SECTION 1. IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac 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
Serious eye damage : Category 1
Skin sensitization : Sub-category 1B
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 1 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms : 
Signal Word : Danger
Hazard Statements : H317 May cause an allergic skin reaction.
                    H318 Causes serious eye damage.
                    H361d Suspected of damaging the unborn child.
                    H372 Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) 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 dust, fume, gas, mist, vapors or spray.
SAFETY DATA SHEET according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
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.
P333 + P313 IF skin irritation or rash occurs: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>No data available</td>
<td>8009-03-8</td>
<td>&gt;= 80 - &lt;= 100 *</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>Zinc monoxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>Methyl 2-hydroxybenzoate</td>
<td>119-36-8</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>No data available</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>D-Camphor</td>
<td>464-49-3</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

*Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

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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. 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: May cause an allergic skin reaction. Causes serious eye damage. Suspected of damaging the unborn child. Causes 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.

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
Chlorine compounds
Nitrogen oxides (NOx)
Sodium 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.
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. 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:
Sweep up or vacuum up spillage and collect in suitable container for disposal. 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 get on skin or clothing. Do not breathe dust, fume, gas, mist, vapors or spray. 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.

Conditions for safe storage:
Keep in properly labeled 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 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</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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### Safety Data Sheet

#### Methyl Salicylate / Diclofenac Formulation

**Version**: 8.4  
**Revision Date**: 09/30/2023  
**SDS Number**: 656957-00018  
**Date of last issue**: 04/04/2023  
**Date of first issue**: 05/02/2016

<table>
<thead>
<tr>
<th>Substance / Formulation</th>
<th>(Form of exposure)</th>
<th>TWA / STEL / TWAEV</th>
<th>Permissible concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist - Inhalable dust)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (respirable dust)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (respirable dust)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
</tr>
</tbody>
</table>

**Further information**: Skin

<table>
<thead>
<tr>
<th>Substance / Formulation</th>
<th>(Form of exposure)</th>
<th>TWA / STEL / TWAEV</th>
<th>Permissible concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>STEL</td>
<td>3 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 ppm 19 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm 19 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV</td>
<td>3 ppm 19 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>2 ppm 12 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 ppm 12 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm</td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.
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: Combined particulates and organic vapor type

Hand protection: Chemical-resistant gloves

Material: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: ointment
Color: light red
Odor: aromatic
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
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according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

Flammability (solid, gas) : Not classified as a flammability hazard
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
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies) Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
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 size : No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity:  
Method: Calculation method
Acute inhalation toxicity:  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

Components:

Petrolatum:
Acute oral toxicity:  
LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

Acute dermal toxicity:  
LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

Zinc oxide:
Acute oral toxicity:  
LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity:  
LC50 (Rat): > 5.7 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:  
LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

Methyl salicylate:
Acute oral toxicity:  
LD50 (Rat): 890 mg/kg

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.4</td>
<td>09/30/2023</td>
<td>656957-00018</td>
<td>04/04/2023</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

**Acute oral toxicity**

- LD50 (Rat): 55 - 240 mg/kg
- LD50 (Mouse): 170 - 389 mg/kg

**Acute toxicity (other routes of administration)**

- LD50 (Rat): 97 - 161 mg/kg
- Application Route: Intravenous
- LD50 (Mouse): 92 - 147 mg/kg
- Application Route: Intravenous

**(+)-Bornan-2-one:**

- Acute oral toxicity: LD50 (Mouse): > 300 - 2,000 mg/kg
  - Remarks: Based on data from similar materials
- Acute toxicity estimate (Humans): > 50 - 500 mg/kg
  - Method: Expert judgment
  - Remarks: Based on data from similar materials

**Acute inhalation toxicity**

- LC50 (Rat): > 0.5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Remarks: Based on data from similar materials

**Acute dermal toxicity**

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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Petrolatum:**

- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

**Zinc oxide:**

- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

**Methyl salicylate:**

- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

- Result: irritating
Methyl Salicylate / Diclofenac Formulation

Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Zinc oxide:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Methyl salicylate:
Species: Tissue Culture
Method: OECD Test Guideline 491
Result: Irreversible effects on the eye

