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



TECHNICAL DATA SHEET Review date:

Version: 6.0

92769-GLYCOLIC ACID 99%

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1. Identification of the substance or preparation

Name: Glycolic acid 99% Bulk code: 92769 Internal code: 55684 Valid from bulk batch: 0117605

1.2. Synonyms

No information available.

2. DESCRIPTION

Appearance: Clear crystals Colour: Colourless Odour: Very mild Origin: Synthetic/petrochemical Geographical origin: USA

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: C₂H₄O₃ CAS: 79-14-1 FC: 201-180-5 INCI: Glycolic acid Molecular weight: 76.05 g/mol

Method of production: Acid and basic saponification (batch process). The starting materials undergo a hydrolysis reaction and are then filtered. Vacuum distillation occurs and the resulting products are separated by centrifugation.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Soluble in water.

5. PROPERTIES/USES

Cosmetic use.

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Its properties include:

- Formaldehyde-free glycolic acid for personal care products.
- Excellent exfoliating agent for skin care (AHA).
- Refines the skin tone, decreases wrinkles and minimises the appearance of pores.
- Excellent properties for hair care.
- Increases denaturation temperature, lubricity and water resistance of hair.

Uses:

- Facial care and cleansing.
- Body care.
- Hair care.

6. <u>DOSAGE</u>

The manufacturer's recommendations for use are:

- < 4%: Minor exfoliation, in cosmetics for daily application.
- 4-12%: Supervised application on prepared skin, special cosmetics.
- > 20%: Professional use.

For optimal efficacy it is recommended to work with a pH between 3.8 and 4.3. If the formulation is sensitive to low pH values, dilute the glycolic acid with parts of the aqueous phase or pre-neutralise to have a pH ~4.0 before adding to the formulation.

Combine with cosmetic ingredients that tolerate lower pH levels.

Please note that this declaration does not affect the manufacturer of the cosmetic preparation's requirement to carry out a safety assessment of the finished product (Article 10).

In addition, this declaration does not guarantee its suitability for a special application by the customer. The user of the product is responsible for complying with all laws, regulations and rules applicable to the use of the product.

7. <u>REMARKS</u>

STORAGE:

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container.

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

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BSE/TSE:

The product is of petrochemical/synthetic origin and does not represent a source of pathogens of transmissible spongiform encephalopathy (TSE) and bovine spongiform encephalopathy (BSE).

GMOs:

The product is not required to be labelled as a GMO. The product does not contain GMOs and is not derived from a GMO.

CMR:

The product is not classified as a CMR substance (Class 1A, 1B and 2) and does not contain any ingredients classified as a CMR substance (Class 1A, 1B and 2) according to Regulation (EC) 1223/2009 in association with Regulation (EC) 1272/2008.

SVHC:

Substances listed in the current candidate list of SVHCs or already included in Annex XIV to Regulation (EC) 1907/2006 are not used as ingredients.

NANOMATERIALS:

The product does not contain any ingredient classified as a nanomaterial according to Commission Recommendation 2011/696 and Regulation (EC) 1223/2009.

ADDITIVES:

Additives such as fragrances, preservatives and antioxidants are not added in the manufacturing process.

RESIDUAL SOLVENTS:

A Class 2 solvent is used to manufacture the product, with reference to chapter 5.4 of EP. The residual content of this solvent does not exceed the maximum concentration limit indicated in the EP guideline (CPMP/ICH/283/95).

RADIATION:

The product has not been treated with ionising radiation during or after the manufacturing process.

PESTICIDES:

Due to the manufacturing process and starting materials, pesticides are not expected to be present in the final product.

IMPURITIES:

- Aflatoxins: Due to the raw starting material and manufacturing process, they are not expected to be present in the final product.
- 1,4-dioxane: No contamination with 1,4-dioxane is expected as the manufacturing process does not include an ethoxylation step.

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- Formaldehyde: No formaldehyde is used to manufacture the HP product nor is formaldehyde expected to be generated in the process. Tests show undetected property (LOD 5 ppm).
- Glycol ether: Glycol ether is not added to the product in the manufacturing process. Glycol ether is not expected to form in the manufacturing process.
- Melamine: Melamine is not added to the product in the manufacturing process. Melamine is not expected to form in the manufacturing process.
- Nitrosamines: No contamination with nitrosamines is expected to be present. The product does not contain nitrosatable or nitrosating substances as ingredients that allow the formation of nitrosamines.
- PAHs: PAHs are not added to the product in the manufacturing process. PAHs are not expected to form in the manufacturing process.
- PBT/vPvB: The product is not classified as PBT or vPvB and does not contain any ingredients classified as PBT/vPvB according to Regulation (EC) 1907/2006.
- Phthalates: Phthalates are not added to the product in the manufacturing process. Phthalates are not expected to form in the manufacturing process.
- By-products: May contain the by-product referred to below, as specified in Annex V to Regulation (EC) 1223/2009, which may be generated during the production process: Formic acid (max. 10 ppm).

CALIFORNIA PROPOSITION 65:

The substances referred to in California Proposition 65 are not intentionally added as ingredients.

HEAVY METALS:

The total amount of heavy metals (such as Pb) may have a maximum value of 10 ppm.

ALLERGENS:

- **Food allergens:** The product is not derived from any gluten-containing cereal. The starting materials are not a source of gluten. The product is not derived from nuts.
- **Cosmetic allergens:** The product is not listed in Annexes II or III to Regulation (EC) 1223/2009. Therefore, its application in cosmetic preparations is not prohibited or restricted under this Regulation. In addition, none of the substances listed in Annex III to Regulation (EC) 1223/2009 are used to manufacture the product.

VEGAN/VEGETARIAN:

The product is not derived from animal sources and is not produced using animal processing aids or derivatives. Therefore, the product is suitable for vegan/vegetarian use.

WADA:

Substances listed on WADA's current Prohibited List are not added or used during or after product production.

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TESTED ON ANIMALS:

The product has not been tested on animals.

REACH:

01-2119485579-17-XXXX.

ISO 16128:

Not applicable.

CSAR:

The NMPA/CSAR Registry for the product reviewed in October 2022 is 005274-01627-8849.

INTERNATIONAL INVENTORIES:

The product is included in the following inventories:

| TSCU (USA) | DSL (Canada) | ENCS (Japan) | KECI (Korea) | AICS (Australia) | IECSC (China) | NZIoC (New Zealand) | NCSI (Taiwan) | PICCS (Philippines) |
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