SAFETY DATA SHEET
Sulfadoxine / Trimethoprim Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sulfadoxine / Trimethoprim Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
          Singapore - Singapore  638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

GHS label elements
Hazard pictograms : ![Signal word](Danger)

Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
                   H361d Suspected of damaging the unborn child.
                   H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

Precautionary statements : Prevention:
                           P201 Obtain special instructions before use.
                           P202 Do not handle until all safety precautions have been read and understood.
                           P260 Do not breathe mist or vapours.
                           P280 Wear protective gloves/ protective clothing/ eye protec-
Other hazards which do not result in classification

None known.

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>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>1,3-Dioxolan-4-ylmethanol</td>
<td>5464-28-8</td>
<td>&gt;= 30 -&lt; 50</td>
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<tr>
<td>Sulfadoxine</td>
<td>2447-57-6</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 -&lt; 10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 2 -&lt; 3</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 soap and plenty of water.
Remove 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 immediately.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
## Most important symptoms and effects, both acute and delayed

- Causes serious eye damage.
- Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure.

## 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 firefighting**: Exposure to combustion products may be a hazard to health.

- **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.

### 6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures**: Use personal protective equipment.
  - Follow safe handling advice and personal protective equipment recommendations.

- **Environmental precautions**: Discharge into the environment must be avoided.
  - 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 : Use only with adequate ventilation.
Advice on safe handling : Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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. 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>Sulfadoxine</td>
<td>2447-57-6</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>PEL (short term)</td>
<td>2 mg/m³</td>
<td>SG OEL</td>
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<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
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</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 : Particulates 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.

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 brown, yellow

Odour : No data available

Odour Threshold : No data available

pH : 9.3 - 10.0

Melting point/freezing point : Not applicable

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable
SAFETY DATA SHEET
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Flammability (liquids) : No data available
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 : 1.210 - 1.250 g/cm3
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
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.
Molecular weight : Not applicable
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
  Acids
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure : Inhalation
  Skin contact
### Acute toxicity
Not classified based on available information.

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

**Components:**

1,3-Dioxan-5-ol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Sulfadoxine:
- Acute oral toxicity: LD50 (Mouse): 5,200 mg/kg

Trimethoprim:
- Acute oral toxicity: LD50 (Rat): 1,500 - 5,300 mg/kg
  LD50 (Mouse): 1,910 - 7,000 mg/kg

Acute toxicity (other routes of administration):
- LD50 (Rat): 400 - 500 mg/kg
  Application Route: Intraperitoneal

  LD50 (Dog): 90 mg/kg
  Application Route: Intravenous

  LD50 (Mouse): 132 mg/kg
  Application Route: Intravenous

Sodium hydroxide:
- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

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

**Product:**
- Result: No skin irritation
Components:

1,3-Dioxan-5-ol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Sulfadoxine:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Irritating

Sodium hydroxide:
Result: Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

1,3-Dioxan-5-ol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Sulfadoxine:
Result: Irritating

Sodium hydroxide:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

Respiratory or skin sensitisation

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

Components:

1,3-Dioxan-5-ol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

trimethoprim:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: In vitro mammalian cell gene mutation test
Result: negative

1,3-Dioxolan-4-ylmethanol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Result: negative

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

Test Type: Chromosomal aberration
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Rat
Result: negative

Test Type: Chromosomal aberration
Species: Humans
Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

trimethoprim:
Effects on fertility:
Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 70 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Effects on newborn
Remarks: Maternal toxicity observed.
Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 70 mg/kg body weight  
Result: Embryotoxic effects.  
Remarks: Maternal toxicity observed.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 15 mg/kg body weight  
Result: Embryotoxic effects., Teratogenic effects

Test Type: Development  
Species: Hamster  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1.7 mg/kg body weight  
Result: Embryotoxic effects., No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects., No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

**STOT - single exposure**
Not classified based on available information.

**Components:**

**Sulfadoxine:**
Assessment : May cause respiratory irritation.

**STOT - repeated exposure**
May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

**Components:**

**trimethoprim:**
Target Organs : Bone marrow  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**trimethoprim:**
Species : Rat  
NOAEL : 100 mg/kg  
LOAEL : 300 mg/kg  
Application Route : Oral
Exposure time: 6 Months
Target Organs: Bone marrow, Liver, Pituitary gland, Thyroid
Species: Rat
LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Bone marrow
Species: Dog
NOAEL: 2.5 mg/kg
LOAEL: 45 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Blood, Thyroid

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Sulfadoxine:
Ingestion: Target Organs: Blood
Symptoms: The most common side effects are:, Nausea, Vomiting, Headache, anemia, Rash, Stevens-Johnson syndrome

trimethoprim:
Ingestion: Target Organs: Bone marrow
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1,3-Dioxan-5-ol:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1
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<td><strong>Toxicity to microorganisms</strong></td>
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<td>EC10:</td>
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<td>Method: OECD Test Guideline 209</td>
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<td><strong>1,3-Dioxolan-4-ylmethanol:</strong></td>
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<td><strong>Toxicity to fish</strong></td>
<td>LL50:</td>
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<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
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<td><strong>Toxicity to algae/aquatic plants</strong></td>
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<td>Method: OECD Test Guideline 209</td>
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<td><strong>Sulfadoxine:</strong></td>
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<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50:</td>
<td>&gt; 100 mg/l</td>
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<td>Exposure time:</td>
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<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50:</td>
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<td>NOEC:</td>
<td>3.9 mg/l</td>
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<td>EC50:</td>
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</table>
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 6.2 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

trimethoprim:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna Straus): 92 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l
Exposure time: 72 h

EC50 (Anabaena flos-aquae): 253 mg/l
Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity): NOEC (Zebrafish): 0.157 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 6 mg/l
Exposure time: 21 d

Persistence and degradability

Components:

1,3-Dioxan-5-ol:
Biodegradability: Result: Inherently biodegradable.
Remarks: Based on data from similar materials
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1,3-Dioxolan-4-ylmethanol:
Biodegradability : Result: Inherently biodegradable.
Remarks: Based on data from similar materials

Sulfadoxine:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 5%
Exposure time: 28 d
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:
Partition coefficient: n-octanol/water : log Pow: -0.65

trimethoprim:
Partition coefficient: n-octanol/water : log Pow: 0.91

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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

- Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
- Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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: USA, ACGIH Threshold Limit Values (TLV)
SG OEL: Singapore, Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / C: Ceiling limit
SG OEL / PEL (short term): Permissible Exposure Level (PEL) Short Term

AICS - Australian Inventory of Chemical Substances; 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 Chemi-
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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.

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