

**ACEF S.p.A.****004742 - GLYCERIN VEGETAL FU-Ph.Eur.**Revision nr.2
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EN

Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code: 004742
Product name: GLYCERIN VEGETAL FU-Ph.Eur.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use: eccipiente per uso farmaceutico e cosmetico.

1.3. Details of the supplier of the safety data sheet

Name: ACEF S.p.A.
Full address: Via Umbria, 8/14
District and Country: 29017 Fiorenzuola d'Arda PC
Italia
Tel.: 0523/241911
Fax: 0523/241968e-mail address of the competent person responsible for the Safety Data Sheet: sicurezza@acef.it

1.4. Emergency telephone number

For urgent inquiries refer to: Centro Antiveleni Milano Niguarda - Tel.02/66101029

2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments

Hazard classification and indication:

2.1.2. Directive 67/548/EEC and following amendments and adjustments

Warning symbols: None

Hazard sentences (R): None

2.2. Label elements

This product is not subject to hazard labeling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms: --

Warning: --

Hazard indication: --

Caution recommendations:

Safety data sheet available for professional users on request.

Label EC: 200-289-5

2.3. Other hazards



Information not available

3. Composition/information on ingredients

3.1. Substances

Contains:

Identification	Conc. %	Classification 67/548/EEC	Classification 1272/2008 (CLP)
GLYCERYN			
CAS 56-81-5	100		
EC 200-289-5			

3.2. Mixtures

Information not relevant

4. First aid measures

4.1. Description of first aid measures

EYES: Irrigate copiously with clean, fresh water for at least 15 minutes. Seek medical advice.

SKIN: Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists, seek medical attention. Wash contaminated clothing before using them again.

INHALATION: Remove to open air. If breathing is irregular, seek medical advice.

INGESTION: Obtain immediate medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed

For symptoms and effects caused by the contained substances see chap. 11

4.3. Indication of any immediate medical attention and special treatment needed

Follow doctor's orders

5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA

The extinction equipment used should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with ties around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. If there are no contraindications, spray solid products with water to prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or the leaked product before donning appropriate protective gear. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, see the other sections of this sheet.

**6.2. Environmental precautions**

The product must not penetrate the sewers, surface water, ground water and neighbouring areas.

6.3. Methods and material for containment and cleaning up

Use inert absorbent material (sand, vermiculite, diatomaceous earth, Kieselguhr, etc.) to soak up leaked product. Collect the majority of the remaining material and deposit it in containers for disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage**7.1. Precautions for safe handling**

Do not smoke while handling and use.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well ventilated place, keep far away from sources of heat, bright flames and sparks and other sources of ignition.

7.3. Specific end use(s)

Information not available

8. Exposure controls/personal protection**8.1. Control parameters**

Information not relevant

8.2. Exposure controls

Observance of safety measures used in handling chemical substances.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear a mask with an B or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

EYE PROTECTION

None required.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Appearance	viscous liquid
Colour	colourless/slightly yellow
Odour	characteristic
Odour threshold	Not available
pH	5,0 (100 g/l, 20°C)
Melting or freezing point	18 °C
Boiling point	290 °C
Distillation range	Not available
Flash point	160 °C
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	0,9 % (v/v) 0 °C
Upper explosive limit	Not available
Vapour pressure	< 0,1 hPa a 20°C
Vapour density	Not available
Specific gravity	1,262 Kg/l
Solubility	soluble in water



Partition coefficient: n-octanol/water	logP: -2,66
Ignition temperature	400 °C
Decomposition temperature	Not available
Viscosity	20°C: 1069 mPas
Reactive Properties	Not available

9.2. Other information

Molecular weight	92,10
VOC (Directive 1999/13/EC) :	0%

10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information

11.1. Information on toxicological effects

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

12. Ecological information

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

Information not available

12.6. Other adverse effects

Information not available

13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.



14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso category None

Substances in Candidate List (Art. 59 REACH)
None

Substances subject to authorisation (Annex XIV REACH)
Information not available

Healthcare controls
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15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains

16. Other information

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atq. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Changes to previous review:

The following sections were modified:

02/03/04/05/09/10/11/12/15