SECTION 1. IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
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

GHS classification in accordance with 29 CFR 1910.1200
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 : 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.

Storage:
P405 Store locked up.
**Disposal:**
P501 Dispose of contents/container to an approved waste disposal plant.

**Other hazards**
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td></td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Methyl salicylate</td>
<td>119-36-8</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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)
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 6.1
Revision Date: 03/23/2020
SDS Number: 656972-00010
Date of last issue: 09/16/2019
Date of first issue: 05/02/2016

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
- 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>OSHA Z-1</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Dust)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Fumes)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>ST (Fumes)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>C (Dust)</td>
<td>15 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Fumes)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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
- Wipe limit: 1000 µg/100 cm² Internal

| (+)-Bornan-2-one | 464-49-3 | TWA | 2 mg/m³ | OSHA Z-1 |
| (+)-Bornan-2-one | 464-49-3 | TWA | 2 ppm | ACGIH |
| (+)-Bornan-2-one | 464-49-3 | STEL | 3 ppm | ACGIH |
| (+)-Bornan-2-one | 464-49-3 | TWA | 2 mg/m³ | NIOSH REL |

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.
**Personal protective equipment**

**Respiratory protection**
- General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

<table>
<thead>
<tr>
<th>Material</th>
<th>Chemical-resistant gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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.

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>ointment</td>
</tr>
<tr>
<td>Color</td>
<td>light red</td>
</tr>
<tr>
<td>Odor</td>
<td>aromatic</td>
</tr>
<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>
</tbody>
</table>
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact
Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Route of Exposure</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LD50 (Rat): &gt; 5.003 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
</tbody>
</table>

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Route of Exposure</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Route of Exposure</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 887 mg/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Route of Exposure</th>
<th>Test Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 55 - 240 mg/kg</td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET
Methyl Salicylate / Diclofenac Formulation

Version 6.1 Revision Date: 03/23/2020 SDS Number: 656972-00010 Date of last issue: 09/16/2019 Date of first issue: 05/02/2016

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
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
Methyl salicylate

Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

(+) - 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
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
Exposure time: 2 Years
Result: negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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

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

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
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.

(+) - Boman-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:

(+) - Boman-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:
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 :

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 (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 :

Toxicity to algae/aquatic plants :

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
### Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): &gt; 0.01 - 0.1 mg/l Exposure time: 21 d Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methyl salicylate:</strong></td>
<td><strong>Toxicity to fish</strong></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 6.25 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC10 (Pseudomonas putida): 140 mg/l Exposure time: 16 h</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 80.1 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### (+)-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)
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

49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Zinc oxide) (Zinc oxide)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide) (Zinc oxide)
Remarks : Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
SARA 313: The following components are subject to reporting levels established by SARA Title III, Section 313:

- Zinc oxide 1314-13-2 >= 10 - < 20 %

US State Regulations

Pennsylvania Right To Know

- Petrolatum 8009-03-8
- Zinc oxide 1314-13-2
- Methyl salicylate 119-36-8
- (+)-Bornan-2-one 464-49-3

California List of Hazardous Substances

- Petrolatum 8009-03-8
- Zinc oxide 1314-13-2
- Methyl salicylate 119-36-8
- (+)-Bornan-2-one 464-49-3

California Permissible Exposure Limits for Chemical Contaminants

- Petrolatum 8009-03-8
- Zinc oxide 1314-13-2
- (+)-Bornan-2-one 464-49-3

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version: 6.1
Revision Date: 03/23/2020
SDS Number: 656972-00010
Date of last issue: 09/16/2019
Date of first issue: 05/02/2016

NFPA 704:

HMIS® IV:

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
NIOSH REL / C: Ceiling value not be exceeded at any time.
OSHA Z-1 / TWA: 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECS - Inventory of Existing Chemical Substances; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHOL - 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; MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable
Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date : 03/23/2020

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.

US / Z8