

Safety Data Sheet

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 07/07/2014 Revision date 20/03/2020
Supersedes 06/01/2017

1.1. Product identifier

Product form	: Substance
Substance name	: Noradrenaline tartrate
CAS-No.	: 108341-18-0
Product code	: 622265
Formula	: C8H11NO3 · C4H6O6 · H2O
Synonyms	: L-(-)-Norepinephrine (+)-bitartrate salt monohydrate L-(-)-Noradrenaline
Product group	: Raw material

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

No additional information available

Supplier

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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

2.1. Classification of the substance or mixture

Acute toxicity (oral), Category 3

20/03/2020 Duchefa Farma B.V.

1/9

Noradrenaline tartrate

622265

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Acute toxicity (dermal), Category 3 H311
Acute toxicity (inhal.), Category 3 H331

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display/Extra classification(s) to display

Hazard pictograms (CLP)



GHS06

Signal word (CLP) : Danger

Hazard statements (CLP) : H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled

Precautionary statements (CLP) : P261 - Avoid breathing dust.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Noradrenaline tartrate	(CAS-No.) 108341-18-0	100	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow affected person to breathe fresh air Allow the victim to rest Seek medical advice.
First-aid measures after skin contact	: Immediately call a POISON CENTER/doctor. Rinse with plenty of water Seek medical advice.
First-aid measures after eye contact	: Rinse immediately with plenty of water Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects	: May produce irregular heart beat and nervous symptoms. Dizziness Blurred vision Cardiac and blood circulation effects Reduced blood pressure This substance is an endocrine disruptor.
Symptoms/effects after skin contact	: Repeated exposure to this material can result in absorption through skin causing significant health hazard. Toxic in contact with skin.
Symptoms/effects after ingestion	: Toxic if swallowed. Swallowing a small quantity of this material will result in serious health hazard.

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	: Foam Dry powder Carbon dioxide Water spray Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: On burning: release of toxic and corrosive gases/vapours (carbon monoxide - carbon dioxide).
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5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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

- General measures : Remove ignition sources.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or 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. Store away from other materials. Residue may be washed down with water.

6.4. Reference to other sections

Reference to other sections (8, 13).

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. Ensure adequate ventilation. Avoid raising dust. Handle in accordance with good industrial hygiene and safety procedures.
- Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container closed when not in use
Keep only in the original container in a cool, well-ventilated place.
- Incompatible products : Strong bases. Strong acids. Oxidizing agent.
- Incompatible materials : Sources of ignition. Direct sunlight. No naked flames. Sparks.
- Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

8.2. Exposure controls

Appropriate engineering controls:

Good ventilation of the workplace required. Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Dust/aerosol mask with filter type P3. Protective goggles. Gloves.

Hand protection:

Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dust production: dust mask with filter type P3



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
Appearance	: Powder.
Molecular mass	: 337.28 g/mol
Colour	: White.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: 3.5 - 5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 100 - 106 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight

Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids

Strong bases

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon monoxide

Carbon dioxide

Nitrous fumes

release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.

Noradrenaline tartrate (108341-18-0)	
LD50 oral rat	164.3 mg/kg

Skin corrosion/irritation : Not classified
pH: 3.5 - 5

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified pH: 3.5 - 5
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: 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
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Toxic if swallowed. Toxic in contact with skin.

SECTION 12: Ecological information**12.1. Toxicity**

Noradrenaline tartrate (108341-18-0)	
LC50 fish 1	> 100 mg/l 96 h.

12.2. Persistence and degradability

Noradrenaline tartrate (108341-18-0)	
Persistence and degradability	Limited biodegradability.
Biodegradation	> 60 %

12.3. Bioaccumulative potential

Noradrenaline tartrate (108341-18-0)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment.

Safety Data Sheet


according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
- Ecology - waste materials : Avoid release to the environment. Hazardous waste due to toxicity.

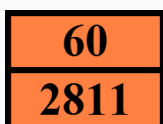
SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**. Overland transport**

- Classification code (ADR) : T2
- Special provisions (ADR) : 274, 614
- Limited quantities (ADR) : 5kg
- Excepted quantities (ADR) : E1
- Vehicle for tank carriage : AT
- Transport category (ADR) : 2
- Hazard identification number (Kemler No.) : 60
- Orange plates :



- Tunnel restriction code (ADR) : E
- EAC code : 2X

- Air transport

No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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**

No REACH Annex XVII restrictions

Noradrenaline tartrate is not on the REACH Candidate List

Noradrenaline tartrate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

		Modified	Change of logo
1.2	Use of the substance/mixture	Added	
7.2	Storage temperature	Added	

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.

SDS EU (REACH Annex II) duchefa nieuwe logo

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.