

Oxybutynin hydrochloride

Safety Data Sheet

1092561

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

2015/830

Date of issue: 01/03/2012 Revision date 04/02/2020

Supersedes 27/03/2019

Version: 3.1

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

1.1. Product identifier

Product form	: Substance
Substance name	: Oxybutynin hydrochloride
IUPAC name	: 4-(Diethylamino)but-2-ynyl (RS)-2-cyclohexyl-2-hydroxy-2-phenylacetate hydrochloride
EC-No.	: 216-139-7
CAS-No.	: 1508-65-2
Product code	: 1092561
Formula	: C ₂₂ H ₃₂ ClNO ₃
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
Function or use category	: Raw material

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@ducheffa.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)
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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	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] show CLP information only

Acute toxicity (oral), Category 4

H302

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)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.

Precautionary statements (CLP)

: P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 - Rinse mouth.

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]
Oxybutynin hydrochloride	(CAS-No.) 1508-65-2 (EC-No.) 216-139-7	99 - 102	Acute Tox. 4 (Oral), H302

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 after inhalation

: Allow affected person to breathe fresh air
Get medical advice and attention if you feel unwell.

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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 Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person Seek medical advice.

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

5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: On exposure to high temperature, may decompose, releasing toxic vapours Nitrogen oxides Carbon monoxide Carbon dioxide.

5.3. Advice for firefighters

Firefighting instructions	: 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****6.1.1. For non-emergency personnel**

Emergency procedures	: Ensure adequate air ventilation. Avoid raising dust.
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6.1.2. For emergency responders

Protective equipment	: Wear proper protective equipment. [In case of inadequate ventilation] wear respiratory protection.
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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Hose down area with water.

6.4. Reference to other sections

No additional information available

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

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from sunlight.

Storage temperature : 15 - 25 °C

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:**

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

Personal protective equipment:

Dust production: dust mask with filter type P1. Safety glasses. Gloves.

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)

Respiratory protection:

Dustmask with filtertype P1



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 394 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 7.4
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 124 - 129 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
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	: Freely soluble in water Soluble in ethanol.
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

No additional information available

10.4. Conditions to avoid

Light (daylight)

Moisture

High temperature.

10.5. Incompatible materials

Strong oxidizers

Bases

Strong reducing agents

Acids.

10.6. Hazardous decomposition productsCarbon oxides (CO, CO₂)

Nitrogen oxides

release of irritant gases/vapours.

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

Acute toxicity : Harmful if swallowed.

Oxybutynin hydrochloride (1508-65-2)	
LD50 oral rat	460 mg/kg
LD50 oral	400 mg/kg dog

Skin corrosion/irritation : Not classified
pH: 7.4Serious eye damage/irritation : Not classified
pH: 7.4

Respiratory or skin sensitisation : Not classified

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**

Oxybutynin hydrochloride (1508-65-2)	
EC50 Daphnia 1	1 - 10 mg/l

12.2. Persistence and degradability

Oxybutynin hydrochloride (1508-65-2)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Oxybutynin hydrochloride (1508-65-2)	
Bioaccumulative potential	No bioaccumulation data available.

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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**

Waste treatment methods : Avoid release to the environment.

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

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	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**

No data available

- 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

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Oxybutynin hydrochloride is not on the REACH Candidate List

Oxybutynin hydrochloride 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:

	Version	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 : Supplier. EP. EDQM.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

SDS EU (REACH Annex II) ducheffa 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.