SAFETY DATA SHEETS

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - Sixth revised edition

Version: 1.0

Creation Date: Aug 17, 2017

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1. Identification

1.1 GHS Product identifier

Product name	mesalamine

1.2 Other means of identification

Product number	-
Other names	5-Aminosalicylic Acid

1.3 Recommended use of the chemical and restrictions on use

Identified uses	For industry use only.
Uses advised against	no data available

2. Hazard identification

2.1 Classification of the substance or mixture

Skin irritation, Category 2

Skin sensitization, Category 1

Eye irritation, Category 2

Specific target organ toxicity – single exposure, Category 3

2.2 GHS label elements, including precautionary statements

Pictogram(s)

Signal word	Warning
Hazard statement(s)	H315 Causes skin irritation
	H317 May cause an allergic skin reaction
	H319 Causes serious eye irritation
	H335 May cause respiratory irritation
Precautionary statement(s)	
Prevention	P264 Wash ... thoroughly after handling.
	P280 Wear protective gloves/protective clothing/eye protection/face protection.
	P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
	P272 Contaminated work clothing should not be allowed out of the workplace.
	P271 Use only outdoors or in a well-ventilated area.
Response	P302+P352 IF ON SKIN: Wash with plenty of water/...
	P321 Specific treatment (see ... on this label).
	P332+P313 If skin irritation occurs: Get medical advice/attention.
	P362+P364 Take off contaminated clothing and wash it before reuse.
	P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
	P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313 If eye irritation persists: Get medical advice/attention.
	P304+P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P312 Call a POISON CENTER/doctor/…if you feel unwell.

Storage

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

Disposal

P501 Dispose of contents/container to ...

2.3 Other hazards which do not result in classification

none

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
mesalamine	mesalamine	89-57-6	none	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound include acute intolerance syndrome characterized by cramping, acute abdominal pain and discomfort, and bloody diarrhea. It may also cause headache, rash, gas (flatulence), nausea, flu, tiredness, weakness, malaise, fatigue, cold, sore throat, leg pain, joint pain, dizziness, bloating, back pain, hemorrhoids, itching, rectal pain, constipation, hair loss, peripheral edema, urinary burning, rectal soreness and burning, asthenia and insomnia. Other symptoms include fever, gastrointestinal problems, anorexia, epigastric pain, skin eruptions of various types, agranulocytosis, leukopenia, eosinophilia, lymphocytosis, atypical mononucleosis syndrome, thrombocytopenia and acute hemolytic anemia. Symptoms of exposure to a related compound include pruritus, erythematous macular or bullous eruptions, acidosis, hypokalemia, crystalluria, vomiting, hepatic necrosis, leukocytosis, laryngeal edema, methemoglobinemia and thyroid suppression. Other symptoms include allergic reactions, gastrointestinal irritation and prolonged prothrombin times. ACUTE/CHRONIC HAZARDS: This compound may be harmful by inhalation, ingestion or skin absorption. It may cause irritation. When heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

To decrease absorption: ... Activated charcoal may also be administered. Supportive care: Fluid and electrolyte imbalance should be corrected by the administration of appropriate intravenous therapy. Vital functions should be monitored and supported.

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5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. A water spray may also be used.

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably

combustible.

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use.Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Commercially available oral mesalamine delayed-release tablets should be stored at a controlled room temperature of 20-25°C, while the commercially available oral extended-release capsules should be stored at 25°C but may be exposed to temperatures ranging from 15-30°C.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique(without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

Wear dust mask when handling large quantities.

Thermal hazards

no data available

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9. Physical and chemical properties

Physical state	White to off-white powder
Colour	White to pinkish crystals
Odour	no data available
Melting point/ freezing point	280°C

Boiling point or initial boiling point and boiling range	403.9°C at 760 mmHg
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available
Flash point	279-281°C
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 21.11°C
Partition coefficient n-octanol/water (log value)	no data available
Vapour pressure	6.10X10-8 mm Hg at 25°C (est)
Density and/or relative density	1.491 g/cm3
Relative vapour density	no data available
Particle characteristics	no data available

10. Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

Mesalamine is unstable in the presence of water and light, since oxidation and, to a lesser extent, light-catalyzed degradation of the drug occur.

10.3 Possibility of hazardous reactions

5-AMINOSALICYLIC ACID is incompatible with acids, acid chlorides, acid anhydrides, chloroformates and strong oxidizers.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

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11. Toxicological information

Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

ANAEROBIC: Mesalamine, present at 250 mg/L, produced 95.6% methane following a lag phase of 65 days using 2-nitrophenol-adapted sludge in batch assays conducted in 120 ml glass serum flasks and is considered completely biodegradable under anaerobic conditions(1). Mesalamine was completely degraded by a mesophilic sludge in 30 days (mesophilic granular sludge from a full-scale UASB reactor treating chemical industry wastewater of Shell Nederland Chemie at Moerdijk, The Netherlands, VSS concn - 25.5 g/L; specific aceticlastic activity - 0.3 COD/L/g VSS, 30°C) following a 20-day lag period(2). It was also completely degraded using a mesophilic floccular sludge from a lab-scale UASB reactor treating cattle manure wastewater - VSS concn 20.5 g/L; specific aceticlastic activity - 0.05 to 0.06 g COD/L/g VSS, so°C; however, specific incubation and acclimation details were not provided(2). Degradation using a thermophilic sludge was 100% in 48 days following a 34 day lag period - full-scale CSTR reactor digesting primary and secondary sludges at Kur'yanovskaya municipal aeration station, Moscow, Russia - VSS concn 20.5 g/L; specific aceticlastic activity 0.1 g COD/L g VSS, 55°C(2).

12.3 Bioaccumulative potential

An estimated BCF of 3 was calculated in fish for mesalamine(SRC), using an estimated log Kow of 0.98(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

Using a structure estimation method based on molecular connectivity indices(1), the Koc of mesalamine can be estimated to be 10(SRC). According to a classification scheme(2), this estimated Koc value suggests that mesalamine is expected to have very high mobility in soil. A predicted Kd value of 1.37

calculated for sludge samples in the UK, suggests that adsorption to sludge is low(3). Estimated pKa values of 2.09, 5.26 and 13.64(4) indicate that this compound will dissociate to the zwitterion form in the environment(SRC).

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: Not dangerous goods.	IMDG: Not dangerous goods.	IATA: Not dangerous goods.

14.2 UN Proper Shipping Name

ADR/RID: unknown
IMDG: unknown
IATA: unknown

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods.	IMDG: Not dangerous goods.	IATA: Not dangerous goods.

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

14.5 Environmental hazards

ADR/RID: no

IMDG: no

IATA: no

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
mesalamine	mesalamine	89-57-6	none
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Not Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.

16. Other information

Information on revision

Creation Date	Aug 17, 2017
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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB - Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC - International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA - European Chemicals Agency, website: https://echa.europa.eu/

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present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.