SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Methyl Salicylate / Diclofenac Formulation

Version 8.4
Revision Date: 09/30/2023
SDS Number: 656972-00018
Date of last issue: 04/04/2023
Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage: Category 1
Skin sensitization: Category 1
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.
P264 Wash skin thoroughly after handling.
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P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must 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 soap and 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.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<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>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Methyl salicylate</td>
<td>119-36-8</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>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</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.
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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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 (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 (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></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 (Res-</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
### Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Personal protective equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ensure adequate ventilation, especially in confined areas.</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Minimize workplace exposure concentrations.</strong></td>
<td>Hand protection</td>
</tr>
</tbody>
</table>

#### Further information: Skin

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>TWA 2 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA 2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL 3 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA 2 mg/m³</td>
</tr>
</tbody>
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#### Hand protection

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

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
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Density: No data available

Solubility(i(es)
    Water solubility: No data available

Partition coefficient: n-octanol/water:
    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: Acute toxicity estimate: 4,005 mg/kg
    Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 50.01 mg/l
    Exposure time: 4 h
    Test atmosphere: dust/mist
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<td>656972-00018</td>
<td>04/04/2023</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

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:**

- **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
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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
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

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
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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:**

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

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

**Zinc oxide:**

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

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

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Three-generation reproduction toxicity study</th>
<th>Species: Rat</th>
<th>Application Route: Ingestion</th>
<th>Result: negative</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
<th>Species: Rat</th>
<th>Application Route: Ingestion</th>
<th>Result: positive</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
<th>Species: Monkey</th>
<th>Application Route: Ingestion</th>
<th>Result: positive</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>Some evidence of adverse effects on development, based on animal experiments.</th>
</tr>
</thead>
</table>

**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.
# Methyl Salicylate / Diclofenac Formulation

## 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

### (+)-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: ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l
Exposure time: 72 h
NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
**Methyl Salicylate / Diclofenac Formulation**

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<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
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<tr>
<td>8.4</td>
<td>09/30/2023</td>
<td>656972-00018</td>
<td>04/04/2023</td>
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</tr>
</tbody>
</table>

**Exposure time:** 72 h  
**Remarks:** Based on data from similar materials

**Toxicity to fish (Chronic toxicity):**  
NOEC (Jordanella floridana (flagfish)): > 0.01 - 0.1 mg/l  
**Exposure time:** 14 Weeks  
**Remarks:** Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**  
NOEC (Ceriodaphnia dubia (water flea)): > 0.01 - 0.1 mg/l  
**Exposure time:** 7 d  
**Remarks:** Based on data from similar materials

**Methyl salicylate:**

**Toxicity to fish:**  
LC50 (Pimephales promelas (fathead minnow)): > 10 - 100 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)): > 10 - 100 mg/l  
**Exposure time:** 48 h  
**Method:** OECD Test Guideline 202  
**Remarks:** Based on data from similar materials

**Toxicity to algae/aquatic plants:**  
ErC50 (Desmodesmus subspicatus (green algae)): 1.6 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
## Methyl Salicylate / Diclofenac Formulation

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

### Toxicity to Fish (Chronic Toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimephales promelas (fathead minnow)</td>
<td>0.32 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td></td>
</tr>
</tbody>
</table>

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

#### Toxicity to Fish

<table>
<thead>
<tr>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danio rerio (zebra fish) &gt; 10 - 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Toxicity to Daphnia and Other Aquatic Invertebrates

<table>
<thead>
<tr>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea) &gt; 1 - 10 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Toxicity to Algae/Aquatic Plants

<table>
<thead>
<tr>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae) &gt; 1 - 10 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Persistence and Degradability

#### 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
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. Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Methyl Salicylate / Diclofenac Formulation

Version 8.4 Revision Date: 09/30/2023 SDS Number: 656972-00018 Date of last issue: 04/04/2023 Date of first issue: 05/02/2016

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

49 CFR
UN/ID/NA 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 : CLASS 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)
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.
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: Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

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

Further information
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Methyl Salicylate / Diclofenac Formulation

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NFPA 704:

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<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
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HMIS® IV:

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<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>0</td>
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</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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

ALLIC - Australian Inventory of Industrial Chemicals; 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; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)

Revision Date: 09/30/2023

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.