

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/11/2020 Revision date: 28/07/2025 Supersedes version of: 03/11/2020 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Pregabalin impurity C
Chemical name : Mandelic acid
EC-No. : 202-007-6
CAS-No. : 90-64-2
Product code : 202000290

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 1 H318
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye damage.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05

Signal word (CLP) : Danger
Hazard statements (CLP) : H318 - Causes serious eye damage.
Precautionary statements (CLP) : P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)

:



GHS05

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Other information

: Active substance (in pharmaceutical products).

Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Mandelic acid	CAS-No.: 90-64-2 EC-No.: 202-007-6	≤ 100	Eye Dam. 1, H318

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye specialist immediately.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

Symptoms/effects after eye contact	: Causes serious eye damage. Redness, pain.
------------------------------------	---

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials : Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Molecular mass	: 152.15 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 139 g/l (20°C)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Mandelic acid (90-64-2)

LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

Mandelic acid (90-64-2)

EC50 - Crustacea [1]	> 100 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)
ErC50 algae	> 100 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.2. Persistence and degradability

Mandelic acid (90-64-2)

Persistence and degradability

Rapidly degradable

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Mandelic acid (90-64-2)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not regulated

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Transport by sea

Not regulated

Air transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.1	Synonyms	Modified
1.1	Name	Modified
1.2	Restrictions on use	Added
1.2	Use of the substance/mixture	Added
1.2	Function or use category	Added
2.1	Adverse physicochemical, human health and environmental effects	Added

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added
2.2	Precautionary statements (CLP)	Added
2.2	Hazard statements (CLP)	Added
2.2	Signal word (CLP)	Added
2.2	Hazard pictograms (CLP)	Added
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after eye contact	Added
4.2	Symptoms/effects after eye contact	Added
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Added
5.2	Hazardous decomposition products in case of fire	Added
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Added
6.1	Emergency procedures	Added
6.1	Protective equipment	Added
6.1	General measures	Added
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Precautions for safe handling	Added
7.1	Hygiene measures	Added
7.2	Packaging materials	Added
7.2	Storage conditions	Added
8.2	Respiratory protection	Added
8.2	Hand protection	Added
8.2	Eye protection	Added
8.2	Appropriate engineering controls	Added
8.2	Skin and body protection	Added
9	Molecular mass	Added
9	Solubility in water	Added
11.1	LD50 oral rat	Added
12.1	ErC50 algae	Added

Pregabalin impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
12.1	EC50 - Crustacea [1]	Added

Full text of H- and EUH-statements:	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H318	Causes serious eye damage.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.