SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
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@msd.com

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
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: H303 May be harmful if swallowed. H316 Causes mild skin irritation. H361d Suspected of damaging the unborn child. H372 Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></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-</td>
<td>15307-79-6</td>
</tr>
<tr>
<td>dichlorophenyl]amino]phenyl]acetate</td>
<td></td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</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 delayed: May be harmful if swallowed. Causes mild skin irritation. 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
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
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.

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.

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>VLE-PPT (Mist)</td>
<td>5 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>VLE-PPT (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VLE-CT (Respirable fraction)</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-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>
</tbody>
</table>

Further information: Skin
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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).

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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
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
- 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
**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>
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<tbody>
<tr>
<td>7.0</td>
<td>10.10.2020</td>
<td>656968-00011</td>
<td>23.03.2020</td>
<td>02.05.2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result</th>
<th>negative</th>
</tr>
</thead>
</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>

<table>
<thead>
<tr>
<th>(+)-Bornan-2-one:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Routes of exposure</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Method</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</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>

| Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: equivocal |
|-------------------------------------------------|-------------------------------------------------|
| Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 474 Result: equivocal |

<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>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: inhalation (dust/mist/fume)
Result: positive

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Methyl salicylate:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Sodium [2-[(2,6-dichlorophenyl]amino]phenyl]acetate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo: Test Type: Chromosomal aberration
Species: CHO
Result: negative

(+) - Bornan-2-one:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials
**Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

**Species:** Mouse

**Application Route:** Skin contact

**Result:** negative

**Remarks:** Based on data from similar materials

## Carcinogenicity

Not classified based on available information.

### Components:

#### Petrolatum:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Zinc oxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Remarks:** Based on data from similar materials

#### Methyl salicylate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

## 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>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
</tbody>
</table>

### Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Application Route: Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Effects on fetal development**
- Name: Methyl Salicylate / Diclofenac Formulation
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Skin contact
- Result: negative
- Remarks: Based on data from similar materials

---

### Zinc oxide:

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

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

---

### Methyl salicylate:

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

**Effects on fetal development**
- Name: Methyl salicylate
- Test Type: Development
- Species: Rat
- Application Route: Inhalation
- 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.

---

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

**Effects on fertility**
- Name: Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate
- 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**
- Name: Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate
- Test Type: Development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: LOAEL: 1 mg/kg body weight
- Result: Embryo-fetal toxicity., No teratogenic effects.

---

**Reproductive toxicity - Assessment**
- Name: Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate
- (+)-Bornan-2-one: Suspected of damaging the unborn child.

---

**SAFETY DATA SHEET**

**Methyl Salicylate / Diclofenac Formulation**

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

STOT-single exposure
Not classified based on available information.

Components:
(+)-Bornan-2-one:
Assessment: May cause respiratory irritation.
Remarks: Based on data from similar materials

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

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

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

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

Zinc oxide:
Species: Rat, male
NOAEL: 0.0015 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 3 Months
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:

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
<table>
<thead>
<tr>
<th>Toxicty to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicty to algae/aquatic plants</td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicty to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Toxicty to fish</th>
<th>LC50: &gt; 0.1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicty to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): &gt; 0.01 - 0.1 mg/l Exposure time: 72 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicty to fish (Chronic toxicity)</td>
<td>NOEC (Jordanella floridiae (flagfish)): &gt; 0.01 - 0.1 mg/l Exposure time: 14 Weeks Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicty to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Ceriodaphnia dubia (water flea)): &gt; 0.01 - 0.1 mg/l Exposure time: 7 d Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Toxicty to fish</th>
<th>LC50 (Danio rerio (zebra fish)): &gt; 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicty to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicty to algae/aquatic plants</td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Desmodesmus subspicatus (green algae)): 6.25 mg/l Exposure time: 72 h</td>
</tr>
</tbody>
</table>
Method: OECD Test Guideline 201

Toxicity to microorganisms:

- EC10 (Pseudomonas putida): 140 mg/l
- Exposure time: 16 h

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

Toxicity to fish:

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

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): 80.1 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

- NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 10 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

(+)-Bornan-2-one:

Toxicity to fish:

- LC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:

- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

- NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
Toxicity to microorganisms: EC50: > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Petrolatum:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Methyl salicylate:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.4 %
Exposure time: 28 d

(+)-Bornan-2-one:

Biodegradability: Result: Readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Zinc oxide:

Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 78 - 2,060

Methyl salicylate:

Partition coefficient: n-octanol/water: log Pow: 2.55

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

Partition coefficient: n-octanol/water: log Pow: 4.51

(+)-Bornan-2-one:

Partition coefficient: n-octanol/water: log Pow: 2.3

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide, 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)
- 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

NOM-002-SCT
- 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

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
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined  
DSL : not determined  
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value  
NOM-010-STPS-2014 / VLE-CT : Short term exposure limit value

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and
Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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


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 is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8