

# Levodropropizine impurity B

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 01/01/2025 Revision date: 03/06/2025 Supersedes version of: 01/01/2025 Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Levodropropizine impurity B  
Chemical name : 1-Phenylpiperazine  
EC-No. : 202-165-6  
CAS-No. : 92-54-6  
Product code : 202400621

#### 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](mailto:sds@edqm.eu), [www.edqm.eu](http://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]

Acute toxicity (oral), Category 3 H301  
Acute toxicity (dermal), Category 2 H310  
Skin corrosion/irritation, Category 1, Sub-Category 1B H314  
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

Toxic if swallowed. Fatal in contact with skin. Causes severe skin burns and eye damage.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :    
GHS05 GHS06

Signal word (CLP) : Danger

# Levodropropizine impurity B

## Safety Data Sheet

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

Hazard statements (CLP)	: H301 - Toxic if swallowed. H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage.
Precautionary statements (CLP)	: P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor. P321 - Specific treatment (see supplemental first aid instruction on this label). P330 - Rinse mouth. P361+P364 - Take off immediately all contaminated clothing and wash it before reuse. 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.

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

Hazard pictograms (CLP)



GHS06

GHS05

### 2.3. Other hazards

Other information : 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]
1-Phenylpiperazine	CAS-No.: 92-54-6 EC-No.: 202-165-6	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=210 mg/kg bodyweight) Acute Tox. 2 (Dermal), H310 (ATE=149 mg/kg bodyweight) Skin Corr. 1B, H314 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. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Take off immediately all contaminated clothing. Rinse immediately and plentifully with water and take medical advice.
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.

# Levodropropizine impurity B

## Safety Data Sheet

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

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. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation : May cause shortness of breath, tightness of the chest, a sore throat and cough.  
Symptoms/effects after skin contact : Fatal in contact with skin. Causes severe burns.  
Symptoms/effects after eye contact : Causes serious eye damage. Redness, pain.  
Symptoms/effects after ingestion : Burns to the gastric/intestinal mucosa.

### 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.

### 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.

# Levodropropizine impurity B

## Safety Data Sheet

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

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

### 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 mist, spray or aerosol exposure: Breathing apparatus with filter (P3). Where excessive vapour may result, wear approved mask .

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Molecular mass	: 163.2 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: ≈ 18 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: 140 °C
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available

# Levodropropizine impurity B

## Safety Data Sheet

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

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 available
Particle characteristics	: Not applicable

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 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)	: Toxic if swallowed.
Acute toxicity (dermal)	: Fatal in contact with skin.
Acute toxicity (inhalation)	: Not classified (Lack of data)

1-Phenylpiperazine (92-54-6)	
LD50 oral rat	210 mg/kg (RTECS No TM2625000)
LD50 dermal rat	149 mg/kg

Skin corrosion/irritation	: Causes severe skin burns.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
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 (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

# Levodropropizine impurity B

## Safety Data Sheet

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

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

#### 12.2. Persistence and degradability

##### 1-Phenylpiperazine (92-54-6)

Persistence and degradability	Not rapidly degradable
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#### 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

No additional information available

#### 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
<b>14.1. UN number or ID number</b>		
UN 2922	UN 2922	UN 2922
<b>14.2. UN proper shipping name</b>		
CORROSIVE LIQUID, TOXIC, N.O.S.	CORROSIVE LIQUID, TOXIC, N.O.S.	Corrosive liquid, toxic, n.o.s.
<b>Transport document description</b>		
UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II, (E)	UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S., 8 (6.1), II	UN 2922 Corrosive liquid, toxic, n.o.s., 8 (6.1), II
<b>14.3. Transport hazard class(es)</b>		
8 (6.1)	8 (6.1)	8 (6.1)

# Levodropropizine impurity B

## Safety Data Sheet

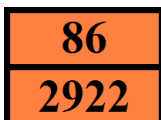
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
<b>14.4. Packing group</b>		
II	II	II
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-B	Dangerous for the environment: No
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: CT1
Special provisions (ADR)	: 274
Limited quantities (ADR)	: 1I
Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02
Mixed packing provisions (ADR)	: MP15
Portable tank and bulk container instructions (ADR)	: T7
Portable tank and bulk container special provisions (ADR)	: TP2
Tank code (ADR)	: L4BN
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Hazard identification number (Kemler No.)	: 86
Orange plates	:



Tunnel restriction code (ADR) : E

#### Transport by sea

Special provisions (IMDG)	: 274
Limited quantities (IMDG)	: 1 L
Excepted quantities (IMDG)	: E2
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
Tank instructions (IMDG)	: T7
Tank special provisions (IMDG)	: TP2
Stowage category (IMDG)	: B
Stowage and handling (IMDG)	: SW2
Properties and observations (IMDG)	: Causes burns to skin, eyes and mucous membranes. Toxic if swallowed, by skin contact or by inhalation.

#### Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y840
PCA limited quantity max net quantity (IATA)	: 0.5L
PCA packing instructions (IATA)	: 851
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 855
CAO max net quantity (IATA)	: 30L
Special provisions (IATA)	: A3, A4, A803
ERG code (IATA)	: 8P

# Levodropropizine impurity B

## Safety Data Sheet

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

### 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
	UN-No. (RID)	Added
	Number of blue cones/lights (ADN)	Added
	Ventilation (ADN)	Added
	Equipment required (ADN)	Added
	Carriage permitted (ADN)	Added
	Excepted quantities (ADN)	Added
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Colis express (express parcels) (RID)	Added
	Special provisions for carriage - Loading, unloading and handling (RID)	Added

# Levodropropizine impurity B

## Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
	Transport category (RID)	<b>Added</b>
	Tank codes for RID tanks (RID)	<b>Added</b>
	Portable tank and bulk container special provisions (RID)	<b>Added</b>
	Portable tank and bulk container instructions (RID)	<b>Added</b>
	Mixed packing provisions (RID)	<b>Added</b>
	Packing instructions (RID)	<b>Added</b>
	Excepted quantities (RID)	<b>Added</b>
	Limited quantities (RID)	<b>Added</b>
	Special provisions (RID)	<b>Added</b>
	Packing group (RID)	<b>Added</b>
	Classification code (RID)	<b>Added</b>
	ERG code (IATA)	<b>Added</b>
	Special provisions (IATA)	<b>Added</b>
	CAO max net quantity (IATA)	<b>Added</b>
	CAO packing instructions (IATA)	<b>Added</b>
	PCA max net quantity (IATA)	<b>Added</b>
	PCA packing instructions (IATA)	<b>Added</b>
	PCA limited quantity max net quantity (IATA)	<b>Added</b>
	PCA Limited quantities (IATA)	<b>Added</b>
	PCA Excepted quantities (IATA)	<b>Added</b>
	Danger labels (IATA)	<b>Added</b>
	Proper Shipping Name (IATA)	<b>Added</b>
	Properties and observations (IMDG)	<b>Added</b>
	Proper Shipping Name (IMDG)	<b>Added</b>
	Danger labels (IMDG)	<b>Added</b>
	EmS-No. (Spillage)	<b>Added</b>
	EmS-No. (Fire)	<b>Added</b>
	Limited quantities (IMDG)	<b>Added</b>
	Stowage and handling (IMDG)	<b>Added</b>
	Stowage category (IMDG)	<b>Added</b>
	Tank special provisions (IMDG)	<b>Added</b>
	Tank instructions (IMDG)	<b>Added</b>
	IBC packing instructions (IMDG)	<b>Added</b>
	Excepted quantities (IMDG)	<b>Added</b>
	Special provisions (IMDG)	<b>Added</b>
	Special provisions for carriage - Loading, unloading and handling (ADR)	<b>Added</b>

# Levodropropizine impurity B

## Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
	Tank code (ADR)	<b>Added</b>
	Portable tank and bulk container special provisions (ADR)	<b>Added</b>
	Portable tank and bulk container instructions (ADR)	<b>Added</b>
	Mixed packing provisions (ADR)	<b>Added</b>
	Packing instructions (ADR)	<b>Added</b>
	Vehicle for tank carriage	<b>Added</b>
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
	Issue date	<b>Modified</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>
1.2	Main use category	<b>Removed</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.2	Hazard pictograms (CLP)	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.2	Symptoms/effects after inhalation	<b>Added</b>
4.2	Symptoms/effects after ingestion	<b>Added</b>
4.2	Symptoms/effects after eye contact	<b>Added</b>
4.2	Symptoms/effects after skin contact	<b>Added</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>

# Levodropropizine impurity B

## Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
6.1	General measures	Added
6.1	Emergency procedures	Modified
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
7.3	Specific end uses	Removed
8.2	Eye protection	Added
8.2	Respiratory protection	Added
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Molecular mass	Added
9	Melting point	Added
9	Flash point	Added
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 dermal rat	Added
11.1	ATE CLP (dermal)	Added
11.1	ATE CLP (oral)	Modified
11.1	LD50 oral rat	Modified
14.1	UN-No. (ADN)	Added
14.1	UN-No. (IMDG)	Added
14.1	UN-No. (IATA)	Added
14.1	UN-No. (ADR)	Added
14.2	Proper Shipping Name (ADN)	Added
14.2	Proper Shipping Name (ADR)	Added
14.3	Danger labels (RID)	Added
14.3	Danger labels (ADR)	Added
14.3	Class (ADR)	Added
14.4	Packing group (ADN)	Added
14.4	Packing group (IATA)	Added

# Levodropropizine impurity B

## Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
14.4	Packing group (IMDG)	<b>Added</b>
14.4	Packing group (ADR)	<b>Added</b>
14.6	Special provisions (ADN)	<b>Added</b>
14.6	Packing instructions (IMDG)	<b>Added</b>
14.6	Transport category (ADR)	<b>Added</b>
14.6	Special provisions (ADR)	<b>Added</b>
14.6	Excepted quantities (ADR)	<b>Added</b>
14.6	Limited quantities (ADR)	<b>Added</b>
14.6	Tunnel restriction code (ADR)	<b>Added</b>
14.6	Hazard identification number (Kemler No.)	<b>Added</b>
14.6	Classification code (ADR)	<b>Added</b>

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B

Safety Data Sheet (SDS), EU

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