

Sumatriptan succinate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 17/10/2018

900965

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Sumatriptan succinate
Chemical name : [3-[2Dimethylamino)ethyl]-1H-indol-5-yl]-N-methylmethanesulfonamide hydrogen butanedioate
CAS-No. : 103628-48-4
Product code : 900965
Formula : C₁₈H₂₇N₃O₆
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

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@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)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Respiratory sensitisation, Category 1 H334
Skin sensitisation, Category 1 H317
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]

Hazard pictograms (CLP)

:



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes.
P308+P313 - IF exposed or concerned: Get medical advice.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sumatriptan succinate	(CAS-No.) 103628-48-4	≈ 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 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.
First-aid measures after inhalation	: Assure fresh air breathing. Get medical advice and attention if you feel unwell.
First-aid measures after skin contact	: Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes. Seek immediate medical advice.
First-aid measures after ingestion	: Rinse mouth. 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. Water spray. dry chemical powder.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : sulphur dioxide. Nitrogen oxides. Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

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 : 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

For containment : Sweeping or shovelling without dust for disposal.

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 : Protect from light. Keep container tightly closed.
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.

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 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 : Powder.
Molecular mass : 413.5 g/mol
Colour : White to off-white.
Odour : No data available
Odour threshold : No data available
pH : 4.5 - 5.3 1% solution
Relative evaporation rate (butylacetate=1) : No data available
Melting point : 165 - 168 °C
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Auto-ignition temperature : 295 °C
Decomposition temperature : No data available
Flammability (solid, gas) : No data available

Safety Data Sheet

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

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 : 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**

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

On heating/burning: release of harmful gases/vapours.

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

Acute toxicity : Not classified

Sumatriptan succinate (103628-48-4)

LD50 oral rat	2939 mg/kg
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Skin corrosion/irritation : Causes skin irritation.
pH: 4.5 - 5.3 1% solution

Serious eye damage/irritation : Causes serious eye irritation.
pH: 4.5 - 5.3 1% solution

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 : 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

Sumatriptan succinate (103628-48-4)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Sumatriptan succinate (103628-48-4)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

Sumatriptan succinate (103628-48-4)	
Ecology - soil	There are no available data for a classification.

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	
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

Safety Data Sheet

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

- 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

Sumatriptan succinate is not on the REACH Candidate List

Sumatriptan succinate 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

Abbreviations and acronyms:

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

Data sources : Supplier. EP. EDQM.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 2	Reproductive toxicity, Category 2
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.

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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