SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
          Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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 in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
Hazard pictograms :
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.
**Precautionary Statements**

**Prevention:**
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.

**Other hazards which do not result in classification**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td></td>
<td>8009-03-8</td>
<td>Short-term (acute) aquatic hazard, Category 1</td>
<td>&gt;= 70 &lt; 90</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td></td>
<td>1314-13-2</td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 10 &lt;= 20</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td></td>
<td>119-36-8</td>
<td>Acute toxicity (Oral), Category 4</td>
<td>&gt;= 2.5 &lt; 5</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td></td>
<td>15307-79-6</td>
<td>Acute toxicity (Oral), Category 3, Skin irritation, Category 2, Eye irritation, Category 2B, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate), Category 1, Short-term (acute) aquatic hazard, Category 3, Long-term (chronic) aquatic hazard,</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 delayed: May be harmful if swallowed. Causes mild skin irritation. May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 8.0  Revision Date: 23.03.2020  SDS Number: 656956-00010  Date of last issue: 16.09.2019
Date of first issue: 02.05.2016

Unsuitable extinguishing media: Dry chemical
None known.

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

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

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

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

SECTION 7. HANDLING AND STORAGE

Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
Use only with adequate ventilation.

Advice on safe handling:
Do not get on skin or clothing.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.
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>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>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-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

| | Wipe limit | 1000 µg/100 cm² | Internal |
| (+)-Bornan-2-one | 464-49-3 | TWA | 2 ppm | ACGIH |
| | | STEL | 3 ppm | ACGIH |

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: Chemical-resistant gloves

Material: 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

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
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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**

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

**SECTION 11. TOXICOLOGICAL INFORMATION**

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
<tr>
<td></td>
<td>Eye contact</td>
</tr>
</tbody>
</table>

**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
### Methyl Salicylate / Diclofenac Formulation

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

### Zinc oxide:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>:</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>:</td>
<td>LC50 (Rat): &gt; 5,7 mg/l</td>
</tr>
<tr>
<td>Exposure time: 4 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>:</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 402</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Methyl salicylate:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>:</th>
<th>LD50 (Rat): 887 mg/kg</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>:</th>
<th>LD50 (Rat): 55 - 240 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Mouse): 170 - 389 mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute toxicity (other routes of administration)</th>
<th>:</th>
<th>LD50 (Rat): 97 - 161 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route: Intravenous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>:</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 402</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>:</th>
<th>LD50 (Mouse): &gt; 300 - 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Acute toxicity estimate (Humans): > 50 - 500 mg/kg |
| Method: Expert judgment |
| Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th>Acute inhalation toxicity</th>
<th>:</th>
<th>LC50 (Rat): &gt; 0,5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 4 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>:</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
- Method: OECD Test Guideline 405
- Result: No eye irritation
- Remarks: Based on data from similar materials

Zinc oxide:
- Species: Rabbit
- Method: OECD Test Guideline 405
- Result: No eye irritation

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
- 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
Genotoxicity in vivo:

- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

Zinc oxide:

- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
    - Method: OECD Test Guideline 476
    - Result: equivocal
  - Test Type: Chromosome aberration test in vitro
    - Result: equivocal

- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Rat
    - Application Route: Inhalation (dust/mist/fume)
    - Method: OECD Test Guideline 474
    - Result: negative

  - Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
    - Species: Rat
    - Application Route: Inhalation (dust/mist/fume)
    - Result: positive

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

Germ cell mutagenicity - Assessment:

- Weight of evidence does not support classification as a germ cell mutagen.

Methyl salicylate:

- Genotoxicity in vitro:
  - Test Type: Chromosome aberration test in vitro
    - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

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

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

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

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

  Test Type: Chromosome aberration test in vitro
  Result: negative

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

  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Skin contact
  Result: negative
  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:
Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials
Effects on fetal development : 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 : 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 : 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**
  - Test Type: Three-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

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

- **Effects on fertility**
  - Test Type: Fertility
  - Species: Rat, male and female
  - Application Route: Oral
  - Fertility: NOAEL: 4 mg/kg body weight
  - Result: No effects on fertility.

- **Effects on fetal development**
  - Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 1 mg/kg body weight
  - Result: Embryo-fetal toxicity, No teratogenic effects.

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

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

(+-)Boman-2-one:

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

**STOT-single exposure**

- Not classified based on available information.

**Components:**

(+-)Boman-2-one:

- **Assessment**
  - May cause respiratory irritation.

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

**STOT-repeated exposure**

- May cause 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:
**SAFETY DATA SHEET**

**Methyl Salicylate / Diclofenac Formulation**

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</tbody>
</table>

- **Species**: Rat
- **NOAEL**: > 200 mg/kg
- **Application Route**: Skin contact
- **Exposure time**: 13 Weeks
- **Remarks**: Based on data from similar materials

**Aspiration toxicity**

- Not classified based on available information.

**Experience with human exposure**

**Components:**

- **Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**
  - **Ingestion**: Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

- **Petrolatum:**
  - **Toxicity to fish**: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
    - Exposure time: 96 h
    - Test substance: Water Accommodated Fraction
    - Method: OECD Test Guideline 203
    - Remarks: Based on data from similar materials
  - **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
    - Exposure time: 48 h
    - Test substance: Water Accommodated Fraction
    - Remarks: Based on data from similar materials
  - **Toxicity to algae/aquatic plants**: NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
    - Exposure time: 72 h
    - Test substance: Water Accommodated Fraction
    - Method: OECD Test Guideline 201
    - Remarks: Based on data from similar materials
  - **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 10 mg/l
    - Exposure time: 21 d
    - Test substance: Water Accommodated Fraction
    - Remarks: Based on data from similar materials

- **Zinc oxide:**
  - **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,1 - 1 mg/l
    - Exposure time: 96 h
    - Remarks: Based on data from similar materials
  - **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 0,01 - 0,1 mg/l
    - Exposure time: 48 h
Remark: Based on data from similar materials

**Toxicity to algae/aquatic plants:**

EC50 (Selenastrum capricornutum (green algae)): > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

NOEC (Selenastrum capricornutum (green algae)): > 0.001 - 0.01 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

**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
Remarks: Based on data from similar materials

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

NOEC (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

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

**Methyl salicylate:**

**Toxicity to fish:**

LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates:**

EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants:**

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
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
**SAFETY DATA SHEET**

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**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

**(+)-Boran-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

**(+)-Boran-2-one**:
- **Partition coefficient: n-octanol/water**: log Pow: 2.3

**Mobility in soil**
No data available

**Other adverse effects**
No data available

**SECTION 13. DISPOSAL CONSIDERATIONS**

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

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**
- **UN number**: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Zinc oxide)

(Zinc oxide)

Class: 9

Packing group: III

Labels: 9

IATA-DGR

UN/ID No.: UN 3077

Proper shipping name: Environmentally hazardous substance, solid, n.o.s.

(Zinc oxide)

(Zinc oxide)

Class: 9

Packing group: III

Labels: Miscellaneous,

Packing instruction (cargo aircraft): 956

Packing instruction (passenger aircraft): 956

Environmentally hazardous: yes

IMDG-Code

UN number: UN 3077

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Zinc oxide)

(Zinc oxide)

Class: 9

Subsidiary risk: ENVIROM.

Packing group: III

Labels: 9 (ENVIROM.)

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

ANTT

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

Hazard Identification Number: 90

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.
SAFETY DATA SHEET

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SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : 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


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)

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

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; 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
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.