

Salbutamol Sulfate

Safety Data Sheet

599131

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 18/08/2013 Revision date 17/03/2020
 Supersedes 11/01/2017

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

1.1. Product identifier

Product form : Substance
 Substance name : Salbutamol Sulfate
 EC-No. : 256-916-8
 CAS-No. : 51022-70-9
 Product code : 599131
 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
 Industrial/Professional use spec : Industrial
 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]

Skin sensitisation, Category 1 H317
 Carcinogenicity, Category 2 H351

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)

: H317 - May cause an allergic skin reaction.
H351 - Suspected of causing cancer.
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.**2.3. Other hazards**

vPvB: not yet assessed

SECTION 3: Composition/information on ingredients**3.1. Substances**

Substance type

: Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Salbutamol Sulfate	(CAS-No.) 51022-70-9 (EC-No.) 256-916-8	100	Skin Sens. 1, H317 Carc. 2, H351 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 after inhalation	: Allow affected person to breathe fresh air Allow the victim to rest If you feel unwell, seek medical advice.
First-aid measures after skin contact	: If skin irritation occurs: Get medical advice/attention. Rinse with plenty of water.
First-aid measures after eye contact	: Rinse immediately with plenty of water Obtain medical attention if pain, blinking or redness persists.
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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Alcohol resistant foam Carbon dioxide Water spray dry chemical powder.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Sulphur oxides Nitrogen oxides Carbon oxides (CO, CO ₂).
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5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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

General measures	: Avoid raising dust. Do not breathe dust.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
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Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

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 procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.
Protect from light
Store in a dry place.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

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:

Safety glasses. Dustproof clothing. Dust/aerosol mask with filter type P3. 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)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

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Respiratory protection:

Dustmask with filtertype P3

**Other information:**

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Colour	: White.
Odour	: detectable.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 250 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Freely soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: not explosive.
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**

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Possible reaction with strong oxidizers.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂)

Sulphur oxides

Nitrogen oxides.

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

Acute toxicity : Not classified

Salbutamol Sulfate (51022-70-9)	
LD50 oral rat	> 2500 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

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

Germ cell mutagenicity : Not classified

Carcinogenicity : Suspected of causing cancer.

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**

No additional information available

12.2. Persistence and degradability

Salbutamol Sulfate (51022-70-9)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Salbutamol Sulfate (51022-70-9)	
Bioaccumulative potential	Not established.

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

Additional information : Avoid release to the environment.

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

Regional legislation (waste) : Disposal must be done according to official regulations.

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

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
Not regulated	Not regulated
14.2. UN proper shipping name	
Not regulated	Not regulated
14.3. Transport hazard class(es)	
Not regulated	Not regulated
Not regulated	Not regulated
14.4. Packing group	
Not regulated	Not regulated
14.5. Environmental hazards	
Not regulated	Not regulated
No supplementary information available	

14.6. Special precautions for user**. Overland transport**

Not regulated

- Air transport

Not regulated

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

Salbutamol Sulfate is not on the REACH Candidate List

Salbutamol Sulfate is not on the REACH Annex XIV List

15.1.2. National regulations

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	The substance is not listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

6.2	Environmental precautions	Modified	
7.1	Precautions for safe handling	Added	
8.2	Personal protective equipment	Added	

Abbreviations and acronyms:

CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
LD50	Median lethal dose

Data sources : EP. Supplier.

Other information : REACH Disclaimer:

This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

Full text of H- and EUH-statements:

Carc. 2	Carcinogenicity, Category 2
Repr. 2	Reproductive toxicity, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
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.

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