SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral) : Category 5
Skin irritation : Category 3
Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : ![Warning Symbol]
Signal Word : Warning
Hazard Statements : H303 May be harmful if swallowed.
H316 Causes mild skin irritation.
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Precautionary Statements

Prevention:
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P273 Avoid release to the environment.

Response:
P312 Call a POISON CENTER/doctor if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P391 Collect spillage.

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

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

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: May be harmful if swallowed. Causes mild skin irritation.
SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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

Hazardous combustion products:
Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Sodium oxides
Metal oxides

Specific extinguishing methods:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657427-00009 Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

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>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>CMP (Fumes)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: lung</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP (Fumes)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP (Dust)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Fumes)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)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></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4 / 22
SECTION 3. HAZARDS IDENTIFICATION

Material safety data sheet

Hazard classification and PPE guidance

Further information: A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories, anosmia, irritation.

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

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapor type

Hand protection

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

Appearance: ointment
# SAFETY DATA SHEET

**Methyl Salicylate / Diclofenac Formulation**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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:
May be harmful if swallowed.

Product:

Acute oral toxicity: Acute toxicity estimate: 4.003 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Petrolatum:

Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Zinc oxide:

Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg

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

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
### 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

### (+)-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

Causes mild skin irritation.

#### 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
SAFETY DATA SHEET
Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657427-00009 Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

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: 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
Genotoxicity in vivo

Test Type: Chromosome aberration test in vitro
Result: negative

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 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
## Reproductive toxicity

Not classified based on available information.

### Components:

#### Petrolatum:

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

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

#### Zinc oxide:

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

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

#### Methyl salicylate:

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

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

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat, male and female</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Fertility: NOAEL: 4 mg/kg body weight</td>
<td>Result: No effects on fertility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td>Result: Embryo-fetal toxicity, No teratogenic effects.</td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**STOT-single exposure**  
Not classified based on available information.

**Components:**

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

<table>
<thead>
<tr>
<th>Assessment</th>
<th>May cause respiratory irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

**Components:**

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 y</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.0015 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
</tbody>
</table>
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
### Ecotoxicity

#### Components:

**Petrolatum:**

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>**Toxicity to daphnia and other</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10.000 mg/l</td>
</tr>
<tr>
<td>aquatic invertebrates**</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>**Toxicity to algae/aquatic</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</td>
</tr>
<tr>
<td>plants**</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>**Toxicity to daphnia and other</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
</tr>
<tr>
<td>aquatic invertebrates (Chronic</td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>toxicity)**</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 0,1 - 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>**Toxicity to daphnia and other</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0,01 - 0,1 mg/l</td>
</tr>
<tr>
<td>aquatic invertebrates**</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>**Toxicity to algae/aquatic</td>
<td>EC50 (Selenastrum capricornutum (green algae)): &gt; 0,1 - 1 mg/l</td>
</tr>
<tr>
<td>plants**</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>NOEC (Selenastrum capricornutum (green algae)): &gt; 0,001 - 0,01 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity)**: 10

**Toxicity to fish (Chronic toxicity)**: NOEC (Oncorhynchus mykiss (rainbow trout)): > 0,01 - 0,1 mg/l | Exposure time: 25 d
<table>
<thead>
<tr>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Daphnia magna (Water flea)): &gt; 0,01 - 0,1 mg/l</td>
</tr>
<tr>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>LC50 (Danio rerio (zebra fish)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae)): 6,25 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>EC10 (Pseudomonas putida): 140 mg/l</td>
</tr>
<tr>
<td>Exposure time: 16 h</td>
</tr>
<tr>
<td>LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l</td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>EC50 (Daphnia magna (Water flea)): 80,1 mg/l</td>
</tr>
<tr>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2 mg/l</td>
</tr>
<tr>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow)): 0,32 mg/l</td>
</tr>
<tr>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
</tr>
<tr>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>
**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

**(+)-Borman-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
**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: 24.04.2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>16.09.2019</td>
<td>657427-00009</td>
<td>Date of first issue: 02.05.2016</td>
</tr>
</tbody>
</table>

- **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  
**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.

**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**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Argentina. Carcinogenic Substances and Agents Registry**: Not applicable
- **Control of precursors and essential chemicals for the preparation of drugs**: Not applicable

**International Regulations**

**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**
- **Sources of key data used to compile the Material Safety**: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version: 7.0
Revision Date: 16.09.2019
SDS Number: 657427-00009
Date of last issue: 24.04.2019
Date of first issue: 02.05.2016


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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
AR OEL / CMP : TLV (Threshold Limit Value)
AR OEL / CMP - CPT : STEL (Short Term Limit Value)

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.
<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>
</table>

AR / Z8