

Issuing Date 06-Sep-2024

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Revision Number 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product Code 56-81-5

Product Name Glycerin

### Other means of identification

*A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.*

EC No (EU Index No) 200-289-5

CAS Number 56-81-5

Chemical Name Glycerin

Synonyms Glycerol, 1,2,3-Propanetriol

Pure substance/mixture Substance

Formula C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>

Molecular Weight 92.09 gm/mol

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

Recommended Use Laboratory chemicals, Pharma Excipients, Biopharma ingredient

Uses advised against No information available

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

Aceto Pharma (India) Private Limited 184-186/P, Vill: Chacharwadi Vasna, Sarkhej-Bavla Highway, Tal-Sanand, Dist-Ahmedabad-382110, Gujarat, India. Web: [www.finarchemicals.com](http://www.finarchemicals.com) E-Mail Address: [safety.amd@actylis.com](mailto:safety.amd@actylis.com); [qa.amd@actylis.com](mailto:qa.amd@actylis.com)

### 1.4. Emergency telephone number

Emergency telephone India: 02717 616 717

Emergency telephone - §45 - (EC)1272/2008
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Europe	112
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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

## 2.2. Label elements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

## Hazard statements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

## 2.3. Other hazards

No information available.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Glycerin	-	-

Chemical name	Endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100(3) or Commission Regulation (EU) 2018/605(4)
Glycerin	-

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Glycerin 56-81-5	99-101	No data available	200-289-5	No data available	-	-	-

**Full text of H- and EUH-phrases: see section 16**

### Acute Toxicity Estimate

No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Glycerin 56-81-5	12600	10000	2.75	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Rinse mouth.

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

<b>Symptoms</b>	No information available.
<b>Effects of Exposure</b>	See Section 11 for additional Toxicological Information.

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

<b>Note to physicians</b>	Treat symptomatically.
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### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
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#### **5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	No information available.
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#### **5.3. Advice for firefighters**

<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	Ensure adequate ventilation.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

#### **6.2. Environmental precautions**

<b>Environmental precautions</b>	See Section 12 for additional Ecological Information.
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#### **6.3. Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
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- Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.
- Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

#### 6.4. Reference to other sections

- Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Advice on safe handling** Ensure adequate ventilation.
- General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage Conditions** Keep container tightly closed in a dry and well-ventilated place.

### 7.3. Specific end use(s)

- Risk Management Measures** The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

- Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Glycerin 56-81-5	-	-	TWA: 10 mg/m <sup>3</sup>	-	TWA: 10 mg/m <sup>3</sup>
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Glycerin 56-81-5	-	TWA: 10 mg/m <sup>3</sup> Ceiling: 15 mg/m <sup>3</sup>	-	TWA: 10 mg/m <sup>3</sup>	TWA: 20 mg/m <sup>3</sup>
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Glycerin 56-81-5	TWA: 10 mg/m <sup>3</sup>	TWA: 200 mg/m <sup>3</sup>	TWA: 200 mg/m <sup>3</sup> Peak: 400 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Glycerin 56-81-5	-	-	-	-	-
Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Glycerin 56-81-5	-	-	-	-	TWA: 10 mg/m <sup>3</sup>
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycerin 56-81-5	TWA: 10 mg/m <sup>3</sup>	-	TWA: 11 mg/m <sup>3</sup>	TWA: 200 mg/m <sup>3</sup> STEL: 400 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Chemical name	Sweden		Switzerland		United Kingdom
Glycerin 56-81-5	-		TWA: 50 mg/m <sup>3</sup> STEL: 100 mg/m <sup>3</sup>		TWA: 10 mg/m <sup>3</sup> STEL: 30 mg/m <sup>3</sup>

- Biological occupational exposure** This product, as supplied, does not contain any hazardous materials with biological limits

**limits** established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Bulgaria	Croatia	Czech Republic
Glycerin 56-81-5	-	-	-	-	-
Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Glycerin 56-81-5	-	-	-	-	-
Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII	
Glycerin 56-81-5	-	-	-	-	-
Chemical name	Latvia	Luxembourg	Romania	Slovakia	
Glycerin 56-81-5	-	-	-	-	-
Chemical name	Slovenia	Spain	Switzerland	United Kingdom	
Glycerin 56-81-5	-	-	-	-	-

**Derived No Effect Level (DNEL) - Workers** No information available

Chemical name	Oral	Dermal	Inhalation
Glycerin 56-81-5	-	-	56 mg/m <sup>3</sup> [5] [6]

**Derived No Effect Level (DNEL) - General Public** No information available.

Chemical name	Oral	Dermal	Inhalation
Glycerin 56-81-5	229 mg/kg bw/day [4] [6]	-	33 mg/m <sup>3</sup> [5] [6]

Chemical name	Oral	Dermal	Inhalation
Glycerin - 56-81-5	-	-	-

**Predicted No Effect Concentration (PNEC)** No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Glycerin 56-81-5	0.885 mg/L	8.85 mg/L	0.0885 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Glycerin 56-81-5	3.3 mg/kg sediment dw	0.33 mg/kg sediment dw	1000 mg/L	0.141 mg/kg soil dw	-

