1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASteward@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 5
Skin corrosion/irritation: Category 3
Specific target organ toxicity - repeated exposure: Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
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,
Precautionary statements:

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

Response:
P301 + P332 + P317 IF SWALLOWED or if skin irritation occurs: Get medical help.
P319 Get medical help if you feel unwell.
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.

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>

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.

5. FIREFIGHTING 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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 8.0 Revision Date: 10.10.2020 SDS Number: 657439-00011 Date of last issue: 23.03.2020 Date of first issue: 02.05.2016

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, vapours or spray.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>IN OEL</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>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fumes)</td>
<td>5 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Fumes)</td>
<td>10 mg/m³</td>
<td>IN OEL</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-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>TWA</td>
<td>2 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 1000 µg/100 cm² Internal
## 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 vapour type

### Hand protection

**Material**: Chemical-resistant gloves

**Remarks**: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

---

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: ointment

**Colour**: light red

**Odour**: aromatic

**Odour 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
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Skin contact
exposure

**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

7 / 21
### Safety Data Sheet

**Methyl Salicylate / Diclofenac Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>10.10.2020</td>
<td>657439-00011</td>
<td>23.03.2020</td>
<td>02.05.2016</td>
</tr>
</tbody>
</table>

- **LD50 (Mouse):** 92 - 147 mg/kg
- **Application Route:** Intravenous

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

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

**Acute oral toxicity**

- LD50 (Mouse): > 300 - 2,000 mg/kg
- 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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Zinc oxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Methyl salicylate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

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

| Result | irritating |

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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 sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.

### Components:

#### Petrolatum:
- **Test Type**: Buehler Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative
- **Remarks**: Based on data from similar materials

#### Zinc oxide:
- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative

#### Methyl salicylate:
- **Test Type**: Local lymph node assay (LLNA)
- **Exposure routes**: Skin contact
Species: Mouse
Result: negative

(+)‐Bornan‐2‐one:

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: 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></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mutagenicity (in vivo mammalian bone‐marrow cytogenetic test, chromosomal analysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>
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
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>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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**

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 foetal development**

- Test Type: Embryo-foetal development
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 foetal development**
- Test Type: Embryo-foetal 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 foetal development**
- Test Type: Development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: LOAEL: 1 mg/kg body weight
- Result: Embryo-foetal toxicity, No teratogenic effects
- Test Type: Development
- Species: Rabbit
- Application Route: Oral
- Developmental Toxicity: LOAEL: 5 mg/kg body weight
- Result: Embryo-foetal toxicity, No teratogenic effects

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

(+)-Bornan-2-one:

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative
### STOT - single exposure
Not classified based on available information.

#### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Assessment</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(+)-Bornan-2-one</td>
<td>May cause respiratory irritation.</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:

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

<table>
<thead>
<tr>
<th>Petrolatum:</th>
<th>Species</th>
<th>5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

#### Zinc oxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
</table>

| NOAEL                             | 0.0015 mg/l |
| Application Route                 | inhalation (dust/mist/fume) |
| Exposure time                     | 3 Months    |
| Method                            | OECD Test Guideline 413 |

#### Methyl salicylate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
</table>

| NOAEL                             | 50 mg/kg |
| Application Route                 | Ingestion |
| Exposure time                     | 2 yr    |

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
</table>

| LOAEL                             | 0.25 mg/kg |
| Application Route                 | Oral   |
## Exposure Information

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>98 w</td>
<td>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</td>
</tr>
</tbody>
</table>

### Species

**Species**: Dog

**LOAEL**: 1 mg/kg

**Application Route**: Oral

**Exposure time**: 12 w

**Target Organs**: Blood

### Species

**Species**: Baboon

**NOAEL**: 0.5 mg/kg

**LOAEL**: 5 mg/kg

**Application Route**: Oral

**Exposure time**: 52 w

**Target Organs**: Gastrointestinal tract, Blood

### Symptoms

Symptoms: constipation, Diarrhoea

### (+)-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, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

## Ecological Information

### Ecotoxicity

**Components:**

#### Petrolatum:

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LL50 (Pimephales promelas (fathead minnow))</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
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: 10 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Test substance: Water Accommodated Fraction
  Remarks: Based on data from similar materials

Zinc oxide:

Toxicity to fish:

- LC50: > 0.1 - 1 mg/l
  Exposure time: 96 h
  Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:

- ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l
  Exposure time: 72 h
  NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
  Exposure time: 72 h
  Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity):

- 1

M-Factor (Chronic aquatic toxicity):

- 1

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
**SAFETY DATA SHEET**

**Methyl Salicylate / Diclofenac Formulation**

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

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

#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Desmodesmus subspicatus (green algae)): 6.25 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
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</table>

#### Toxicity to microorganisms

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#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Desmodesmus subspicatus (green algae)): 49.2 mg/l</th>
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<tr>
<td>Exposure time</td>
<td>72 h</td>
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#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC: 0.32 mg/l</th>
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<tbody>
<tr>
<td>Exposure time</td>
<td>32 d</td>
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#### Toxicity to microorganisms

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

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<tr>
<th>Method</th>
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#### Toxicity to microorganisms

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<tr>
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<th>EC50 (Pimephales promelas (fathead minnow)): &gt; 1 - 10 mg/l</th>
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<td>Exposure time</td>
<td>48 h</td>
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#### Toxicity to microorganisms

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</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
</tbody>
</table>
## 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

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

Partition coefficient: n-octanol/water: log Pow: 2.3
Mobility in soil
No data available

Other adverse effects
No data available

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.

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 IMO instruments
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.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

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.

Date format: dd.mm.yyyy

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- IN OEL: India. Permissible levels of certain chemical substances in work environment.
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
- IN OEL / STEL: Short-term exposure Limit STEL (15 min)

AIIC - 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
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.

IN / EN