

Ritodrine Hydrochloride

Safety Data Sheet

646091

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

2015/830

Date of issue: 29/05/2019

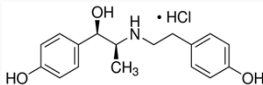
Revision date 11/06/2020

Supersedes 29/05/2019

Version: 2.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Ritodrine Hydrochloride
Chemical name	: 4-1(1-hydroxy-2-[[2-(4-hydroxyphenyl)ethyl]amino]propyl)phenolhydrochloride(1:1)
EC-No.	: 245-514-8
CAS-No.	: 23239-51-2
Product code	: 646091
Formula	: C ₁₇ H ₂₁ NO ₃ HCL
Chemical structure	: 
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	: Tocolytic

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 - Nederland

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)
------------------	--

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

Reproductive toxicity, Category 2 H361

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

GHS08

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP) : P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 - Rinse mouth.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

Other hazards not contributing to the classification : None.

PBT: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ritodrine Hydrochloride	(CAS-No.) 23239-51-2 (EC-No.) 245-514-8	100	Acute Tox. 4 (Oral), H302 Repr. 2, H361

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. Never give anything by mouth to an unconscious person.
First-aid measures after inhalation	: Remove to fresh air, keep the patient warm and at rest If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Rinse with plenty of water Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Get medical advice/attention.

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

Symptoms/effects after skin contact	: Skin rash/inflammation. Redness. May cause skin irritation.
Symptoms/effects after eye contact	: Eye irritation. Redness. Mydriasis.

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	: Alcohol resistant foam dry chemical powder Carbon dioxide Water spray.
------------------------------	---

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: On burning: release of harmful gases/vapours Carbon oxides (CO, CO ₂) Nitrogen oxides hydrogen chloride.
--	---

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

Protective equipment : Use the personal protective equipment as indicated in chapter 8.
Emergency procedures : Avoid contact with skin, eyes and clothing. 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 : Sweeping or shovelling without dust for disposal. Cover spill with non combustible material, e.g.: sand, earth, vermiculite.
Methods for cleaning up : Sweep up, shovel or vacuum. Residue may be washed down with water.

6.4. Reference to other sections

See Heading 8. See Heading 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 : Keep container tightly closed.
Store in a dry place.
Store in a well-ventilated place.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

see chapter 1.2.

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 P3. Gloves. Protective goggles.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Hand protection:

Wear gloves according to EN374 to protect against skin effects from powders.

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	: 323.8 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.5 - 6 (2% solution in water)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: $\approx 200\text{ }^{\circ}\text{C}$
Freezing point	: No data available
Boiling point	: 512
Flash point	: 176 $^{\circ}\text{C}$
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: The product is not flammable
Vapour pressure	: No data available
Relative vapour density at 20 $^{\circ}\text{C}$: No data available
Relative density	: No data available
Density	: 1.213 g/cm ³
Solubility	: Soluble in water Soluble in methanol.
Log Pow	: 1.61
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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 polymerization.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides

hydrogenchloride.

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

Acute toxicity : Harmful if swallowed.

Ritodrine Hydrochloride (23239-51-2)	
LD50 oral rat	1840 mg/kg
LD50 oral	687 mg/kg mouse

Skin corrosion/irritation : Not classified
pH: 4.5 - 6 (2% solution in water)

Serious eye damage/irritation : Not classified
pH: 4.5 - 6 (2% solution in water)

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

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

STOT-single exposure : Not classified

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

Ritodrine Hydrochloride (23239-51-2)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Ritodrine Hydrochloride (23239-51-2)	
BCF fish 1	1
Log Pow	1.61

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

Other adverse effects : None known.

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

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Remove to an authorized incinerator equipped with an afterburner and a flue gas scrubber.

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	
Not applicable	Not applicable
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Not applicable

- Air transport

Not applicable

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

Ritodrine Hydrochloride is not on the REACH Candidate List

Ritodrine 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:

1.3	Additional information	Modified	change of logo
10.6	Hazardous decomposition products	Modified	

Abbreviations and acronyms:

CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
LD50	Median lethal dose
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
vPvB	Very Persistent and Very Bioaccumulative

Data sources : Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Repr. 2	Reproductive toxicity, Category 2
H302	Harmful if swallowed.
H361	Suspected of damaging fertility or the unborn child.

SDS EU (REACH Annex II) duchefa nieuwe logo

Ritodrine Hydrochloride

646091

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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.