

Homatropine hydrobromide

Safety Data Sheet

252077

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

2015/830

Issue date: 10/04/2015

Revision date 25/11/2020

Supersedes 20/02/2017

Version: 2.1

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

1.1. Product identifier

Product form : Substance
 Substance name : Homatropine hydrobromide
 EC-No. : 200-105-3
 CAS-No. : 51-56-9
 Product code : 252077
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

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

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 1 H310
 Acute toxicity (inhalation:dust,mist) Category 1 H330

Full text of H statements : see section 16

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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 to display

Hazard pictograms (CLP)

:



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed.
H310+H330 - Fatal in contact with skin or if inhaled

Precautionary statements (CLP)

: P260 - Do not breathe Dust.
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.
P310 - Immediately call a POISON CENTER/doctor.

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]
Homatropine hydrobromide	(CAS-No.) 51-56-9 (EC-No.) 200-105-3	50 - 100	Acute Tox. 3 (Oral), H301 Acute Tox. 1 (Dermal), H310 Acute Tox. 1 (Inhalation:dust,mist) , H330

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

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First-aid measures after inhalation	: Allow affected person to breathe fresh air If breathing is difficult, give oxygen Seek medical advice.
First-aid measures after skin contact	: Wash with plenty of water/... Seek a medical assistance, even if there are no immediate symptoms.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical attention immediately.
First-aid measures after ingestion	: Immediately call a POISON CENTER/doctor.

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	: Water Carbon dioxide ABC powder.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic and irritating gases are released.
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5.3. Advice for firefighters

Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Protective clothing.
Emergency procedures	: Evacuate unnecessary personnel.
Measures in case of dust release	: Avoid dust to spread.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Avoid raising dust.
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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 : Avoid raising dust.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature : 15 - 25 °C

Storage area : Keep container tightly closed and dry.

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

Hand protection:

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:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 356.3 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: ≈ 6.20 g/L
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ≈ 215 (≥ 0) °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available

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Decomposition temperature	: $\approx 215\text{ }^{\circ}\text{C}$
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water. Water: 100 g/l
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

Do not overheat the product.

10.3. Possibility of hazardous reactions

Dust clouds can be explosive.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition productsCarbon oxides (CO, CO₂)

Nitrogen oxides

Hydrogen bromide.

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

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

Homatropine hydrobromide (51-56-9)	
LD50 oral rat	154 mg/kg
Skin corrosion/irritation	: Irritating to the skin and mucous membranes (Based on available data, the classification criteria are not met) pH: ≈ 6.20 g/L
Serious eye damage/irritation	: Not classified pH: ≈ 6.20 g/L
Respiratory or skin sensitisation	: Not classified

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Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

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

No additional information available

12.2. Persistence and degradability

No additional information available

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. Other adverse effects


No additional information available

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

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
1544	Not applicable
14.2. UN proper shipping name	
ALKALOIDS, SOLID, N.O.S. / ALKALOID SALTS, SOLID, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	Not applicable
	Not applicable

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ADR	IATA
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)	: 43, 274		
Limited quantities (ADR)	: 5kg		
Excepted quantities (ADR)	: E1		
Packing instructions (ADR)	: P002, IBC08, LP02, R001		
Special packing provisions (ADR)	: B3		
Mixed packing provisions (ADR)	: MP10		
Portable tank and bulk container instructions (ADR)	: T1		
Portable tank and bulk container special provisions (ADR)	: TP33		
Tank code (ADR)	: SGAH, L4BH		
Tank special provisions (ADR)	: TU15, TE19		
Vehicle for tank carriage	: AT		
Transport category (ADR)	: 2		
Special provisions for carriage - Bulk (ADR)	: VV9		
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28		
Special provisions for carriage - Operation (ADR)	: S9		
Hazard identification number (Kemler No.)	: 60		
Orange plates	: <table><tr><td>60</td></tr><tr><td>1544</td></tr></table>	60	1544
60			
1544			
Tunnel restriction code (ADR)	: E		
EAC code	: 2X		

- Air transport

No data available

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

Homatropine hydrobromide is not on the REACH Candidate List

Homatropine hydrobromide 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:

1		Modified	change of logo
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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.

Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 1
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.

SDS EU (REACH Annex II) ducheфа 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.

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