

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: AMANTADINE SULPHATE
Chemical name	: 1-aminoadamantansulphate
IUPAC name	: 1-aminoadamantansulphate
EC-No.	: 250-604-5
CAS-No.	: 31377-23-8
Product code	: 70550
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: 2.(C10H17N).H2SO4
Synonyms	: 1-aminoadamantansulphate
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES: NC12CC3CC(CC(C3)C1)C2.OS(=O)=O

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API,Industrial use,Medicinal use,Laboratory use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: Chemical intermediate, Antiviral, antiparkinsonian
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

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1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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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]**

Acute toxicity (oral), Category 4	H302
Reproductive toxicity, Category 2	H361fd
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412
Full text of H- and EUH-statements: see section 16	

AMANTADINE SULPHATE

Safety Data Sheet

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

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Harmful to aquatic life with long lasting effects. Suspected of damaging fertility. Suspected of damaging the unborn child. Dust may form explosive mixture in air.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.
H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P281 - Use personal protective equipment as required.
P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
AMANTADINE SULPHATE	CAS-No.: 31377-23-8 EC-No.: 250-604-5	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : IF exposed or concerned: Get medical advice/attention. Never give anything by mouth to an unconscious person.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
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 with plenty of water. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

AMANTADINE SULPHATE

Safety Data Sheet

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

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

No additional information available

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 : Apply water spray or fog to cool nearby equipment. Foam. Dry powder. Carbon dioxide. Sand. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Explosion hazard : Avoid raising powdered material due to explosion hazard.
- Hazardous decomposition products in case of fire : Carbon monoxide. Carbon dioxide. Nitrogen oxides. fume.

5.3. Advice for firefighters

- Precautionary measures fire : Keep away from combustible materials.
- Firefighting instructions : Contain the extinguishing fluids by bunding. Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Dust/aerosol mask. Safety glasses. Protective gloves. Equip cleanup crew with proper protection.

6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Avoid contact during pregnancy/while nursing.

AMANTADINE SULPHATE

Safety Data Sheet

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

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature. Store in a well-ventilated place. Keep cool. Store in a closed container. Keep container closed when not in use. Keep only in the original container in a cool, well ventilated place away from : Oxidizing agent, Heat sources, Direct sunlight, Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use. Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. In case of splash hazard: safety glasses. Dust production: dust mask with filter type P3.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

Eye protection		
Type	Field of application	Standard
Safety glasses	Dust, Fine dust	EN 166

8.2.2.2. Skin protection

Skin and body protection	
Type	Standard
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

AMANTADINE SULPHATE

Safety Data Sheet

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

Hand protection:

In case of repeated or prolonged contact wear gloves

Hand protection		
Type	Material	Standard
Disposable gloves	Nitrile rubber (NBR), Polyvinylalcohol (PVA), Butyl rubber, Natural rubber, Polyvinylchloride (PVC)	EN 374-2

Other skin protection Materials for protective clothing		
Condition	Material	Standard
Good resistance:	Synthetic material, Tyvek®, Polyethylene	EN 13034, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust formation: dust mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Molecular mass	: 400.6 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 300 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4.9 (100 g/l, H ₂ O, 20°C)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 2 % (20°C)
Partition coefficient n-octanol/water (Log Kow)	: 2.43 [KOWWIN v1.67 estimate; Amantadine]
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.066 g/cm ³

AMANTADINE SULPHATE

Safety Data Sheet

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

Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

On exposure to high temperature, may decompose, releasing toxic gases. Nitrogen oxides. Carbon monoxide. Carbon dioxide. fume.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

(Amantadine, CAS n°: 768-94-5)	
LD50, oral, mouse	1080 mg/kg
LD50, intravenous, mouse	233 mg/kg
(Amantadine hydrochloride, CAS n°: 665-66-7)	
LD50, oral, rat	890 mg/kg
LD50, oral, mouse	700 mg/kg

Skin corrosion/irritation	: Not classified pH: 4.9 (100 g/l, H ₂ O, 20°C)
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AMANTADINE SULPHATE

Safety Data Sheet

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

Serious eye damage/irritation	: Not classified pH: 4.9 (100 g/l, H ₂ O, 20°C)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility. Suspected of damaging the unborn child.
Additional information	: May damage fertility. Suspected of damaging the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water	: WGK class (Germany): 3
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

AMANTADINE SULPHATE (31377-23-8)

Persistence and degradability	Not readily biodegradable.
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12.3. Bioaccumulative potential

AMANTADINE SULPHATE (31377-23-8)

Partition coefficient n-octanol/water (Log Kow)	2.43 [KOWWIN v1.67 estimate; Amantadine]
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

AMANTADINE SULPHATE

Safety Data Sheet

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not applicable
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IMDG

Transport hazard class(es) (IMDG)	: Not applicable
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IATA

Transport hazard class(es) (IATA)	: Not applicable
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ADN

Transport hazard class(es) (ADN)	: Not applicable
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RID

Transport hazard class(es) (RID)	: Not applicable
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14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

AMANTADINE SULPHATE

Safety Data Sheet

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

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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

15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : Conform to current legislation, regulations and orders.

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

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

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

Explosives Precursors Regulation (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 (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)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

AMANTADINE SULPHATE

Safety Data Sheet

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

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
H302	Harmful if swallowed.
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H412	Harmful to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2

Safety Data Sheet (SDS), EU

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.