SAFETY DATA SHEET

Ivermectin Liquid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ivermectin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Brihnager - Off Pune Nagar Road
         Wagholi - Pune - India  412 207
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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 5
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - single exposure (Oral): Category 2 (Central nervous system)
Specific target organ toxicity - single exposure: Category 3
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Central nervous system)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1
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GHS label elements

Hazard pictograms:

Signal word: Danger

Hazard statements:

H303 May be harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.
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.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P332 + P317 IF SWALLOWED or if skin irritation occurs: Get medical help.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P316 IF exposed or concerned: Get emergency medical help immediately.
P337 + P317 If eye irritation persists: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

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.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

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.

In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. 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: May be harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May damage the unborn child. 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire: Exposure to combustion products may be a hazard to health.
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.

7. HANDLING AND STORAGE

Technical measures

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

Local/Total ventilation

- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling

- Do not get on skin or clothing.
- Do not breathe mist or vapours.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. 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 labelled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.

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

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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>5-Hydroxy-N-methyl-2- pyrrolidone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>100 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

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.
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Filter type: Combined particulates and organic vapour type
Hand protection: Chemical-resistant gloves
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.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Colour: light yellow
Odour: characteristic
Odour Threshold: No data available
pH: Not applicable
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: > 100 °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 : No data available
Density : 0.90 - 0.92 g/cm³
Solubility(ies)
  Water solubility : insoluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition 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.
Particle size : Not applicable

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
May be harmful if swallowed.

Product:
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Acute oral toxicity  :  Acute toxicity estimate: 4,463 mg/kg
                      Method: Calculation method

Acute dermal toxicity  :  Acute toxicity estimate: > 5,000 mg/kg
                         Method: Calculation method

Components:

N-Methyl-2-pyrrolidone:
Acute oral toxicity  :  LD50 (Rat): 4,150 mg/kg

Acute inhalation toxicity  :  LC50 (Rat): > 5.1 mg/l
                           Exposure time: 4 h
                           Test atmosphere: dust/mist
                           Method: OECD Test Guideline 403

Acute dermal toxicity  :  LD50 (Rat): > 5,000 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
Causes skin irritation.

Components:

N-Methyl-2-pyrrolidone:
Result  :  Skin irritation

Ivermectin:
Species  :  Rabbit
Result  :  No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.
Components:

N-Methyl-2-pyrrolidone:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Ivermectin:
Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Hamster
Application Route: Ingestion
Method: OECD Test Guideline 475
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

Carcinogenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

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
May damage the unborn child.

Components:

N-Methyl-2-pyrrolidone:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: inhalation (vapour)
Result: positive

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

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

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

**Components:**

**N-Methyl-2-pyrrolidone:**
Assessment: May cause respiratory irritation.

**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:**

**N-Methyl-2-pyrrolidone:**
Species: Rat, male
NOAEL: 169 mg/kg
LOAEL: 433 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408

Species: Rat
NOAEL: 0.5 mg/l
LOAEL: 1 mg/l
Application Route: Inhalation (dust/mist/fume)
Exposure time: 96 Days
Method: OECD Test Guideline 413
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Species: Rabbit
NOAEL: 826 mg/kg
LOAEL: 1,653 mg/kg
Application Route: Skin contact
Exposure time: 20 Days

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:

N-Methyl-2-pyrrolidone:
Skin contact: Symptoms: Skin irritation

Ivermectin:
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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Methyl-2-pyrrolidone:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: DIN 38412

Toxicity to algae/aquatic plants:
ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC50: > 600 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 12.5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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

M-Factor (Acute aquatic toxicity): 10,000
M-Factor (Chronic aquatic toxicity): 10,000

Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 73 %
Exposure time: 28 d
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Method: OECD Test Guideline 301C

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

Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:
Partition coefficient: n-octanol/water : log Pow: -0.46
Method: OECD Test Guideline 107

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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)

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)
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Revision Date: 27.08.2021
SDS Number: 1204466-00012
Date of last issue: 10.10.2020
Date of first issue: 09.01.2017

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 IMO instruments
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

16. OTHER INFORMATION

Further information
Date format : dd.mm.yyyy
Full text of other abbreviations
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
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.

IN / EN