## SAFETY DATA SHEET

**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>6.1</td>
<td>03/23/2020</td>
<td>656957-00010</td>
<td>09/16/2019</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

### SECTION 1. IDENTIFICATION

- **Product name**: Methyl Salicylate / Diclofenac Formulation
- **Other means of identification**: No data available
- **Company name of supplier**: Merck & Co., Inc
- **Address**: 2000 Galloping Hill Road, Kenilworth - New Jersey - U.S.A. 07033
- **Telephone**: 908-740-4000
- **Telefax**: 908-735-1496
- **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

### SECTION 2. HAZARDS IDENTIFICATION

- **Reproductive toxicity**: Category 2
- **Specific target organ toxicity - repeated exposure**: Category 1 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

### GHS label elements

- **Hazard pictograms**: ![Hazard Pictogram]
- **Signal Word**: Danger
- **Hazard Statements**: 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/ spray. 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/ face protection.
- **Response**: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste dispos-AL plant.

Other hazards
None known.

SECTION 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>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 80 - &lt;= 100</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Methyl salicylate</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>15307-79-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</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 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 : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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

Hazardous combustion products : Carbon oxides
                                 Chlorine compounds
                                 Nitrogen oxides (NOx)
                                 Sodium 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, 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.
                            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 swallow.
                          Avoid contact with eyes.
                          Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure
assessment
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Fumes)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Fumes)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</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>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: Skin

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Wipe limit</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1000 µg/100 cm²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 mg/m³</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
<td>3 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
<td>3 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA EV</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>STEV</td>
<td>3 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
</tr>
<tr>
<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

**Remarks**: 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: Safety glasses

**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. Wash contaminated clothing before re-use.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: ointment

**Color**: light red

**Odor**: aromatic
## SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>EXPLOSIVE PROPERTIES</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 6.1
Revision Date: 03/23/2020
SDS Number: 656957-00010
Date of last issue: 09/16/2019
Date of first issue: 05/02/2016

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: Acute toxicity estimate: 4,003 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
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
SAFETY DATA SHEET
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Version 6.1  Revision Date: 03/23/2020  SDS Number: 656957-00010  Date of last issue: 09/16/2019
Date of first issue: 05/02/2016

Methyl salicylate:
Acute oral toxicity  :  LD50 (Rat): 887 mg/kg

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

(+-)Bornan-2-one:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

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: Rabbit
Result: No eye irritation

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
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
<table>
<thead>
<tr>
<th>Material</th>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide</td>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td></td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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

  - 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:
- Test Type: Chromosomal aberration
  - 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
- Exposure time: 2 Years
- Result: negative
Reproductive toxicity
Suspected of damaging the unborn child.

**Components:**

**Petrolatum:**
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

**Zinc oxide:**
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

**Methyl salicylate:**
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

**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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
Methyl Salicylate / Diclofenac Formulation

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

**(+)-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

Zinc oxide:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Selenastrum capricornutum (green algae)): > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
NOEC (Selenastrum capricornutum (green algae)): > 0.001 - 0.01 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): > 0.01 - 0.1 mg/l
Exposure time: 25 d
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
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) :
NOEC (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

Methyl salicylate:

Toxicity to fish :
LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates :
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants :
ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 6.25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms :
EC10 (Pseudomonas putida): 140 mg/l
Exposure time: 16 h

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

Toxicity to fish :
LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates :
EC50 (Daphnia magna (Water flea)): 80.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants :
EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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:
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 : 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, N.O.S. (Zinc oxide) (Zinc oxide)
- Class : 9
- Packing group : III
- Labels : 9

**IATA-DGR**
- UN/ID No. : UN 3077
- Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Zinc oxide) (Zinc oxide)
- 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)(1)

Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
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) (Zinc oxide)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide)(Zinc oxide)

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


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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