SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 as amended by Regulation (EU) No. 2020/878, and
Regulation (EC) No. 1272/2008

Issuing Date 06-Sep-2024 **Revision Date** 20-Sep-2024 **Revision Number** 2

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 C3H8O3

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.actylislab.comE-Mail Address: safety.amd@actylis.com; qa.amd@actylis.com

1.4. Emergency telephone number

Emergency telephone India: 02717 616 717

Emergency telephone - §45 - (EC)1272/2008	
Europe	**112**

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 >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

Symptoms	No information available.
Effects of Exposure	See Section 11 for additional Toxicological Information.

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

Note to physicians	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.

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/m³	-	TWA: 10 mg/m³
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Glycerin 56-81-5	-	TWA: 10 mg/m³ Ceiling: 15 mg/m³	-	TWA: 10 mg/m³	TWA: 20 mg/m³
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Glycerin 56-81-5	TWA: 10 mg/m³	TWA: 200 mg/m³	TWA: 200 mg/m³ Peak: 400 mg/m³	TWA: 10 mg/m³	-
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/m³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycerin 56-81-5	TWA: 10 mg/m³	-	TWA: 11 mg/m³	TWA: 200 mg/m³ STEL: 400 mg/m³	TWA: 10 mg/m³

Chemical name	Sweden	Switzerland	United Kingdom
Glycerin 56-81-5	-	TWA: 50 mg/m³ STEL: 100 mg/m³	TWA: 10 mg/m³ STEL: 30 mg/m³

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/m³ [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/m³ [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

Engineering controls Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment

Eye/face protection No special protective equipment required.

Skin and body protection Apron. Antistatic boots.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls 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

Physical state	Liquid
Color	Colorless
Odor	No information available.
Odor Threshold	No information available

Property	**Values**	**Remarks • Method**
Melting point / Freezing point	18.2 °C	None known
Boiling point / boiling range	290 °C	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Flash Point	199 °C	None known
Autoignition temperature °C	370 °C	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic Viscosity	No data available	None known
Dynamic Viscosity	No Data Available	None known
Water solubility	Miscible in water 1000 g/L @ 25 °C	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	-1.75 @ 25 °C	None known
Vapor Pressure	26 Pa @ 100 °C	None known
Relative density	1.261 g/cm³ at 20 °C	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor Density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

Molecular Weight	92.09 gm/mol

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

	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

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
Japan (ENCS)	Complies
Inventory of Existing Chemical Substances in China	Complies
Korea (KECL)	Complies
Philippines (PICCS)	Complies
AIIC	Complies
NZIoC	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
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End of Safety Data Sheet