble in lipophilic components or alcohols.

5. PROPERTIES/USES

Cosmetic use.

NOT SUITABLE orally.

For use in cosmetics for hair, skin and oral care (use in mouthwashes, toothpastes, etc.).

The product is the sodium salt of ascorbic acid's monophosphate ester. It is used as a stabilised source of vitamin C in cosmetic products, and has anti-ageing, oral antibacterial, skin lightening and anti-acne activities.

Recommendations for use:

- It is recommended that the formulations made have a pH of 6 or higher.
- Non-ionic emulsifiers show better stability with the product.
- 0.05–0.1% sodium metabisulphite may be added to improve the colour stability of the preparation.
- It is recommended to add a chelating agent to the formulation, such as EDTA.
- The product is sensitive to oxygen, so it is recommended to pre-boil the aqueous phase for 10 mins. to remove all dissolved oxygen, in addition to using combinations of water-soluble and oil-soluble antioxidants. The following antioxidants should be avoided: ferulic acid, nordihydroguaiaretic acid, rosmarinic extract, propyl gallate, tert-butylhydroquinone.
- Saturated lipids show good compatibility with the product while unsaturated lipids should be avoided.
- The formulations may develop a typically caramel odour, especially at high temperatures (e.g., 40–45°C). This can be avoided by adding 1:1 urea to the product combined with 0.1% sodium metabisulphite. This combination could also decrease discolouration in the final formulation.

The product is safe for its intended purpose. Avoid ingestion, inhalation of dust or direct contact by implementing protective measures and personal hygiene.

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6. DOSAGE

The dosage will be according to the formulation, with the recommended use levels:

Product type	Recommended use level (%)
Rinse-Off	
Shower gel	Max 1%
Hand wash soap	Max 1%
Shampoo	Max 1%
Make-up remover	/
Feminine hygiene	/
Leave-On	
Hair styling products	Max 1%
Semi-permanent hair dyes (and lotions)	/
Oxidative/permanent hair dyes	/
Body lotion	Max 15%
Face cream	Max 15%
Hand cream	Max 15%
Liquid foundation	Max 15%
Eye shadow	/
Mascara	/
Eyeliner	/
Deodorant non-spray	/
Deodorant aerosol spray	/
Deodorant spray	/
Suncare	
Suncare Lotion - Oils	Max 10%
Suncare Sprays	/
Oral	
Lipstick, lip salve	/
Toothpaste (adult)	Max 3%
Mouthwash	Max 3%
Baby - Infants	
Baby products	Max 1%
Products for infants	Max 5%

The product is to be added to the formulation at temperatures below 35–40°C.

In O/W emulsions: In aqueous solution separately or directly as powder. Homogenise the emulsion after adding the product and adjust the final pH to 6 or higher with common neutralising agents.

In W/O emulsions: Dissolve the product entirely in the aqueous phase. If the aqueous phase is to be heated, dissolve it in a separate part of the composition water of the cold emulsion.

In gels: At high concentrations it can reduce the viscosity of formulations due to the presence of electrolytes, so it is recommended to use derivatives of cellulose, carbomer, hydroxypropyl methylcellulose or xanthan gum.



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7. REMARKS

STORAGE:

Store at room temperature in a cool, dry place protected from sunlight in a hermetically sealed container away from heat and moisture. It is quite stable when exposed to air if shielded from moisture and heat.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product is not an animal or human derivative, and furthermore, no animal or human products are used in the manufacturing process.

GMOs:

The product is manufactured by traditional processes (chemical synthesis, fermentation, extraction, but excluding fermentation processes using GMO microorganisms) and does not contain GMO DNA.

CMR:

The product does not contain intentionally added substances classified and listed in Annex VI as Class 1a, 1b or 2 CMR substances under Regulation (EC) 1272/2008 and its amendments.

SVHC:

According to the composition of the product and the manufacturing process, the product does not contain any of the substances listed on the ECHA website in concentrations higher than 0.1%.

NANOMATERIALS:

The product does not contain nanomaterials as defined in Regulation (EC) 1223/2009 (Article 2 (k)).

VOCs:

The product does not contain VOC substances according to the positive list contained in the Swiss VOC Regulation.

IRRADIATION:

The product has not undergone ionisation or irradiation.

PESTICIDES:

The product does not contain plant-based ingredients, so the product is not expected to contain pesticide residues.



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ANTIOXIDANTS:

The product does not contain antioxidants.

RESIDUAL SOLVENTS:

The product is compliant with ICH Q3C (R7) Guideline for residual solvents, the USP/NF chemical test <467> (residual solvents limit) and general chapter 5.4 <Residual solvents> and its limit tests 2.4.24 of the Ph. Eur. <Identification and control of residual solvents>.

Only a Class 2 solvent (methanol) may be present below the limit of Option 1 (methanol: < 3000 mg/kg).

