

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

Product form	: Substance
Trade name	: Dexmedetomidine hydrochloride
Chemical name	: 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole hydrochloride
IUPAC name	: 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole hydrochloride
EC-No.	: 682-047-2
CAS-No.	: 145108-58-3
Product code	: 72200
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C13H17CN2
Synonyms	: (+)-4-(S)-[1-(2,3-Dimethylphenyl)ethyl]-1H-imidazole Hydrochloride; (S)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole hydrochloride; 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole hydrochloride; 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole;hydrochloride
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES: Cc1cccc(c1C)[C@H](C)c2c[nH]cn2.Cl
	InChI Key: VPNGEIHDP SLNMU-MERQFXBCSA-N

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

Main use category	: Industrial use, Professional use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: Sedative/analgesic; alpha-2-adrenergic agonist agent
Use of the substance/mixture	: Pharmaceuticals
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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Roma, 8 - P.I. Cova Solera
08191 Rubí
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T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS IBERICA S.L. MGRC
Polígono Industrial Rubi Sur-César Martinell i Brunet , 10
08191 Rubí – Barcelona
Spain
T +34 93 586 05 20
hse@moehs.es

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
Acute toxicity (dermal), Category 4	H312
Acute toxicity (inhal.), Category 4	H332
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Reproductive toxicity, Category 2	H361d

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Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation H335

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

Adverse physicochemical, human health and environmental effects

Harmful if swallowed, in contact with skin or if inhaled. Suspected of damaging the unborn child. May irritate eyes and skin. May cause respiratory irritation.

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H361d - Suspected of damaging the unborn child.

Precautionary statements (CLP)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing dust.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves, face protection, eye protection.
P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell.
P330 - Rinse mouth.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
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.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

PBT: not yet assessed

vPvB: not yet assessed

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
Dexmedetomidine hydrochloride	CAS-No.: 145108-58-3 EC-No.: 682-047-2	≈ 100

3.2. Mixtures

Not applicable

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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	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
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. Wash contaminated clothing before reuse. Immediately call a POISON CENTER/doctor.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Repeated exposure to this material can result in absorption through skin causing significant health hazard. Harmful in contact with skin. Causes skin irritation.
Symptoms/effects after eye contact	: Causes eye irritation. Causes serious eye irritation.
Symptoms/effects after ingestion	: 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

Never give anything by mouth to an unconscious person.

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

Explosion hazard	: Avoid raising powdered material due to explosion hazard.
Reactivity in case of fire	: Reacts violently with (strong) oxidizers.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Nitrogen oxides. Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Precautionary measures fire	: Keep away from combustible materials. Minimize generation of dust which may be combustible. Stop leak if safe to do so. Evacuate area.
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. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. Avoid contact with skin and eyes.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel. Avoid breathing dust. Avoid contact with skin and eyes.
Measures in case of dust release	: Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment	: Use personal protective equipment as required. Safety glasses. Dust/aerosol mask. Protective gloves. Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

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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

For containment	: Collect spillage.
Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. On land, sweep or shovel into suitable containers. Minimise generation of dust. Collect spillage. Store away from other materials.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid dust formation. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Use only outdoors or in a well-ventilated area. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust.
Hygiene measures	: Wash contaminated clothing before reuse. Separate working clothes from town clothes. Launder separately. Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Oxidizing agent, Heat sources, Direct sunlight. Keep container tightly closed.
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.

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 5 (< 0.001 mg/m3)

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Dust extraction (suction). Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment. Use in contained systems.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Safety glasses. Dust/aerosol mask with filter type P3. Dustproof clothing. Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. 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:

Wear suitable protective clothing

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

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Polyvinylalcohol (PVA), Natural rubber, Butyl rubber, Polyvinylchloride (PVC), Latex, Vinyl, Neoprene rubber (HNBR), Fluoroelastomer (FKM)	EN 374-2

Other skin protection

Materials for protective clothing

Condition	Material	Standard
Good resistance:	Tyvek®, Polyvinylchloride (PVC), Polyvinylalcohol (PVA)	EN 13034, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

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Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask, Powered 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	: ≈ 236.74 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: ≈ 381 °C [Experimental boiling point by BIOSYNTH]
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: ≈ 191 °C [Experimental flash point by BIOSYNTH]
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
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
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

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SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under use and storage conditions as recommended in section 7.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7. Not established.

10.3. Possibility of hazardous reactions

Reacts vigorously with strong oxidizers and acids. Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Oxidizing agent. Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

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)	: Harmful in contact with skin.
Acute toxicity (inhalation)	: Harmful if inhaled.

Dexmedetomidine hydrochloride (145108-58-3)

LD50 oral rat	440 mg/kg [Predicted by T.E.S.T.]
LD50, intravenous, Dog	2 mg/kg

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: 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	: Suspected of damaging the unborn child.
Additional information	: May damage fertility. Suspected of damaging the unborn child. Based on available data, the classification criteria are not met

Dexmedetomidine hydrochloride (145108-58-3)

Embryo/fetal development: NOAEL, subcutaneous, rat	0.020 mg/kg Not teratogenic, Fetotoxicity
Peri-/Postnatal Development: NOAEL, subcutaneous, rat, Developmental toxicity, May damage the unborn child.	2 mg/kg bw/day

STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met

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Dexmedetomidine hydrochloride (145108-58-3)

Repeated Dose Toxicity: NOAEL, intramuscular, Dog, liver, central nerve	0.010 mg/kg bw/day (days 28)
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Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

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

Potential adverse human health effects and symptoms : Harmful if swallowed, Harmful in contact with skin.

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

Dexmedetomidine hydrochloride (145108-58-3)

EC50 - Crustacea [1]	2.26 mg/l [Predicted by T.E.S.T]
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12.2. Persistence and degradability

Dexmedetomidine hydrochloride (145108-58-3)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Dexmedetomidine hydrochloride (145108-58-3)

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Dexmedetomidine hydrochloride (145108-58-3)

PBT: not yet assessed

vPvB: not yet assessed

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.

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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.

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

IMDG

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

IATA

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

ADN

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

RID

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

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

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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

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 – : The substance is not listed

Vruchtbaarheid

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

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Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed
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

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
SDS	Safety Data Sheet
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEL	No-Observed Adverse Effect Level

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

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Full text of H- and EUH-statements:

H361d	Suspected of damaging the unborn child.
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.