

# Dextromethorphan Hydrobromide

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 03/04/2023 Revision date: 12/04/2023 Supersedes version of: 03/04/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Dextromethorphan Hydrobromide  
Chemical name : Dextromethorphan Hydrobromide Monohydrate  
Product code : 201600269

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

##### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.  
Use of the substance/mixture : For professional use only  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

#### 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 4 H302  
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411  
Full text of H- and EUH-statements: see section 16

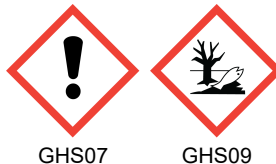
##### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) : Warning  
Hazard statements (CLP) : H302 - Harmful if swallowed.  
H411 - Toxic to aquatic life with long lasting effects.  
Precautionary statements (CLP) : P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P273 - Avoid release to the environment.  
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.  
P330 - Rinse mouth.  
P391 - Collect spillage.

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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

**No labelling required**

### 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]
Dextromethorphan Hydrobromide Monohydrate	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Aquatic Chronic 2, H411

Full text of H- and EUH-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 skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).  
First-aid measures after eye contact : Rinse eyes with water as a precaution.

### 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 : Extinguishing blanket.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

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### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

No additional information available

### 6.3. Methods and material for containment and cleaning up

No additional information available

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

No additional information available

### 7.2. Conditions for safe storage, including any incompatibilities

No additional information available

### 7.3. Specific end use(s)

See Heading 1.

## 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

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

No additional information available

##### 8.2.2.2. Skin protection

##### Skin and body protection:

Lab coat

##### Hand protection:

Protective gloves

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### 8.2.2.3. Respiratory protection

No additional information available

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 10 – 33,3 g/l
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

### 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

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

None known.

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### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

None under normal use. See Section 7.

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## 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) : Not classified (Lack of data)  
Acute toxicity (inhalation) : Not classified (Lack of data)

#### Dextromethorphan Hydrobromide Monohydrate

LD50 oral rat	> 300 – ≤ 2000 mg/kg (estimated value)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

No additional information available

## 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) : Toxic to aquatic life with long lasting effects.

### 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. Endocrine disrupting properties

No additional information available

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### 12.7. Other adverse effects

No additional information available

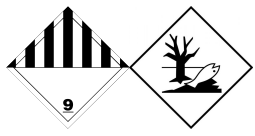
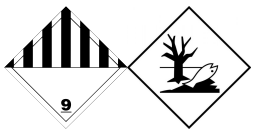

## SECTION 13: Disposal considerations

### 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 3077	UN 3077	UN 3077
<b>14.2. UN proper shipping name</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Transport hazard class(es)</b>		
9	9	9
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10

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Portable tank and bulk container instructions (ADR) : T1, BK1, BK2, BK3

Portable tank and bulk container special provisions (ADR) : TP33

(ADR)

Tank code (ADR) : SGAV, LGBV

Vehicle for tank carriage : AT


Transport category (ADR) : 3

Special provisions for carriage - Packages (ADR) : V13

Special provisions for carriage - Bulk (ADR) : VC1, VC2

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13

Hazard identification number (Kemler No.) : 90

Orange plates : 

Tunnel restriction code (ADR) : -

### Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969

Limited quantities (IMDG) : 5 kg

Excepted quantities (IMDG) : E1

Packing instructions (IMDG) : LP02, P002

Special packing provisions (IMDG) : PP12

IBC packing instructions (IMDG) : IBC08

IBC special provisions (IMDG) : B3

Tank instructions (IMDG) : BK1, BK2, BK3, T1

Tank special provisions (IMDG) : TP33

EmS-No. (Fire) : F-A

EmS-No. (Spillage) : S-F

Stowage category (IMDG) : A

Stowage and handling (IMDG) : SW23

### Air transport

PCA Excepted quantities (IATA) : E1

PCA Limited quantities (IATA) : Y956

PCA limited quantity max net quantity (IATA) : 30kgG

PCA packing instructions (IATA) : 956

PCA max net quantity (IATA) : 400kg

CAO packing instructions (IATA) : 956

CAO max net quantity (IATA) : 400kg

Special provisions (IATA) : A97, A158, A179, A197, A215

ERG code (IATA) : 9L

## 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

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### PIC Regulation (Prior Informed Consent)

Not applicable.

### POP Regulation (Persistent Organic Pollutants)

Not applicable.

### 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

No additional information available

## 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Supersedes version of	Added	
	Revision date	Added	
1.1	Name	Modified	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Hazard statements (CLP)	Modified	
2.2	Hazard pictograms (CLP)	Modified	
2.2	Precautionary statements (CLP)	Modified	
11.1	LD50 oral rat	Modified	
11.1	Reason for no classification	Added	
11.1	ATE CLP (oral)	Modified	
12.1	Reason for no classification	Added	
14	Transport information	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
H302	Harmful if swallowed.
H411	Toxic to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU



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