CONTAMINANTS:

The product does not contain any of the following products:

- Alcohol and denatured alcohol
- Formaldehyde or formaldehyde releasers
- Acetaldehyde
- Phthalates
- Glycol ethers
- 1,4-Dioxane
- Free amines
- Nitrosamines
- Acrylamide
- Residual monomers
- Dioxin/PCBs
- PAH(s)

HEAVY METALS:

The product may contain:

- Arsenic \leq 1 ppm
- Lead \leq 1 ppm
- Mercury \leq 0.1 ppm
- Cadmium \leq 0.5 ppm
- Nickel \leq 2 ppm
- Antimony \leq 2 ppm

The analysis has been carried out based on the general monographs of the USP <232> and <233> (ICP-MS). Procedures are based on GMPs and standards include Critical Control Point Analysis (HACCP).

CALIFORNIA PROPOSITION 65:

Based on knowledge of the production process, trace amounts of impurities listed under California Proposition 65 on safe drinking water and toxic enforcement (Act 1986) (Proposition 65 listed and dated 23 November 2018) may be present in chemicals used



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during the manufacturing process, and it can be indicated that the final product will be below the maximum limits set forth below:

Methanol \leq 3000 ppm

Arsenic \leq 1 ppm

Lead \leq 1 ppm

Mercury \leq 0.1 ppm

Cadmium \leq 0.5 ppm

Nickel \leq 2 ppm

These limits may vary in the final product depending on the rest of the components that make up the final formula. Therefore, it is recommended to calculate the final consumer's exposure with the reference values.

NAGOYA PROTOCOL:

Not applicable.

ALLERGENS:

- **Food allergens:** Not applicable.
- **Cosmetic allergens:** The product does not contain any of the substances listed in Annexes II (prohibited substances), III (restricted substances), IV, V and VI to Cosmetics Regulation (EC) 1223/2009. In addition, none of the potential fragrance allergens listed in Regulation (EC) 1223/2009 and its corresponding amendments are intentionally added and are not expected to be present in the final product.

VEGAN/VEGETARIAN:

The information provided here refers to the production process, the raw materials used in this production process and the possible use of animals in toxicology tests, avoiding the latter whenever possible and only performing them if requested by governmental legal bodies to comply with legal obligations. Therefore, the manufacturer accepts no responsibility for the product meeting the vegan requirements defined by different organisations.

HALAL:

The product is not Halal certified.

KOSHER:

The product is not Kosher certified.

TESTED ON ANIMALS:

The product and its components have not been tested on animals for cosmetic purposes since September 2004, thus complying with Regulation (EC) 1223/2009.

CITES:

Not applicable.



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ECOCERT:

Not applicable.

NATRUE:

Yes.

COSMOS:

Not applicable.

REACH:

01-0000017158-68-0001

REGULATORY STATUS:

CHINA: The product is registered in the IECSC inventory and in the IECIC.

Country/region ¹	Chemical Inventory	Chemical Registration status based on the listing of individual ingredients in inventory and volume exemption applying (Y/N/R/E)	Cosmetic ¹ Claims on finished cosmetic products must comply with national cosmetic legislation (Y/N)
Andean	No inventory	No inventory	Y
ASEAN	No inventory	No inventory	Y
Australia	AICS	Y	Y
Canada	DSL NDSL ICL	R ($\leq 100\text{kg/y}$) - CAS 66170-10-3 listed on ICL	R ($\leq 100\text{kg/y}$)
China	IECSC	Y	See separate statement
Europe	EINECS/ELINCS	Y	Y
Japan	ENCS (CSCL)	E	Y
Korea	KECI (TCCA)	E	Y
Mercosur	No inventory	No inventory	Y
Mexico	INSQ	Inventory is not supported by legal framework	Y
Philippines	PICCS	E	Y
Switzerland	EINECS/ELINCS	Y	Y
Taiwan	NECI	Y	Y (as whitener max 3% Sodium Ascorbyl Phosphate)
USA	TSCA	E	Y Sodium Ascorbyl Phosphate: CIR: safe as used, see CIR report

¹ above product can be freely imported and sold as cosmetic ingredient also into further countries as e.g. Algeria, Bahrain, Brunei Darussalam, Egypt, Morocco, the Russian Federation, Tunisia, Turkey, the United Arab Emirates, as long as the safe use is warranted and the products do comply with the legal requirements as laid down in the Regulation on Cosmetic Products (EC) No. 1223/2009

Chemical:

Yes (Y): The product contains only substances that are listed in the respective chemical inventories and that have been notified as a new chemical by the manufacturer or are exempt from chemical notification.

No (N): The product contains at least one substance not listed or not notified or not exempt (which does not comply with that chemical inventory).



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Restricted (R): The product contains at least one substance not listed or not notified or not exempt from the respective chemical notification, but which can be imported into the respective country under volume exemption (e.g., Australia, Canada, Europe, Switzerland).

Exempt (E): Under specific exemptions affecting cosmetic ingredients (e.g., Japan).

Cosmetic:

Yes (Y): Product can be freely sold as a cosmetic ingredient for the application and recommended level of use. If there is any condition of use for the active substance, it should be mentioned.

No (N): Product not for sale in the specific country (contains at least one substance not allowed in cosmetics in the corresponding country).

CSAR:

NMPA submission code: 004100-00666-8542

Tariff item number:

29362700