

SAFETY DATA SHEET

spectrum®



Revision date 17-April-2020

Revision Number 2

1. Identification

Product identifier

Product Name MESALAMINE, USP

Other means of identification

Product Code(s) M1540

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

| | |
|--|-------------|
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2A |
| Specific target organ toxicity (single exposure) | Category 3 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Appearance Crystalline powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear protective gloves/eye protection/face protection

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
If eye irritation persists: Get medical advice/attention
IF ON SKIN: Wash with plenty of water and soap
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor if you feel unwell

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% | Trade secret |
|---------------|---------|----------|--------------|
| Mesalamine | 89-57-6 | 100 | * |

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

Skin contact

Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

| | |
|---|---|
| Ingestion | Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. |
| Self-protection of the first aider | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). |

Most important symptoms and effects, both acute and delayed

| | |
|-----------------|--|
| Symptoms | May cause redness and tearing of the eyes. Burning sensation. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting. |
|-----------------|--|

Indication of any immediate medical attention and special treatment needed

| | |
|---------------------------|------------------------|
| Note to physicians | Treat symptomatically. |
|---------------------------|------------------------|

5. Fire-fighting measures

| | |
|---|--|
| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Large Fire | CAUTION: Use of water spray when fighting fire may be inefficient. |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. |
| Specific hazards arising from the chemical | No information available. |
| Hazardous combustion products | Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). |
| Explosion data | |
| Sensitivity to mechanical impact | none. |
| Sensitivity to static discharge | none. |
| Special protective equipment for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

| | |
|-----------------------------|--|
| Personal precautions | Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. |
| Other information | Refer to protective measures listed in Sections 7 and 8. |

Methods and material for containment and cleaning up

| | |
|--------------------------------|---|
| Methods for containment | Prevent further leakage or spillage if safe to do so. |
| Methods for cleaning up | Pick up and transfer to properly labeled containers. |

7. Handling and storage

Precautions for safe handling

| | |
|--------------------------------|---|
| Advice on safe handling | Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation, wear suitable respiratory equipment. |
|--------------------------------|---|

Conditions for safe storage, including any incompatibilities

Storage Conditions Protect from light. Sensitive to light. Store in light-resistant containers. Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline powder
Color White
Odor No information available
Odor threshold No information available

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---|-----------------------------|-------------------------|
| pH | no data available | None known |
| Melting point / freezing point | 260 - 280 °C / 500 - 536 °F | None known |
| Boiling point / boiling range | no data available | None known |
| Flash point | 280 °C / 536 °F | None known |
| Evaporation rate | no data available | None known |
| Flammability (solid, gas) | no data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive limits | No data available | |
| Vapor pressure | No data available | None known |
| Vapor density | no data available | None known |

| | | |
|----------------------------------|--|------------|
| Relative density | no data available | None known |
| Water solubility | No data available | None known |
| Solubility(ies) | Soluble in dilute hydrochloric acid | None known |
| | Very slightly soluble in acetone | |
| | Practically insoluble in Chloroform | |
| | Practically insoluble in Ethyl Acetate | |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |
| <u>Other information</u> | | |
| Explosive properties | No information available | |
| Oxidizing properties | No information available | |
| Softening point | No information available | |
| Molecular weight | 153.14 | |
| VOC Content (%) | No information available | |
| Liquid Density | No information available | |
| Bulk density | No information available | |

10. Stability and reactivity

| | |
|---|--|
| Reactivity | No information available. |
| Chemical stability | Stable under recommended storage conditions. |
| Possibility of hazardous reactions | None under normal processing. |
| Conditions to avoid | None known based on information supplied. |
| Incompatible materials | Strong acids. Strong bases. Strong oxidizing agents. |
| Hazardous decomposition products | None known based on information supplied. |

11. Toxicological information

Information on likely routes of exposure

Product Information

| | |
|---------------------|--|
| Inhalation | Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. May cause drowsiness or dizziness. |
| Eye contact | Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation. |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|-----------------|--|
| Symptoms | Redness. May cause redness and tearing of the eyes. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting. |
|-----------------|--|

Acute toxicity

Numerical measures of toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------------|----------------------|---------------------|-----------------|
| Mesalamine 89-57-6 | = 2800 mg/kg (Rat) | > 5 g/kg (Rabbit) | - |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

| | |
|--|--|
| Skin corrosion/irritation | Classification based on data available for ingredients. Irritating to skin. |
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Causes serious eye irritation. |
| Respiratory or skin sensitization | No information available. |
| Germ cell mutagenicity | No information available. |
| Reproductive toxicity | No information available. |
| STOT - single exposure | May cause respiratory irritation. May cause drowsiness or dizziness. |
| STOT - repeated exposure | No information available. |
| Aspiration hazard | No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

| | |
|--------------------------------------|---|
| Ecotoxicity | The environmental impact of this product has not been fully investigated. |
| Persistence and degradability | No information available. |
| Bioaccumulation | Inherently biodegradable. |
| Other adverse effects | No information available. |

13. Disposal considerations

Waste treatment methods

| | |
|--|---|
| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| Contaminated packaging | Do not reuse empty containers. |

14. Transport information

| | |
|--------------------------|---------------|
| <u>DOT</u> | not regulated |
| <u>TDG</u> | not regulated |
| <u>MEX</u> | not regulated |
| <u>ICAO (air)</u> | not regulated |
| <u>IATA</u> | not regulated |
| <u>IMDG</u> | not regulated |
| <u>RID</u> | not regulated |
| <u>ADR</u> | not regulated |

ADN

not regulated

15. Regulatory information

International Inventories

| | |
|----------------------|---|
| TSCA | Complies |
| DSL/NDSL | Complies |
| EINECS/ELINCS | Complies |
| ENCS | This product complies with ENCS: |
| IECSC | This product complies with China: |
| KECL | Complies |
| PICCS | Complies |
| AICS | All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS). |

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 1

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2

Flammability 1

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | | |
|---------|-----------------------------|------|----------------------------------|
| TWA | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | | |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 17-April-2020

Revision Note No information available.

Disclaimer

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End of Safety Data Sheet