

Trade name: Lidocaini hydrochloridum

Substance number: 065048

Version: 3 / CH

Date revised: 02.10.2019

Replaces Version: 2 / CH

Print date: 02.10.19

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

1.1. Product identifier

Lidocaini hydrochloridum

Item No. 06504800

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

Use of the substance/preparation

Active pharmaceutical substance

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9100 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification ***

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H302 Harmful if swallowed.

Precautionary statements ***

P264.1 Wash hands thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P301+P312 IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P330 Rinse mouth.
P501.3 Disposal in compliance with local and national regulations.

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Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains *** 2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate

SECTION 3: Composition/information on ingredients *****Hazardous ingredients *******2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate**

CAS No. 6108-05-0

EINECS no. 200-803-8

Concentration >= 97 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

If you feel unwell, seek medical advice (show the label where possible).

After inhalation

Ensure supply of fresh air. Summon a doctor immediately.

After skin contact

Remove contaminated, soaked clothing immediately and dispose of safely. Wash off immediately with soap and water. In case of contact with skin wash off with warm water.

After eye contact

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. By continuous complaints consult a physician.

After ingestion

If swallowed, rinse mouth with water (only if the person is conscious). Call in a physician immediately and show him the Safety Data Sheet. Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water spray jet, Foam, Dry chemical extinguisher, Dry powder, Sand

Non suitable extinguishing media

Water spray jet

5.2. Special hazards arising from the substance or mixture

In case of fires, hazardous combustion gases are formed; Avoid inhalation of smoke and vapours.

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

Use self-contained breathing apparatus. Use personal protective clothing.

Other information

Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

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Respiratory protection

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater. In case the product spills into sewage waters, immediately inform the authorities.

6.3. Methods and material for containment and cleaning up

Avoid raising dust. Clean contaminated floors and objects thoroughly, observing environmental regulations. Ensure adequate ventilation.

6.4. Reference to other sections

Information regarding personal protective measures, see Section 8.

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Avoid contact with skin, eyes and clothing. Avoid inhaling dusts/ billows/ steams. Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep only in original container. Keep in a cool place. Keep container tightly closed in a well-ventilated place.

Hints on storage assembly

Do not store with acids. Alkalies

Storage classes

Storage class according to TRGS 510	13	Non- combustible solids
Storage category (Switzerland)	11/13	Other solid hazardous substances with hazardous classification/labelling

Further information on storage conditions

Keep away from sources of ignition. Protect from direct sunlight.

SECTION 8: Exposure controls/personal protection**8.2. Exposure controls****General protective and hygiene measures**

Wash hands before breaks and after work. Wash contaminated clothing before reuse. Do not eat, drink or smoke during work time.

Respiratory protection

Dust mask; Particle filter P3

Hand protection

Gloves	
Appropriate Material	rubber
Appropriate Material	PVA
Appropriate Material	PVC
Appropriate Material	Natural Latex

Eye protection

Safety glasses

Body protection

Protective clothing

SECTION 9: Physical and chemical properties

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9.1. Information on basic physical and chemical properties

Form	Powder		
Colour	white		
Odour	characteristic		
pH value			
Value	4.0	to	5.5
Concentration/H ₂ O	5	%	
Melting point			
Value	77		°C
Initial boiling point and boiling range			
Value	351		°C
Pressure	760	mmHg	
Flash point			
Value	179		°C
Flammability (solid, gas)	No data available		
Upper/lower flammability or explosive limits			
Remarks	No data available		
Vapour pressure			
Remarks	No data available		
Density			
Remarks	No data available		
Solubility in water			
Remarks	soluble		
Partition coefficient: n-octanol/water			
log Pow	2.1		
Minimum ignition energy			
Minimum ignition energy	appr. 40	to	50 MJ
Viscosity			
Remarks	Not applicable		

9.2. Other information

Bulk density			
Value	400		kg/m ³
Other information	Forms explosive mixture with air are possible.		

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under recommended storage and handling conditions (see section 7).

10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

10.4. Conditions to avoid

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Protect from direct sunlight. Protect from extreme heat and cold.

10.5. Incompatible materials

Reactions with strong alkalis. strong acids

10.6. Hazardous decomposition products

nitrous oxides (NOx), Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

ATE	292	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)**2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate**

Species	rat	
LD50	317	mg/kg

2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate

Species	mouse	
LD50	292	mg/kg

Skin corrosion/irritation

Species	rabbit
Remarks	slightly irritating (skin)

Serious eye damage/irritation

Species	rabbit
Remarks	slightly irritating (Eye)

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

Remarks No data available.

12.2. Persistence and degradability**Biodegradability**

Remarks Quantitative data concerning the ecological effect are not available.

12.3. Bioaccumulative potential**Partition coefficient: n-octanol/water**

log Pow 2.1

12.5. Results of PBT and vPvB assessment**Evaluation of persistence and bioaccumulation potential (Components)****2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide hydrochloride monohydrate**

The Substance doesn't meets PBT/vPvB-criteria

12.6. Other adverse effects**General information / ecology**

Do not allow it to reach ground water, water bodies or sewage system.

SECTION 13: Disposal considerations

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13.1. Waste treatment methods**Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	Non-dangerous goods	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information *****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Water Hazard Class (Germany) *****

Water Hazard Class (Germany) WGK 3

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302 Harmful if swallowed.

CLP categories listed in Chapter 3

Acute Tox. 4 Acute toxicity, Category 4

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
 This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.