SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
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 the OSHA Hazard Communication Standard (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 or 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 and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

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>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>In case of eye contact</td>
<td>Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.</td>
</tr>
<tr>
<td>If swallowed</td>
<td>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</td>
</tr>
<tr>
<td>Most important symptoms and effects, both acute and delayed</td>
<td>Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Protection of first-aiders</td>
<td>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).</td>
</tr>
<tr>
<td>Notes to physician</td>
<td>Treat symptomatically and supportively.</td>
</tr>
</tbody>
</table>

SECTION 5. FIRE-FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray Alcohol-resistant foam Carbon dioxide (CO2)</th>
</tr>
</thead>
</table>
SECTION 5. FIRE FIGHTING MEASURES

Unsuitable extinguishing media: Dry chemical

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 (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.
Avoid contact with 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.
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 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></td>
<td></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>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 (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></td>
<td></td>
<td>TWA (Dust)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fumes)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Fumes)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C (Dust)</td>
<td>15 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 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>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>

Further information: Skin
- Wipe limit: 1000 µg/100 cm² Internal
- (+)-Bornan-2-one: TWA 2 mg/m³ OSHA Z-1
- TWA 2 ppm ACGIH
- STEL 3 ppm ACGIH
- 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**
- Material: 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.

## 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</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 7.0  Revision Date: 10/10/2020  SDS Number: 656972-00011  Date of last issue: 03/23/2020  Date of first issue: 05/02/2016

range

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
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition : 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: 50.01 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

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
Result: negative
Remarks: Based on data from similar materials

**Zinc oxide:**
Test Type: Maximization Test
Routes of exposure: Skin contact
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal injection</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 474</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 476</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 474</td>
</tr>
</tbody>
</table>
### 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

**Genotoxicity in vivo**
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

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

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - 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

**Genotoxicity in vivo**
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative
Carcinogenicity
Not classified based on available information.

Components:

Petrolatum:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative
- Remarks: Based on data from similar materials

Zinc oxide:
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 1 Year
- 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
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

Identified as a known or anticipated carcinogen by NTP.
Result: Embryo-fetal toxicity., No teratogenic effects.

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

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

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

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

STOT-single exposure
Not classified based on available information.

Components:

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

Assessment: May cause respiratory irritation.
Remarks: Based on data from similar materials

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

Components:

Zinc oxide:
Assessment: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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

Zinc oxide:
Species: Rat, male
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>7.0</td>
<td>10/10/2020</td>
<td>656972-00011</td>
<td>03/23/2020</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

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
NOAEL: > 200 mg/kg
LOAEL: 5 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
  Method: OECD Test Guideline 203
  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: > 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
  Exposure time: 72 h
  Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) :
  NOEC (Jordanella floridae (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**

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Danio rerio (zebra fish)):</th>
<th>&gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>&gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Compound</th>
<th>ErC50 (Desmodesmus subspicatus (green algae)):</th>
<th>27 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

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

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

**Toxicity to fish**

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

**Toxicity to daphnia and other aquatic invertebrates**

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

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>71.9 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

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

**Toxicity to microorganisms (Chronic toxicity)**

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

**Toxicity to microorganisms (Chronic toxicity)**

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

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

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Danio rerio (zebra fish)):</th>
<th>&gt; 10 - 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>1 - 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
</tbody>
</table>
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>7.0</td>
<td>10/10/2020</td>
<td>656972-00011</td>
<td>03/23/2020</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:
- **ErC50** (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 202
  - 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, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)
- 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, 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)
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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.

SECTION 15. REGULATORY INFORMATION

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
California List of Hazardous Substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>SDS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
</tr>
</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Substance</th>
<th>SDS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
</tr>
</tbody>
</table>

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

**NFPA 704:**

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**HMIS® IV:**

- **HEALTH:**
  - *: 3
- **FLAMMABILITY:**
  - 1
- **PHYSICAL HAZARD:**
  - 0

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
**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>7.0</td>
<td>10/10/2020</td>
<td>656972-00011</td>
<td>03/23/2020</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACGIH / STEL</th>
<th>NIOSH REL / TWA</th>
<th>NIOSH REL / ST</th>
<th>NIOSH REL / C</th>
<th>OSHA Z-1 / TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>:</td>
<td>:</td>
<td>:</td>
<td>:</td>
</tr>
<tr>
<td>Short-term exposure limit</td>
<td>Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek</td>
<td>STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday</td>
<td>Ceiling value not be exceeded at any time.</td>
<td>8-hour time weighted average</td>
</tr>
</tbody>
</table>

AIIC - 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) 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: 10/10/2020

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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