SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657438-00009 Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Methyl Salicylate / Diclofenac Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone: 44 1 670 59 30 00
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 2
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   H373: May cause damage to organs through prolonged or repeated exposure.
   H400: Very toxic to aquatic life.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms: 
   Signal word: Warning
   Hazard statements: H373 May cause damage to organs through prolonged or repeated exposure.
   H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
P273  Avoid release to the environment.

**Response:**
P314  Get medical advice/ attention if you feel unwell.
P391  Collect spillage.

Hazardous components which must be listed on the label:
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate

### 2.3 Other hazards
None known.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2 215-222-5 030-013-00-7</td>
<td>Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8 204-317-7</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6 239-346-4</td>
<td>Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 Aquatic Chronic 2; H411</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3 207-355-2</td>
<td>Flam. Sol. 2; H228 Acute Tox. 3; H301 Acute Tox. 3; H331 Skin Irrit. 2; H319 Acute Tox. 3; H331 STOT SE 3; H335 Aquatic Chronic 2; H411</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>OELV - 8 hrs (TWA) (fume, respirable)</td>
<td>2 mg/m3</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 15 min (STEL) (Fumes)</td>
<td>10 mg/m3</td>
<td>IE OEL</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>
<tr>
<td>Further information</td>
<td>Skin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl salicylate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>285 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>213 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>3 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>83 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>83 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.83 mg/kg bw/day</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.632 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4.348 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl salicylate</td>
<td>Fresh water</td>
<td>20 µg/l</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

Personal protective equipment

Eye protection
Wear the following personal protective equipment:
Safety glasses
Equipment should conform to I.S. EN 166

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.

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
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 (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
- 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.

9.2 Other information
Flammability (liquids): No data available
Molecular weight: No data available
Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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:

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

(+)-Bornan-2-one:
- Acute oral toxicity: LD50 (Mouse): > 300 - 2,000 mg/kg
  Remarks: Based on data from similar materials
  Acute toxicity estimate (Humans): > 50 - 500 mg/kg
  Method: Expert 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:

Zinc oxide:
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version: 7.0
Revision Date: 16.09.2019
SDS Number: 657438-00009
Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

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:

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:

Zinc oxide:
### Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Component</th>
<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><strong>Methyl Salicylate</strong></td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td><strong>(+)-Borman-2-one</strong></td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Germ cell mutagenicity
Not classified based on available information.

### Components:

#### Zinc oxide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 476</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: equivocal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: equivocal</td>
<td></td>
</tr>
</tbody>
</table>

| 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                                       |                  |
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version 7.0  Revision Date: 16.09.2019  SDS Number: 657438-00009  Date of last issue: 24.04.2019  Date of first issue: 02.05.2016

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:

**Zinc oxide:**
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 1 Years
- 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:

**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
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.

STOT - single exposure
Not classified based on available information.

Components:

(+)-Boman-2-one:

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

STOT - repeated exposure
May cause damage to organs 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:**

### 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
- **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, 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, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash |

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Zinc oxide:**

| Toxicity to fish (Chronic toxicity) | NOEC: > 0.01 - 0.1 mg/l  
Species: Oncorhynchus mykiss (rainbow trout)  
Remarks: Based on data from similar materials |

| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC: > 0.01 - 0.1 mg/l  
Species: Daphnia magna (Water flea)  
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 |
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to Daphnia and Other Aquatic Invertebrates</th>
<th>Toxicity to Algae/Aquatic Plants</th>
<th>Toxicity to Microorganisms</th>
<th>Toxicity to Fish</th>
<th>Chronic Toxicity</th>
<th>Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</td>
<td>EC₅₀ (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>Er₅₀ (Desmodesmus subspicatus (green algae)): 27 mg/l</td>
<td>EC₁₀ (Pseudomonas putida): 140 mg/l</td>
<td>LC₅₀ (Pimephales promelas (fathead minnow)): 166.6 mg/l</td>
<td>NOEC: 0.32 mg/l</td>
<td>NOEC: 10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 16 h</td>
<td>Exposure time: 96 h</td>
<td>Species: Pimephales promelas (fathead minnow)</td>
<td>Species: Daphnia magna (Water flea)</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td>Method: OECD Test Guideline 210</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

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

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC: 10 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

**(+)-Broman-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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

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
- 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

12.2 Persistence and degradability

Components:

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

(+)-Broman-2-one:
- Biodegradability: Result: Readily biodegradable.
  Method: OECD Test Guideline 301F
  Remarks: Based on data from similar materials

12.3 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

(+)-Broman-2-one:
- Partition coefficient: n-octanol/water: log Pow: 2.3
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657438-00009 Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) (Zinc oxide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) (Zinc oxide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) (Zinc oxide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) ()</td>
</tr>
</tbody>
</table>
IATA  :  Environmentally hazardous substance, solid, n.o.s.  
(Zinc oxide)  
(Zinc oxide)

14.3 Transport hazard class(es)

ADN  :  9
ADR  :  9
RID  :  9
IMDG  :  9
IATA  :  9

14.4 Packing group

ADN
Packing group  :  III
Classification Code  :  M7
Hazard Identification Number  :  90
Labels  :  9

ADR
Packing group  :  III
Classification Code  :  M7
Hazard Identification Number  :  90
Labels  :  9
Tunnel restriction code  :  (-)

RID
Packing group  :  III
Classification Code  :  M7
Hazard Identification Number  :  90
Labels  :  9

IMDG
Packing group  :  III
Labels  :  9
EmS Code  :  F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft)  :  956
Packing instruction (LQ)  :  Y956
Packing group  :  III
Labels  :  Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous  :  yes
Methyl Salicylate / Diclofenac Formulation

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined
DSL: not determined
SAFETY DATA SHEET
going to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version 7.0  Revision Date: 16.09.2019  SDS Number: 657438-00009  Date of last issue: 24.04.2019

Date of first issue: 02.05.2016

IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other 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 H-Statements

H228: Flammable solid.
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H331: Toxic if inhaled.
H335: May cause respiratory irritation.
H361d: Suspected of damaging the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H411: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
Flam. Sol.: Flammable solids
Repr.: Reproductive toxicity
Skin Irrit.: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th></th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

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

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.