SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Section 1: Identification

Product name : Ivermectin (3.5%) Formulation

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

Acute toxicity (Oral) : Category 4
Specific target organ toxicity - single exposure (Oral) : Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Central nervous system)

GHS label elements

Hazard pictograms : Warning
Hazard statements : H302 Harmful if swallowed.
H371 May cause damage to organs (Central nervous system) if swallowed.
H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
Precautionary statements : Prevention:
P260 Do not breathe vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON
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Date of first issue: 29.07.2019

If you feel unwell, Rinse mouth.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
May cause damage to organs if swallowed.
May cause damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray
Alcohol-resistant foam
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| Unsuitable extinguishing media | Carbon dioxide (CO2)  
Dry chemical |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific hazards during firefighting</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
</tbody>
</table>
| Hazardous combustion products | Carbon oxides  
Metal oxides |
| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area. |
| Special protective equipment for firefighters | In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment. |
| Hazchem Code | 3Z |

Section 6: Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**: Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

- **Environmental precautions**: Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

- **Methods and materials for containment and cleaning up**: Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

- **Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

- **Local/Total ventilation**: Use only with adequate ventilation.

- **Advice on safe handling**: Do not breathe vapours.  
Do not swallow.  
Avoid contact with eyes.
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Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types: Strong oxidizing agents.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>WES-TWA</td>
<td>10 mg/m3 (NZ OEL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m3 (Aluminium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th></th>
<th>Wipe limit</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum tristearate</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to
protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**Personal protective equipment**

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

  - **Filter type**
  - **Hand protection**
    - Combined particulates and organic vapour type

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Eye protection** : Wear safety glasses with side shields or goggles.

  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.

  - Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - Use appropriate degowning techniques to remove potentially contaminated clothing.

**Section 9: Physical and chemical properties**

**Appearance** : gel

**Colour** : off-white

**Odour** : characteristic

**Odour Threshold** : No data available

**pH** : No data available

**Melting point/freezing point** : No data available

**Initial boiling point and boiling range** : 170 °C

**Flash point** : 237.2 °C

**Evaporation rate** : No data available

**Flammability (solid, gas)** : Not applicable

**Flammability (liquids)** : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 0.93 - 0.95
Density : No data available
Solubility(ies)
   Water solubility : practically insoluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, dynamic : 382 - 384 mPa.s (25 °C)
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation
                   Skin contact
                   Ingestion
Eye contact

**Acute toxicity**
Harmful if swallowed.

**Product:**

- **Acute oral toxicity**: Acute toxicity estimate: 1,511 mg/kg
  Method: Calculation method

- **Acute dermal toxicity**: Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

**Components:**

**Ivermectin:**

- **Acute oral toxicity**: LD50 (Rat): 50 mg/kg
  LD50 (Mouse): 25 mg/kg
  LD50 (Monkey): > 24 mg/kg
  Target Organs: Central nervous system
  Symptoms: Vomiting, Dilatation of the pupil
  Remarks: No mortality observed at this dose.

- **Acute inhalation toxicity**: LC50 (Rat): 5.11 mg/l
  Exposure time: 1 h
  Test atmosphere: dust/mist

- **Acute dermal toxicity**: LD50 (Rabbit): 406 mg/kg
  LD50 (Rat): > 660 mg/kg

**Aluminum tristearate:**

- **Acute oral toxicity**: LD50 (Rat, female): > 2,000 mg/kg
  Remarks: Based on data from similar materials

- **Acute inhalation toxicity**: LC50 (Rat): > 5.15 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
  Remarks: Based on data from similar materials

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Ivermectin:**

- **Species**: Rabbit
- **Result**: No skin irritation

**Aluminum tristearate:**

- **Species**: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ivermectin:**
- Species: Rabbit
- Result: Mild eye irritation

**Aluminum tristearate:**
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
- Remarks: Based on data from similar materials

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Ivermectin:**
- Exposure routes: Dermal
- Species: Humans
- Result: Does not cause skin sensitisation.

**Aluminum tristearate:**
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative
- Remarks: Based on data from similar materials

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Ivermectin:**
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
- Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Aluminum tristearate:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

**Components:**

**Ivermectin:**
Species: Rat
Application Route: Oral
NOAEL: 1.5 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials

Species: Mouse
Application Route: Oral
NOAEL: 2.0 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

**Components:**

**Ivermectin:**
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 0.6 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development:
- Test Type: Development
  - Species: Mouse
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 0.2 mg/kg body weight
  - Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

  Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0.4 mg/kg body weight
  - Result: Embryotoxic effects and adverse effects on the offspring were detected.
  - Remarks: The mechanism or mode of action may not be relevant in humans.

  Test Type: Development
  - Species: Rabbit
  - Application Route: Oral
  - Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

**Aluminum tristearate:**

Effects on fertility:
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 416
  - Result: negative
  - Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

**STOT - single exposure**
May cause damage to organs (Central nervous system) if swallowed.

**Components:**

**Ivermectin:**
- Target Organs: Central nervous system
- Assessment: Causes damage to organs.
STOT - repeated exposure
May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

Ivermectin:
Target Organs: Central nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ivermectin:
Species: Dog
NOAEL: 0.5 mg/kg
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Target Organs: Central nervous system
Symptoms: Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species: Monkey
NOAEL: 1.2 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 0.4 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: spleen, Bone marrow, Kidney

Aluminum tristearate:
Species: Rat
NOAEL: >= 5,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Ivermectin:
Skin contact: Remarks: Can be absorbed through skin.
Eye contact: Remarks: May irritate eyes.
Section 12: Ecological information

Ecotoxicity

Components:

Ivermectin:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l
Exposure time: 96 h
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.000025 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Aluminum tristearate:

Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

Components:

Ivermectin:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 240 d

Bioaccumulative potential

Components:

Ivermectin:
Bioaccumulation: Bioconcentration factor (BCF): 74
Partition coefficient: n-octanol/water: log Pow: 3.22
Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
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UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: 3Z

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSN0 Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NZ / EN