1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 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

2. HAZARDS IDENTIFICATION

GHS Classification
Specific target organ toxicity - repeated exposure: Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms:
Signal word: Warning
Hazard statements: H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:
Prevention:
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
Response:
P314 Get medical advice/ attention 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Petrolatum</td>
</tr>
<tr>
<td></td>
<td>Zinc oxide</td>
</tr>
<tr>
<td></td>
<td>Methyl salicylate</td>
</tr>
<tr>
<td></td>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
</tr>
<tr>
<td></td>
<td>(+)-Bornane-2-one</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 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.

7. HANDLING AND STORAGE

Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSOAL 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.
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>NAB (Mist)</td>
<td>5 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Sampled by a method that does not collect</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>vapour.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD (Mist)</td>
<td>10 mg/m³</td>
<td>ID 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>NAB (Fumes)</td>
<td>5 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NAB (Inhalable dust)</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Further information: Total inhalable particulates, containing no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>asbestos and with a crystalline silica content of &lt; 1%.</td>
<td></td>
<td></td>
<td></td>
<td></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>
<tr>
<td>Further information: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>PSD</td>
<td>3 ppm</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Adopted in Year 1996, Not classified as car-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NAB</td>
<td>2 ppm</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Adopted in Year 1996, Not classified as car-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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: 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

Flammability (solid, gas): Not classified as a flammability hazard
SAFETY DATA SHEET
Methyl Salicylate / Diclofenac Formulation

Version: 7.0
Revision Date: 2020/10/10
SDS Number: 656963-00011
Date of last issue: 2020/03/23
Date of first issue: 2016/05/02

Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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

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
                                     Ingestion
                                     Eye contact
Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 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

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

Remarks: Based on data from similar materials

Methyl salicylate:
Acute oral toxicity: LD50 (Rat): 887 mg/kg

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Acute oral toxicity: LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous

LD50 (Mouse): 92 - 147 mg/kg
Application Route: Intravenous
**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 judgement  
Remarks: Based on data from similar materials  

**Acute inhalation toxicity**  
LC50 (Rat): > 0.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: Based on data from similar materials  

**Acute dermal toxicity**  
LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials  

**Skin corrosion/irritation**  
Not classified based on available information.  

**Components:**

**Petrolatum:**  
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation  
Remarks: Based on data from similar materials  

**Zinc oxide:**  
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation  

**Methyl salicylate:**  
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation  

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

**(+)-Bornan-2-one:**  
Species: Rabbit  
Result: No skin irritation  
Remarks: Based on data from similar materials  

**Serious eye damage/eye irritation**  
Not classified based on available information.
Components:

Petrolatum:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405
- **Remarks**: Based on data from similar materials

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

Methyl salicylate:
- **Species**: Rabbit
- **Result**: No eye irritation

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
- **Result**: Mild eye irritation

(+)-Bornan-2-one:
- **Result**: Eye irritation
- **Remarks**: Based on data from similar materials

Respiratory or skin 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>negative</td>
</tr>
</tbody>
</table>

(**)-Bornan-2-one:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Petrolatum:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</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>Result: negative</td>
<td></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>Result: equivocal</td>
<td>Method: OECD Test Guideline 476</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>Result: equivocal</td>
<td>Remarks: 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: Rat</td>
<td>Application Route: inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

**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
**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
- Species: Rat
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

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:**

(+)-Bornan-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 yr

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 yr

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
- **Species:** Rat
- **LOAEL:** 0.25 mg/kg
- **Application Route:** Oral
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>98 w</td>
<td>Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate</td>
<td>Dog</td>
<td>1 mg/kg</td>
<td>Oral</td>
<td>12 w</td>
<td>Blood</td>
<td>constipation, Diarrhoea</td>
</tr>
</tbody>
</table>

Species: Dog
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 12 w
Target Organs: Blood
Symptoms: constipation, Diarrhoea

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, Diarrhoea

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

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)):** $\geq$ 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: $> 0.1 - 1$ 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)
- **M-Related Toxicity:** 1

### M-Related Toxicity (Chronic toxicity)
- **NOEC (Jordanella floridae (flagfish)):** $> 0.01 - 0.1$ mg/l
  - **Exposure time:** 14 Weeks
  - **Remarks:** Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC (Ceriodaphnia dubia (water flea)):** $> 0.01 - 0.1$ mg/l
  - **Exposure time:** 7 d
  - **Remarks:** Based on data from similar materials

### M-Related Toxicity (Chronic aquatic toxicity)
- **M-Related 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
  - **Method:** OECD Test Guideline 201

- **NOEC (Desmodesmus subspicatus (green algae)):** 6.25 mg/l
  - **Exposure time:** 72 h
  - **Method:** OECD Test Guideline 201
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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 : yyyy/mm/dd

Full text of other abbreviations
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.