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Result: Mild eye irritation

(+)-Bornan-2-one:
Result: Eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials
Zinc oxide:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Methyl salicylate:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: positive
Assessment: Probability or evidence of low to moderate skin sensitization rate in humans

(+) - Bornan-2-one:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:
Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: equivocal
SAFETY DATA SHEET
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Methyl Salicylate / Diclofenac Formulation

Version 8.4  Revision Date: 09/30/2023  SDS Number: 656957-00018  Date of last issue: 04/04/2023  Date of first issue: 05/02/2016

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo:

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: inhalation (dust/mist/fume)
Method: OECD Test Guideline 474
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: inhalation (dust/mist/fume)
Result: positive

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

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.

Methyl salicylate:
Genotoxicity in vitro:
Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo:
Species: CHO
Result: negative

(+) - Bornan-2-one:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Petrolatum:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

**Zinc oxide:**
Species: Mouse
Application Route: Ingestion
Exposure time: 1 Years
Result: negative
Remarks: Based on data from similar materials

**Methyl salicylate:**
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Species: Mouse
Application Route: Oral
**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

### Petrolatum:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Reproduction/Developmental toxicity screening test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td>Application Route: Skin contact</td>
<td>Reproduction/Developmental toxicity screening test</td>
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<tr>
<td>Result: negative</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>Reproduction/Developmental toxicity screening test</td>
</tr>
</tbody>
</table>

### Zinc oxide:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Two-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Two-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Two-generation reproduction toxicity study</td>
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<tr>
<td>Remarks: Based on data from similar materials</td>
<td>Two-generation reproduction toxicity study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Embryo-fetal development</td>
</tr>
<tr>
<td>Application Route: Inhalation (dust/mist/fume)</td>
<td>Embryo-fetal development</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 414</td>
<td>Embryo-fetal development</td>
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<tr>
<td>Result: negative</td>
<td>Embryo-fetal development</td>
</tr>
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<td>Remarks: Based on data from similar materials</td>
<td>Embryo-fetal development</td>
</tr>
</tbody>
</table>

### Methyl salicylate:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Three-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Three-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Three-generation reproduction toxicity study</td>
</tr>
<tr>
<td>Result: negative</td>
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</tr>
</tbody>
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<tr>
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<tr>
<td>Species: Rat</td>
<td>Embryo-fetal development</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Embryo-fetal development</td>
</tr>
<tr>
<td>Result: positive</td>
<td>Embryo-fetal development</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td>Embryo-fetal development</td>
</tr>
</tbody>
</table>

| Test Type: Embryo-fetal development  | Embryo-fetal development                                     |
| Species: Monkey                      | Embryo-fetal development                                     |
| Application Route: Ingestion         | Embryo-fetal development                                     |
| Result: positive                     | Embryo-fetal development                                     |
| Remarks: Based on data from similar materials | Embryo-fetal development                                     |
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

Version 8.4  Revision Date: 09/30/2023  SDS Number: 656957-00018  Date of last issue: 04/04/2023

Date of first issue: 05/02/2016

Remarks: Based on data from similar materials

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Effects on fertility:
- Test Type: Fertility
- Species: Rat, male and female
- Application Route: Oral
- Fertility: NOAEL: 4 mg/kg body weight
- Result: No effects on fertility.

Effects on fetal development:
- Test Type: Development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: LOAEL: 1 mg/kg body weight
- Result: Embryo-fetal toxicity, No teratogenic effects.

- Test Type: Development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 5 mg/kg body weight
  - Result: Embryo-fetal toxicity, No teratogenic effects.

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

(+) Bornan-2-one:

Effects on fetal development:
- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

STOT-single exposure
Not classified based on available information.

