

Sulfasalazine

Safety Data Sheet

551538

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 24/07/2012 Revision date 29/07/2020
Supersedes 08/03/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Sulfasalazine
IUPAC name : 2-Hydroxy-5-[2-[4-(pyridin-2-ylsulfamoyl)phenyl]diazenyl]benzoic acid
EC-No. : 209-974-3
CAS-No. : 599-79-1
Product code : 551538
Formula : C₁₈H₁₄N₄O₅S
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
Function or use category : Raw material

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]

Respiratory sensitisation, Category 1

H334

Sulfasalazine

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

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
classification(s) to display

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351 - Suspected of causing cancer.
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.
P260 - Do not breathe dust.
P281 - Use personal protective equipment as required.
P308+P313 - IF exposed or concerned: Get medical advice.
P341 - If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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]
Sulfasalazine	(CAS-No.) 599-79-1 (EC-No.) 209-974-3	97 - 101.5	Resp. Sens. 1, H334 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	: Remove victim to fresh air If not breathing, give artificial respiration Seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person Seek medical advice.

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

Symptoms/effects	: Exposure may produce an allergic reaction Irritation to eyes, skin and respiratory tract Nervous system disorder Gastrointestinal complaints Damage to liver. May cause photosensitization.
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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	: All extinguishing agents can be used.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Sulphur oxides.
Explosion hazard	: Product is not explosive.

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

Emergency procedures	: Ensure adequate air ventilation. Avoid raising dust.
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6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment. [In case of inadequate ventilation] wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Sodium hypochlorite solution.

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 : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from sunlight.

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

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:

Wear suitable protective clothing.

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	: 398.4 g/mol
Colour	: Yellow Yellow-brown.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 260 - 265 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 370 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: 0 mm Hg 25°C
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.488 g/cm ³
Solubility	: Material nearly insoluble in water Soluble in : Sodium hypochlorite solution. Water: < 0.1 g/100ml 25°C
Log Pow	: 2.88
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

None under normal conditions.

10.4. Conditions to avoid

High temperature

heat

Light (daylight).

10.5. Incompatible materials

Strong oxidizers

Strong bases.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides

Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sulfasalazine (599-79-1)	
LD50 oral rat	15600 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

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 : 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

No additional information available

12.3. Bioaccumulative potential

Sulfasalazine (599-79-1)	
Log Pow	2.88

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

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations 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	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

No data available

- 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

Sulfasalazine is not on the REACH Candidate List

Sulfasalazine 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:

		Added	new company logo
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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.

Full text of H- and EUH-statements:

Carc. 2	Carcinogenicity, Category 2
Repr. 2	Reproductive toxicity, Category 2
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.

SDS EU (REACH Annex II) ducheфа 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.