SECTION 1. IDENTIFICATION

Product name: Sulfamethoxazole / Trimethoprim 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
Skin corrosion: Category 1A
Serious eye damage: Category 1
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 1 (Bone marrow)

GHS label elements
Hazard pictograms: 

Signal Word: Danger
Hazard Statements:
- H314 Causes severe skin burns and eye damage.
- H361d Suspected of damaging the unborn child.
- H372 Causes 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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection...
and face protection.

Response:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

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

Other hazards
Corrosive to the respiratory tract.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>No data available</td>
<td>723-46-6</td>
<td>33.9271</td>
<td></td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>2,4-Pyrimidinedia-</td>
<td>738-70-5</td>
<td>6.7854</td>
<td></td>
</tr>
<tr>
<td></td>
<td>mine, 5-[(3,4,5- trimethoxy-phenyl)methyl]-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Caustic soda</td>
<td>1310-73-2</td>
<td>5.0891</td>
<td></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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
In case of skin contact: Get medical attention immediately. 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 immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Get medical attention immediately. 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. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Causes digestive tract burns. Corrosive to respiratory system. Causes serious eye damage. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Causes severe burns.

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.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulfur 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

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.

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
If sufficient ventilation is unavailable, use with local exhaust ventilation.
Do not get on skin or clothing.
Do not breathe mist or vapors.
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
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

<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>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>400 µg/m³ (OEB 2)</td>
<td>Internal</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>(c)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C</td>
<td>ACGIH</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.
Laboratory operations do not require special containment.

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
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.

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: suspension
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
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<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
<td>pH</td>
<td>9.5 - 12.5</td>
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<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling</td>
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<tr>
<td>range</td>
<td></td>
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<tr>
<td>Flash point</td>
<td>No data available</td>
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<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
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<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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<tr>
<td>Relative density</td>
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<td>1.179 g/cm³</td>
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<td>Solubility(ies)</td>
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<td>Water solubility</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Autoignition temperature</td>
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<td>Decomposition temperature</td>
<td>No data available</td>
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<td>Viscosity</td>
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<td>Viscosity, kinematic</td>
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<td>Explosive properties</td>
<td>Not explosive</td>
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<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
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<td>Molecular weight</td>
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<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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, Acids
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:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
Sulfamethoxazole:
Acute oral toxicity: LD50 (Mouse): 2,300 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
Causes severe burns.

Components:

Sulfamethoxazole:
Species: Rabbit
Result: No skin irritation

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

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

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

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Sulfamethoxazole:
Test Type: Magnusson-Kligman-Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Trimethoprim:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

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

Germ cell mutagenicity
Not classified based on available information.
Components:

Sulfamethoxazole:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Humans
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.

Components:

Sulfamethoxazole:
Species: Mouse
Application Route: Ingestion
Exposure time: 26 weeks
Result: negative

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 fetal 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: 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.

**STOT-repeated exposure**
Causes 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
NOAEL: 300 mg/kg
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:

Trimethoprim:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sulfamethoxazole:

Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0268 mg/l
Exposure time: 96 h

NOEC (Synechococcus leopoliensis (blue-green algae)): 
Toxicity to fish (Chronic toxicity):
- NOEC (Danio rerio (zebra fish)): 0.533 mg/l
  Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 0.01 mg/l
  Exposure time: 30 d

Toxicity to microorganisms:
- NOEC (activated sludge): 3.76 mg/l
  Method: OECD Test Guideline 301D

Trimethoprim:
- LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna Straus (Water flea)): 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

Toxicity to microorganisms:
- EC10: 16.7 mg/l
  Exposure time: 3 hrs
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- EC50: > 1,000 mg/l
  Exposure time: 3 hrs
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Persistence and degradability

Components:

Sulfamethoxazole:
Biodegradability: Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 301D

Trimethoprim:

Bioaccumulative potential

Components:

Sulfamethoxazole:
Bioaccumulation: Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): < 120
Partition coefficient: n-octanol/water: log Pow: 0.89

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

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. Do not dispose of waste into sewer.
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 1824
Proper shipping name: SODIUM HYDROXIDE SOLUTION
Class: 8
Packing group: II
Labels: 8

IATA-DGR
UN/ID No.: UN 1824
Proper shipping name: Sodium hydroxide solution
Class: 8
Packing group: II
Labels: Corrosive
Packing instruction (cargo aircraft): 855
Packing instruction (passenger aircraft): 851

IMDG-Code
UN number: UN 1824
Proper shipping name: SODIUM HYDROXIDE SOLUTION (Sulfamethoxazole)
Class: 8
Packing group: II
Labels: 8
EmS Code: F-A, S-B
Marine pollutant: yes

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 1824
Proper shipping name: SODIUM HYDROXIDE SOLUTION
Class: 8
Packing group: II
Labels: 8
ERG Code: 154
Marine pollutant: yes (Sulfamethoxazole)

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:
DSL: not determined
AICS: not determined
IECSC: not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / C : Ceiling limit
CA AB OEL / (c) : ceiling occupational exposure limit
CA BC OEL / C : ceiling limit
CA QC OEL / C : Ceiling


Revision Date : 04/04/2023
Date format : mm/dd/yyyy
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.