

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

SECTION 1. IDENTIFICATION

Product name : Ivermectin Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity : Category 1 (Central nervous system)
- single exposure (Oral)

Specific target organ toxicity : Category 1 (Central nervous system)
- repeated exposure (Oral)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H370 Causes damage to organs (Central nervous system) if swallowed.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P308 + P311 IF exposed or concerned: Call a doctor.

Storage:
P405 Store locked up.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

Version 6.0 Revision Date: 07/06/2024 SDS Number: 6097531-00016 Date of last issue: 04/06/2024
Date of first issue: 06/30/2020

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---------------|---------------------|------------|-----------------------|
| Oils, sesame | Sesamum indicum oil | 8008-74-0 | 81.3 |
| Ivermectin | No data available | 70288-86-7 | 1 |

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 : Causes damage to organs if swallowed.
Causes 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
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

- | | | |
|--|---|---|
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon 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 fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

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 diking or other appropriate containment to keep material from spreading. If diked 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 mist or vapors. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

Version 6.0 Revision Date: 07/06/2024 SDS Number: 6097531-00016 Date of last issue: 04/06/2024
Date of first issue: 06/30/2020

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.

Conditions for safe storage : Keep in properly labeled 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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------|------------|----------------------------------|--|-----------|
| Oils, sesame | 8008-74-0 | TWAEV (Mist) | 10 mg/m ³ | CA QC OEL |
| Ivermectin | 70288-86-7 | TWA | 30 µg/m ³ (OEB 3) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 300 µg/100 cm ² | Internal |

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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 : Particulates type

Hand protection

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,

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

| | |
|--------------------------|--|
| Skin and body protection | : 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. 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. |
| 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. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---------------------|
| Appearance | : oily |
| Color | : light yellow |
| Odor | : characteristic |
| Odor Threshold | : No data available |
| pH | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : 167.5 °C |
| Flash point | : 219.2 °C |
| Evaporation rate | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Flammability (liquids) | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapor pressure | : No data available |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

| | | |
|--|---|--|
| Relative vapor density | : | No data available |
| Relative density | : | 0.88 - 0.92 |
| Density | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | practically insoluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | : | |
| 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 characteristics | : | |
| Particle size | : | Not applicable |

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

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

Components:

Oils, sesame:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Oils, sesame:

Species : Rabbit
Result : No skin irritation

Ivermectin:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

Components:

Oils, sesame:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Ivermectin:

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Oils, sesame:

| | | |
|--------------------|---|--|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Routes of exposure | : | Skin contact |
| Result | : | negative |

Ivermectin:

| | | |
|--------------------|---|------------------------------------|
| Routes of exposure | : | Dermal |
| Species | : | Humans |
| Result | : | Does not cause skin sensitization. |

Germ cell mutagenicity

Not classified based on available information.

Components:

Oils, sesame:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) |
| | | Result: negative |

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

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 fetal 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 |
|--|---|--|

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

Components:

Ivermectin:

| | | |
|---------------|---|--------------------------|
| Target Organs | : | Central nervous system |
| Assessment | : | Causes damage to organs. |

STOT-repeated exposure

Causes 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 |
| LOAEL | : | 0.8 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | spleen, Bone marrow, Kidney |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ivermectin:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

| | | |
|--------------|---|--|
| Skin contact | : | Remarks: Can be absorbed through skin. |
| Eye contact | : | Remarks: May irritate eyes. |
| Ingestion | : | Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination |

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 |

Persistence and degradability

Components:

Oils, sesame:

| | | |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

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 |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. 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. (Ivermectin, 2,6-Di-tert-butyl-p-cresol) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

IATA-DGR

| | | |
|--|---|---|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (Ivermectin, 2,6-Di-tert-butyl-p-cresol) |
| 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, 2,6-Di-tert-butyl-p-cresol) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

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

Not applicable for product as supplied.

Domestic regulation

TDG

| | | |
|----------------------|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin, 2,6-Di-tert-butyl-p-cresol) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| ERG Code | : | 171 |
| Marine pollutant | : | yes(Ivermectin, 2,6-Di-tert-butyl-p-cresol) |

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

The ingredients of this product are reported in the following inventories:

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

| | | |
|-------------------|---|--|
| CA QC OEL | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants |
| CA QC OEL / TWAEV | : | Time-weighted average exposure value |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ivermectin Formulation

| | | | |
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| Version | Revision Date: | SDS Number: | Date of last issue: 04/06/2024 |
| 6.0 | 07/06/2024 | 6097531-00016 | Date of first issue: 06/30/2020 |

Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 07/06/2024
Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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CA / Z8