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Revision Number 3

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

1.1. Product identifier

Product Code 57-55-6
Product Name Propylene Glycol

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) 200-338-0
CAS Number 57-55-6
Chemical Name Propylene Glycol
Synonyms Methyl Glycol, Propane-1,2-diol, 1,2-Dihydroxypropane
Pure substance/mixture Substance
Formula C₃H₈O₂
Molecular Weight 76.09 g/mol

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

Recommended Use Laboratory chemicals, ERC1 - Manufacture of substances, Pharma Excipients
Uses advised against Do not use where contact with food or drinking water is possible

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].
EUH210 - Safety data sheet available on request.

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
Propylene Glycol	-	-

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)
Propylene Glycol	-

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)
Propylene Glycol 57-55-6	>95	No data available	200-338-0	No data available	-	-	-

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

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

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
Propylene Glycol 57-55-6	20000	20800	No data available	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

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.
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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	Combustible material. Most vapors are heavier than air. Vapors may spread along ground and collect in low or confined areas (sewers, basements, tanks). May form explosive mixtures with air.
Hazardous Combustion Products	Carbon monoxide. Carbon dioxide (CO ₂).

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.
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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 Soak up with inert absorbent material.

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 away from open flames, hot surfaces and sources of ignition. 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

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Propylene Glycol 57-55-6	-	-	-	-	TWA: 150 ppm TWA: 474 mg/m ³ TWA: 10 mg/m ³
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Propylene Glycol 57-55-6	-	-	-	-	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Propylene Glycol 57-55-6	-	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Propylene Glycol 57-55-6	TWA: 10 mg/m ³ TWA: 150 ppm TWA: 470 mg/m ³ STEL: 1410 mg/m ³ STEL: 30 mg/m ³ STEL: 450 ppm	-	-	TWA: 7 mg/m ³	TWA: 7 mg/m ³

Chemical name	Luxembourg	Malta	Netherlands	Norway	Poland
Propylene Glycol 57-55-6	-	-	-	TWA: 25 ppm TWA: 79 mg/m ³ STEL: 37.5 ppm STEL: 118.5 mg/m ³	TWA: 100 mg/m ³
Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Propylene Glycol 57-55-6	-	-	-	-	-
Chemical name	Sweden		Switzerland	United Kingdom	
Propylene Glycol 57-55-6	-		-	TWA: 150 ppm TWA: 474 mg/m ³ TWA: 10 mg/m ³ STEL: 450 ppm STEL: 1422 mg/m ³ STEL: 30 mg/m ³	

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Chemical name	European Union	Austria	Bulgaria	Croatia	Czech Republic
Propylene Glycol 57-55-6	-	-	-	-	-
Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Propylene Glycol 57-55-6	-	-	-	-	-
Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII	
Propylene Glycol 57-55-6	-	-	-	-	
Chemical name	Latvia	Luxembourg	Romania	Slovakia	
Propylene Glycol 57-55-6	-	-	-	-	
Chemical name	Slovenia	Spain	Switzerland	United Kingdom	
Propylene Glycol 57-55-6	-	-	-	-	

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

Chemical name	Oral	Dermal	Inhalation
Propylene Glycol 57-55-6	-	-	168 mg/m ³ [4] [6] 10 mg/m ³ [5] [6]

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

Chemical name	Oral	Dermal	Inhalation
Propylene Glycol 57-55-6	-	-	50 mg/m ³ [4] [6] 10 mg/m ³ [5] [6]

Chemical name	Oral	Dermal	Inhalation
Propylene Glycol - 57-55-6	-	-	-

Predicted No Effect Concentration (PNEC) No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Propylene Glycol 57-55-6	260 mg/L	183 mg/L	26 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Propylene Glycol 57-55-6	572 mg/kg sediment dw	57.2 mg/kg sediment dw	20000 mg/L	50 mg/kg soil dw	-

8.2. Exposure controls

Engineering controls Showers, eyewash stations, and ventilation systems.

Personal Protective Equipment

Eye/face protection Avoid contact with eyes. Goggles.

Hand protection Wear suitable gloves.

Skin and body protection No special protective equipment required.

Respiratory protection Use appropriate respiratory protection.
Particulates filter conforming to EN 143.

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

Environmental exposure controls Prevent product from entering drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / Freezing point	-20 °C	None known
Boiling point / boiling range	184 °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	104 °C	None known
Autoignition temperature °C	400 °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	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	-1.07 @ 20 °C Log Pow	None known
Vapor Pressure	20 Pa	None known
Relative density	1.03	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	76.09 g/mol
Molecular Formula	C3H8O2

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 Incompatible materials. Excessive heat.

10.5. Incompatible materials

Incompatible materials Acids. Strong oxidizing agents.

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****Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Propylene Glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	-

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
Propylene Glycol	-

Carcinogenicity No information available.

Chemical name	European Union
Propylene Glycol	-

Reproductive toxicity No information available.

Chemical name	European Union
Propylene Glycol	-

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Propylene Glycol	EC50: =19000mg/L (96h, Pseudokirchneriella subcapitata)	LC50: =51600mg/L (96h, Oncorhynchus mykiss) LC50: 41 - 47mL/L (96h, Oncorhynchus mykiss) LC50: =51400mg/L (96h, Pimephales promelas) LC50: =710mg/L (96h, Pimephales promelas)	-	EC50: >1000mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence/Degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Propylene Glycol	-1.07

12.4. Mobility in soil

Mobility in Soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment UN.

Chemical name	PBT and vPvB assessment
Propylene Glycol	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

National regulations

France**Occupational Illnesses (R-463-3, France)**

Chemical name	French RG number
Propylene Glycol - 57-55-6	RG 84

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Propylene Glycol	-	-	-

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
Propylene Glycol - 57-55-6	-	-

Persistent Organic Pollutants

Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex Number
Propylene Glycol - 57-55-6	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Propylene Glycol - 57-55-6	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Propylene Glycol - 57-55-6	-	-

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

Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Propylene Glycol - 57-55-6	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Propylene Glycol - 57-55-6	-

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Propylene Glycol - 57-55-6	-

Chemical name	EU - Water Framework Directive (2000/60/EC)
Propylene Glycol - 57-55-6	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Propylene Glycol - 57-55-6	-

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		

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method

STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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