Components:

(+) Bornan-2-one:
Assessment: May cause respiratory irritation.
Remarks: Based on data from similar materials

STOT-repeated exposure
Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:

Zinc oxide:
Assessment: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Petrolatum:
Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Zinc oxide:
Species: Rat, male
NOAEL: 0.0015 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 3 Months
Method: OECD Test Guideline 413

Methyl salicylate:
Species: Rat
NOAEL: 50 mg/kg
LOAEL: 250 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat
LOAEL: 0.25 mg/kg
Application Route: Oral
Exposure time: 98 w
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species: Dog
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 12 w
Target Organs: Blood

Species: Baboon
NOAEL: 0.5 mg/kg
LOAEL: 5 mg/kg
Application Route: Oral
Exposure time: 52 w
Target Organs: Gastrointestinal tract, Blood
Symptoms: constipation, Diarrhea
Methyl Salicylate / Diclofenac Formulation

(+)-Bornan-2-one:
Species: Rat
NOAEL: > 200 mg/kg
Application Route: Skin contact
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Sodium [2-(2,6-dichlorophenyl)amino]phenyl]acetate:
Ingestion: Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Zinc oxide:
Toxicity to fish: LC50: > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Desmodesmus subspicatus (green algae)): 1.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC10 (Pseudomonas putida): 140 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 16 h</td>
</tr>
</tbody>
</table>

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): 80.1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Pimephales promelas (fathead minnow)): &gt; 10 - 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 10 - 100 mg/l</th>
</tr>
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<tr>
<td></td>
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</tr>
<tr>
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<td>Method: OECD Test Guideline 202</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Desmodesmus subspicatus (green algae)): 1.6 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Desmodesmus subspicatus (green algae)): 0.79 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Jordanella floridae (flagfish)): &gt; 0.01 - 0.1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 14 Weeks</td>
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<td></td>
<td>Remarks: Based on data from similar materials</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Ceriodaphnia dubia (water flea)): &gt; 0.01 - 0.1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
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<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Ec50 (Daphnia magna (Water flea)): &gt; 10 - 100 mg/l</th>
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<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
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<td>Method: OECD Test Guideline 202</td>
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</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 0.01 - 0.1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): &gt; 0.01 - 0.1 mg/l</th>
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</table>

**Toxicity to daphnia and other aquatic invertebrates:**

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<tr>
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<td></td>
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</tbody>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Ec50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to fish:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Pimephales promelas (fathead minnow)): &gt; 10 - 100 mg/l</th>
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<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
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<thead>
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<th>Substance</th>
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</table>

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</tr>
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<tr>
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</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Ec50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l</th>
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<tbody>
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</table>
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

Version 8.4
Revision Date: 09/30/2023
SDS Number: 656957-00018
Date of last issue: 04/04/2023
Date of first issue: 05/02/2016

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

(+)-Bornan-2-one:

Toxicity to fish:
LC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms:
EC50: > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Petrolatum:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials
Methyl Salicylate / Diclofenac Formulation

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</tr>
</tbody>
</table>

**Methyl salicylate:**

Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.4%
Exposure time: 28 d

**(+)-Bornan-2-one:**

Biodegradability: Result: Readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Zinc oxide:**

Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 78 - 2,060

**Methyl salicylate:**

Partition coefficient: n-octanol/water: log Pow: 2.55

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Partition coefficient: n-octanol/water: log Pow: 4.51

**(+)-Bornan-2-one:**

Partition coefficient: n-octanol/water: log Pow: 2.3

**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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Methyl Salicylate / Diclofenac Formulation

Version 8.4 Revision Date: 09/30/2023 SDS Number: 656957-00018 Date of last issue: 04/04/2023
Date of first issue: 05/02/2016

N.O.S.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Class: 9
Packing group: III
Labels: 9
Environmentally hazardous: yes

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

Domestic regulation

TDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Class: 9
Packing group: III
Labels: 9
ERG Code: 171
Marine pollutant: yes (Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

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

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA AB OEL / STEL: 15-minute occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA BC OEL / STEL: short-term exposure limit
CA QC OEL / TWA: Time-weighted average exposure value
CA QC OEL / STEV: Short-term exposure value

AIIIC - 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 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 Develop-
<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<td>04/04/2023</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/30/2023
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.

CA / Z8