## 8.2. Exposure controls

<b>Engineering controls</b>	Ensure adequate ventilation, especially in confined areas.
<b>Personal Protective Equipment</b>	
<b>Eye/face protection</b>	No special protective equipment required.
<b>Skin and body protection</b>	Apron. Antistatic boots.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Environmental exposure controls</b>	Do not allow into any sewer, on the ground or into any body of water.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Liquid
<b>Color</b>	Colorless
<b>Odor</b>	No information available.
<b>Odor Threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / Freezing point</b>	18.2 °C	None known
<b>Boiling point / boiling range</b>	290 °C	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability limit</b>	No data available	
<b>Lower flammability limit</b>	No data available	
<b>Flash Point</b>	199 °C	None known
<b>Autoignition temperature °C</b>	370 °C	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Kinematic Viscosity</b>	No data available	None known
<b>Dynamic Viscosity</b>	No Data Available	None known
<b>Water solubility</b>	Miscible in water 1000 g/L @ 25 °C	None known
<b>Solubility in other solvents</b>	No information available	None known
<b>Partition coefficient: n-octanol/water</b>	-1.75 @ 25 °C	None known
<b>Vapor Pressure</b>	26 Pa @ 100 °C	None known
<b>Relative density</b>	1.261 g/cm <sup>3</sup> at 20 °C	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Vapor Density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	
<b>Particle Size Distribution</b>	No information available	

### 9.2. Other information

<b>Molecular Weight</b>	92.09 gm/mol
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9.2.1. Information with regard to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

**Reactivity** No information available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

#### **Explosion Data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** None under normal processing.

### **10.4. Conditions to avoid**

**Conditions to avoid** None known based on information supplied.

### **10.5. Incompatible materials**

**Incompatible materials** None known based on information supplied.

### **10.6. Hazardous decomposition products**

**Hazardous Decomposition Products** None known based on information supplied.

## **SECTION 11: Toxicological information**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

#### **Information on likely routes of exposure**

##### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Skin contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available.

#### **Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

#### **Acute toxicity**

##### **Numerical measures of toxicity**

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerin	= 12600 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 2.75 mg/L ( Rat ) 4 h

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

Chemical name	European Union
Glycerin	-

**Carcinogenicity** No information available.

Chemical name	European Union
Glycerin	-

**Reproductive toxicity** No information available.

Chemical name	European Union
Glycerin	-

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

#### 11.2. Information on other hazards

##### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

##### 11.2.2. Other information

**Other Adverse Effects** No information available.

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea



			microorganisms	
Glycerin	-	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	-	-

**12.2. Persistence and degradability**

**Persistence/Degradability** No information available.

**12.3. Bioaccumulative potential**

**Bioaccumulation** There is no data for this product.

Chemical name	Partition coefficient
Glycerin	-1.75

**12.4. Mobility in soil**

**Mobility in Soil** The product is water soluble, and may spread in water systems.

**12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment** UN.

Chemical name	PBT and vPvB assessment
Glycerin	The substance is not PBT / vPvB

**12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

**12.7. Other adverse effects**

No information available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

**SECTION 14: Transport information****IATA**

- 14.1. UN number or ID number Not regulated  
 14.2. UN proper shipping name Not regulated  
 14.3. Transport hazard class(es) Not regulated  
 14.4. Packing group Not regulated  
 14.5. Environmental hazard Not applicable  
 14.6. Special precautions for user  
 Special Provisions None

**IMDG**

- 14.1. UN number or ID number Not regulated  
 14.2. UN proper shipping name Not regulated

14.3. Transport hazard class(es)	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	Not applicable
14.6. Special precautions for user	
Special Provisions	None
14.7. Maritime transport in bulk according to IMO instruments	No information available

**RID**

14.1. UN-No	Not regulated
14.2. UN proper shipping name	Not regulated
14.3. Transport hazard class(es)	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	Not applicable
14.6. Special precautions for user	
Special Provisions	None

**ADR**

14.1. UN number or ID number	Not regulated
14.2. UN proper shipping name	Not regulated
14.3. Transport hazard class(es)	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	Not applicable
14.6. Special precautions for user	
Special Provisions	None

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Chemical name	French RG number
Glycerin - 56-81-5	-

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Glycerin	-	-	-

**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

**Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Glycerin - 56-81-5	-	-

**Persistent Organic Pollutants**

Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex

Chemical name	Number
Glycerin - 56-81-5	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Glycerin - 56-81-5	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Glycerin - 56-81-5	-	-

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Glycerin - 56-81-5	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Glycerin - 56-81-5	-

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Glycerin - 56-81-5	-

Chemical name	EU - Water Framework Directive (2000/60/EC)
Glycerin - 56-81-5	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Glycerin - 56-81-5	-

**International Inventories**

<b>TSCA</b>	Complies
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>Japan (ENCS)</b>	Complies
<b>Inventory of Existing Chemical Substances in China</b>	Complies
<b>Korea (KECL)</b>	Complies
<b>Philippines (PICCS)</b>	Complies
<b>AIIC</b>	Complies
<b>NZIoC</b>	Complies

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AIIC** - Australian Inventory of Industrial Chemicals

**NZIoC** - New Zealand Inventory of Chemicals

**15.2. Chemical safety assessment**

**Chemical Safety Report** No information available

**SECTION 16: Other information**

**Key or legend to abbreviations and acronyms****Legend**

SVHC: Substances of Very High Concern for Authorization:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances

vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
+	Sensitizers		

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

European Chemicals Agency (ECHA) (ECHA\_API)

Environmental Protection Agency

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006****Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**