

1084-GLYCERINE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Glycerine

Bulk code: 1084

Internal code: 50834

1.2. Synonyms

Glycerin, glicerol, 1,2,3-propanetriol, trihydroxy propane

2. DESCRIPTION

Appearance: Viscous liquid.

Colour: Clear, free of suspended matter.

Odour: Odourless.

Origin: Pure plant based. The raw material used to make glycerine is rapeseed oil (produced from conventional European non-GMO rapeseed), sunflower oil and flaxseed oil produced and processed in both south-east Asia and Europe.

3. COMPOSITION/INFORMATION ON COMPONENTSFormula: $C_3H_8O_3$

CAS: 56-81-5

EINECS: 200-289-5

INCI: Glycerin

Method of production: It is produced by extraction/hot pressing/batching of the raw materials and the refined glycerine is then obtained through esterification/distillation.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Miscible with water, alcohol and propylene glycol, poorly soluble in acetone and practically insoluble in chloroform, ether, fixed and volatile oils.

Very hygroscopic.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

Food use.

1084-GLYCERINE

The product is compliant with the following regulations:

- **Regulation (EC) No 178/2002** of the European Parliament and of the Council of 28 January 2002 laying down the **general principles and requirements of food law**, establishing the **European Food Safety Authority** and laying down **procedures in matters of food safety**.
- **Regulation (EC) No 852/2004** of the European Parliament and of the Council of 29 April 2004 on the **hygiene of foodstuffs**.
- Commission **Regulation (EU) No 231/2012** of 9 March 2012 laying down **specifications for food additives** listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Does not contain any substances listed in Annex II (prohibited substances), nor any of the substances listed in Annex III (substances subject to restrictions) according to the European Cosmetics Directive 1223/2009.

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

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

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

BSE/TSE:

Pure glycerine is of plant origin and thus does not contain animal-derived ingredients. Therefore, it is BSE/TSE free as regards the source, manufacture and treatment.

GMOs:

Triacetin, palm free, it is based on raw materials that are not genetically modified. Genetically modified products are also not used for the production process.

The product is compliant with the requirements of EU Regulations 1829/2003 of 22 September 2003 on genetically modified food and feed and 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed additives produced from genetically modified organisms.

CMR substances:

The product does not contain any substances classified as a Class 1A, 1B or 2 CMR substance in Annex VI to Regulation No 1272/2008.

1084-GLYCERINE**SVHC:**

It is not on the Candidate List of Substances in Annex XVI to REACH.

NANOMATERIALS:

The product does not contain any substances classified as a nanomaterial according to the European definition contained in Article 2 of Regulation (EC) No 1223/2009.

VOCs:

The content is <1% (1999/13/EC; 2004/42/EC; 2010/75/EU; SR 814.018).

RADIATION:

The product has not been exposed to ionisation, radioactive or gamma radiation, electron emissions or any other type of radiation processes at any time during the manufacturing process.

RESIDUAL SOLVENTS:

During the manufacturing process, two class 2 solvents such as methanol and hexane may be used. Due to the manufacturing process, there are no detectable residual solvents in the final product (<1 ppm for methanol and hexane).

COLOURANTS/ADDITIVES/PRESERVATIVES:

The product does not contain colourants, additives or preservatives.

HEAVY METALS:

The heavy metal content is compliant with the pharmacopoeia (<5 ppm).

IMPURITIES:

- Dioxins: The product is compliant with the regulations listed in 1333/2008/EC; 2002/79/EC; Ph. Eur. 5.1.4; 299/2008/EC; 396/2005/EC; EC 231/2012 (E 422) and does not contain dioxins or furans. The following substances are not included in the product:
 - o Value of basic substances
 - Dioxins and furans: PCDD/F (17 Kongenere) <0.074 pg/g
 - Dioxin-like PCBs (WHO 12 PCBs) <8.6 pg/g
 - Non-dioxin-like PCBs (ICES-6) <0.369 ng/g
- Aldehydes: The product is compliant with the regulations listed in 1333/2008/EC; 2002/79/EC; Ph. Eur. 5.1.4; 299/2008/EC; 396/2005/EC; EC 231/2012 (E 422); EC 1223/2009 and aldehydes are certified based on the Ph.Eur test method 8.0/0496 being <10 ppm. The product does not contain aldehydes above the legal limits for E 422 (the product contains <5 ppm aldehydes).
- Halogenated compounds: The product complies with the regulations listed in 1333/2008/EC; 2002/79/EC; Ph. Eur. 5.1.4; 299/2008/EC; 396/2005/EC; EC 231/2012 (E 422) and halogenated compounds are certified according to the Ph.Eur test method 8.0/0496 being <35 ppm. The product does not contain halogen compounds above the legal limits for E 422 (the product contains <35 ppm halogen compounds).
- Phenol: The product is compliant with the regulations listed in 1333/2008/EC; 2002/79/EC; Ph. Eur. 5.1.4; 299/2008/EC; 396/2005/EC; EC 231/2012 (E 422) and does not contain phenol. The product does not contain phenol, m.p.-cresol, o-phenylphenol or 4-chloro-3-methylphenol.

1084-GLYCERINE

ALLERGENS:

- **Food allergens:** The product does not contain any of the food allergens listed in Annex II to Regulation (EU) 1169/2011, nor any of the substances listed on the ALBA list (gluten, lactose, latex, among others).
- **Cosmetic allergens:** The product does not contain any of the allergens listed in Annex III to Directive 2003/15.

NUTRITIONAL COMPOSITION:

Nutritional value	Value
Energy value	992 kJ/100 g / 238 kcal/100 g
Fat	<0.1%
Saturated fat	<0.1%
Unsaturated fat	<0.1%
Carbohydrates	99.2%
Of which sugars:	
Glucose	<0.1%
Fructose	<0.1%
Sucrose	<0.1%
Lactose	<0.1%
Maltose	<0.1%
Protein	<0.1%
Sodium / Salt	<0.1%

VEGAN/VEGETARIAN:

Animal products have not been involved in the production and development of the product, nor have tests (including tests for efficacy, toxicity, safety, cosmetic purposes, etc.) been carried out on any type of animal, or on derivatives.

The Vegan Society understands the word "animal" to refer to the entire animal kingdom, which is all vertebrates and all multicellular invertebrates.

TESTED ON ANIMALS:

The product has not been tested on animals for cosmetic purposes.

ISO 16128:

The product meets the requirements of ISO 16128-1 to be defined as a 100% derived natural cosmetic ingredient.

REACH:

Not applicable. It is not under the restrictions of 1907/2006/EC.