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 23-Oct-2024 **Revision Date** 23-Oct-2024 **Revision Number** 1

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

1.1. Product identifier

Product Code 56-40-6

Product Name Glycine

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) 200-272-2

CAS Number 56-40-6

Chemical Name Glycine

Synonyms Aminoacetic acid, Aminoethanoic acid

Pure substance/mixture Substance

Formula C2H5NO2

Molecular Weight 75.07 g/mol

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

Recommended Use Laboratory chemicals, Manufacture of substances, used as 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.com E-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
Glycine	-	-

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)
Glycine	-

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)
Glycine 56-40-6	>98	No data available	200-272-2	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
Glycine 56-40-6	7930	No data available	No data available	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 Dust irritates eyes and air passages. None known.

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 Dry chemical, CO2, water spray or alcohol-resistant foam.

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 Thermal decomposition can lead to release of irritating and toxic gases and vapors.

Hazardous Combustion Products Carbon oxides. Carbon monoxide. Nitrogen oxides.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Wear self contained breathing apparatus for fire fighting if necessary.

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 Cover powder spill with plastic sheet or tarp to minimize spreading. Do not touch or walk through spilled material. Prevent dust cloud.

Methods for cleaning up Avoid generation of dust. Do not dry sweep dust. Wet dust with water before sweeping or use a vacuum to collect dust. Pick up and transfer to properly labeled containers. Use personal protective equipment as required.

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 Avoid contact with skin and eyes. Avoid generation of dust. Do not breathe dust. Ensure adequate ventilation. Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
Glycine 56-40-6	-	-	-	-	-
Chemical name	**Cyprus**	**Czech Republic**	**Denmark**	**Estonia**	**Finland**
Glycine 56-40-6	-	-	-	-	-
Chemical name	**France**	**Germany TRGS**	**Germany DFG**	**Greece**	**Hungary**
Glycine 56-40-6	-	-	-	-	-
Chemical name	**Ireland**	**Italy MDLPS**	**Italy AIDII**	**Latvia**	**Lithuania**
Glycine 56-40-6	-	-	-	TWA: 5 mg/m^3	-
Chemical name	**Luxembourg**	**Malta**	**Netherlands**	**Norway**	**Poland**
Glycine 56-40-6	-	-	-	-	-

Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Glycine 56-40-6	-	-	-	-	-

Chemical name	Sweden	Switzerland	United Kingdom
Glycine 56-40-6	-	-	-

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
Glycine 56-40-6	-	-	-	-	-

Chemical name	Denmark	Finland	France	Germany DFG	Germany TRGS
Glycine 56-40-6	-	-	-	-	-

Chemical name	Hungary	Ireland	Italy MDLPS	Italy AIDII
Glycine 56-40-6	-	-	-	-

Chemical name	Latvia	Luxembourg	Romania	Slovakia
Glycine 56-40-6	-	-	-	-

Chemical name	Slovenia	Spain	Switzerland	United Kingdom
Glycine 56-40-6	-	-	-	-

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

Chemical name	Oral	Dermal	Inhalation
Glycine 56-40-6	-	-	-

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

Chemical name	Oral	Dermal	Inhalation
Glycine 56-40-6	-	-	-

Chemical name	Oral	Dermal	Inhalation
Glycine - 56-40-6	-	-	-

Predicted No Effect Concentration (PNEC) No information available.

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Glycine 56-40-6	-	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Glycine 56-40-6	-	-	-	-	-

8.2. Exposure controls

Engineering controls Ventilation systems.

Personal Protective Equipment

Eye/face protection Goggles.

Hand protection Nitrile rubber.

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective nitrile rubber gloves		

Skin and body protection Apron.

Respiratory protection Use appropriate respiratory protection.

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 Solid Powder
Color White
Odor Odorless.
Odor Threshold No information available

Property	Values	Remarks • Method
Melting point / Freezing point	235 °C 245 °C	None known
Boiling point / boiling range	375.67 °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	No data available	None known
Autoignition temperature °C	No data available	None known
Decomposition temperature	>233°C	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	Soluble in water 250 g/L	None known
Solubility in other solvents	No information available	None known
Partition coefficient: n-octanol/water	No data available	None known
Vapor Pressure	0 Pa @ 25 °C	None known
Relative density	1.161 g/cm³	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	75.07 g/mol
Molecular Formula	C2H5NO2

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 Bases. Oxidizing agent.

10.6. Hazardous decomposition products

Hazardous Decomposition Products Carbon monoxide. Carbon dioxide (CO2). Nitrogen oxides (NOx).

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
Glycine	7930 mg/kg (Rat)	-	-

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
Glycine	-

Carcinogenicity No information available.

Chemical name	European Union
Glycine	-

Reproductive toxicity No information available.

Chemical name	European Union
Glycine	-

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
Glycine	-	LC50: >1000mg/L (96h, Oryzias latipes)	-	-

12.2. Persistence and degradability

Persistence/Degradability Soluble in water Persistence is unlikely based on information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Glycine	-3.21

12.4. Mobility in soil

Mobility in Soil Will likely be mobile in the environment due to its water solubility.

12.5. Results of PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Glycine	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 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

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
Glycine - 56-40-6	-

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

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
Glycine - 56-40-6	-	-

Persistent Organic Pollutants
Not applicable

Chemical name	Persistent Organic Pollutants per (EC) 2019/1021 - Annex Number
Glycine - 56-40-6	-

Chemical name	European Export/Import Restrictions per (EC) 649/2012 - Annex Number
Glycine - 56-40-6	-

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Glycine - 56-40-6	-	-

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

Chemical name	Ozone depletion potential (ODP)	Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Glycine - 56-40-6	-	-

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Glycine - 56-40-6	-

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Glycine - 56-40-6	-

Chemical name	EU - Water Framework Directive (2000/60/EC)
Glycine - 56-40-6	-

Chemical name	EU - Environmental Quality Standards (2008/105/EC)
Glycine - 56-40-6	-

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Complies
KECL	Complies
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	Sk*	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

Issuing Date 23-Oct-2024

Revision Date 23-Oct-2024

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