

Haloperidol

Safety Data Sheet

537640

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 23/03/2015 Revision date 02/04/2020
 Supersedes 06/03/2017

Version: 3.0

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

1.1. Product identifier

Product form : Substance
 Substance name : Haloperidol
 EC-No. : 200-155-6
 CAS-No. : 52-86-8
 Product code : 537640
 Formula : C₂₁H₂₃ClFNO₂
 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
 Industrial/Professional use spec : For professional use only
 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
 Skin corrosion/irritation, Category 2 H315

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Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317
Reproductive toxicity, Category 2 H361
Specific target organ toxicity — Single exposure, Category 3, H335
Respiratory tract irritation

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)

:



GHS06



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

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] |
|-------------|---|-----|--|
| Haloperidol | (CAS-No.) 52-86-8 (EC-No.) 200-155-6 | 100 | Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Repr. 2, H361 STOT SE 3, H335 |

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 general | : If medical advice is needed, have product container or label at hand. |
| First-aid measures after inhalation | : Allow affected person to breathe fresh air Seek medical attention immediately. |
| First-aid measures after skin contact | : Wash skin with mild soap and water. |
| First-aid measures after eye contact | : Immediately rinse with plenty of water. |
| First-aid measures after ingestion | : Immediately call a POISON CENTER/doctor. Rinse mouth. |

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|------------------------------|---|
| Suitable extinguishing media | : dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂). |
|------------------------------|---|

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| Hazardous decomposition products in case of fire | : Nitrogen oxides Carbon oxides (CO, CO ₂) Halogenated compounds. |
|--|---|

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |
| Other information | : Avoid direct discharge into drains. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------|-----------------------------------|
| General measures | : Evacuate unnecessary personnel. |
|------------------|-----------------------------------|

6.1.1. For non-emergency personnel

| | |
|----------------------|------------------------|
| Protective equipment | : Protective clothing. |
|----------------------|------------------------|

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

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

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 : Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Protect from light.

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

| Haloperidol (52-86-8) | |
|----------------------------------|----|
| DNEL/DMEL (Workers) | |
| Acute - systemic effects, dermal | <= |

8.2. Exposure controls

Appropriate engineering controls:

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

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 | : 375.9 g/mol |
| Colour | : White. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : 8 (1% solution) |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : 148 °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 | : Insoluble in water. |
| 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

Protect from light.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Halogenated compounds

Carbon oxides (CO, CO₂)

Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Toxic if swallowed.

| Haloperidol (52-86-8) | |
|-----------------------|-----------|
| LD50 oral rat | 128 mg/kg |

Skin corrosion/irritation : Causes skin irritation.

pH: 8 (1% solution)

Serious eye damage/irritation : Causes serious eye irritation.

pH: 8 (1% solution)

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

| Haloperidol (52-86-8) | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |

12.3. Bioaccumulative potential

| Haloperidol (52-86-8) | |
|---------------------------|------------------------------------|
| Bioaccumulative potential | No bioaccumulation data 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

Regional legislation (waste) : 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 | |
| 2811 | Not applicable |
| 14.2. UN proper shipping name | |
| TOXIC SOLID, ORGANIC, N.O.S. | Not applicable |
| 14.3. Transport hazard class(es) | |
| 6.1 | Not applicable |
|  | Not applicable |
| 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) : 274, 614
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 - : S9
Operation (ADR)

Hazard identification number : 60
(Kemler No.)

Orange plates :

| |
|------|
| 60 |
| 2811 |

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

Haloperidol is not on the REACH Candidate List

Haloperidol 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:

| 1.4 | Emergency telephone | Modified | Added additional information |
|------|---|----------|------------------------------|
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Removed | H311 |
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Removed | H331 |
| 2.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Added | H315; H317; H319; H335 |
| 4.1 | First-aid measures after skin contact | Modified | |
| 4.1 | First-aid measures general | Modified | |
| 4.3 | Other medical advice or treatment | Added | |
| 8.2 | Appropriate engineering controls | Added | |
| 13.1 | Regional legislation (waste) | Added | |

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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. EP. Supplier.

Full text of H- and EUH-statements:

| | |
|---------------------|--|
| Acute Tox. 3 (Oral) | Acute toxicity (oral), Category 3 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Repr. 2 | Reproductive toxicity, Category 2 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H301 | Toxic if swallowed. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |
| H361 | Suspected of damaging fertility or the unborn child. |

SDS EU (REACH Annex II) duchefa 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.