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

Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657437-00009 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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone: 908-740-4000
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>215-222-5</td>
<td>030-013-00-7</td>
<td>204-317-7</td>
<td>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
<td>204-317-7</td>
<td></td>
<td></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</td>
<td>239-346-4</td>
<td></td>
<td></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</td>
<td>207-355-2</td>
<td></td>
<td></td>
<td>Flam. Sol. 2; H228 Acute Tox. 3; H301 Acute Tox. 3; H331 Eye Irrit. 2; H319 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.
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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.
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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.

7.2 Conditions for safe storage, including any incompatibilities 
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

7.3 Specific end use(s)  
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<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>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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>TWA</td>
<td>2 ppm 13 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 ppm 19 mg/m3</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<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</td>
<td>17.5 mg/m3</td>
</tr>
</tbody>
</table>
Methyl Salicylate / Diclofenac Formulation

<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>
<tr>
<td></td>
<td>Marine water</td>
<td>2 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>200 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>140 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.33 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.033 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.35 mg/kg</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>Fresh water</td>
<td>20.6 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>6.1 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 µg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>117.8 mg/kg dry weight (d.w.)</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>
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<td>Fresh water</td>
<td>20 µg/l</td>
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<tr>
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<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 µg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>117.8 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

Effects

Workers

Inhalation
Acute systemic effects
285 mg/m3

Skin contact
Long-term systemic effects
6 mg/kg bw/day

Consumers

Inhalation
Long-term systemic effects
4 mg/m3

Skin contact
Long-term systemic effects
3 mg/kg bw/day

Ingestion
Long-term systemic effects
1 mg/kg bw/day

Consumers

Inhalation
Acute systemic effects
213 mg/m3

Skin contact
Long-term systemic effects
83 mg/kg bw/day

Ingestion
Long-term systemic effects
5 mg/kg bw/day

Zinc oxide

Workers
Inhalation
Long-term systemic effects
5 mg/m3

Skin contact
Long-term systemic effects
83 mg/kg bw/day

Ingestion
Long-term systemic effects
0.83 mg/kg bw/day

(+)-Bornan-2-one

Workers
Inhalation
Long-term systemic effects
17.632 mg/m3

Skin contact
Long-term systemic effects
10 mg/kg bw/day

Ingestion
Long-term systemic effects
5 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:
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 BS 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 clothing (gloves, aprons, boots, etc).

**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
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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

**Methyl salicylate:**

**Acute oral toxicity**:  
LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

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

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

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

**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:**

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:
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
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Result : negative

(+) - Broman - 2 - one:

Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

Zinc oxide:

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytophenetic 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 cytophenetic 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
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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
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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
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:
- **Species**: Rat
  - **Application Route**: Oral
  - **Developmental Toxicity**: LOAEL: 1 mg/kg body weight
  - **Result**: Embryo-foetal toxicity, No teratogenic effects

- **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:**

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

**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
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Method

OECD Test Guideline 413

Methyl salicylate:

Species
NOAEL
LOAEL
Application Route
Exposure time

Rat
50 mg/kg
250 mg/kg
Ingestion
2 yr

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

Species
LOAEL
Application Route
Exposure time
Target Organs

Rat
0.25 mg/kg
Oral
98 w
Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species
LOAEL
Application Route
Exposure time
Target Organs

Dog
1 mg/kg
Oral
12 w
Blood

Species
LOAEL
Application Route
Exposure time
Target Organs
Symptoms

Baboon
0.5 mg/kg
Oral
52 w
Gastrointestinal tract, Blood
constipation, Diarrhoea

(+)-Bornan-2-one:

Species
NOAEL
Application Route
Exposure time
Remarks

Rat
> 200 mg/kg
Skin contact
13 Weeks
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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>Methyl salicylate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide:</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 0.1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0.01 - 0.1 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
<td>EC50 (Selenastrum capricornutum (green algae)): &gt; 0.1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials</td>
<td>NOEC (Selenastrum capricornutum (green algae)): &gt; 0.001 - 0.01 mg/l Exposure time: 72 h Remarks: Based on data from similar materials</td>
<td>NOEC: &gt; 0.01 - 0.1 mg/l Exposure time: 25 d Species: Oncorhynchus mykiss (rainbow trout) Remarks: Based on data from similar materials</td>
<td>NOEC: &gt; 0.01 - 0.1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials</td>
<td>10</td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Methyl salicylate:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Remarks:**

- Based on data from similar materials

**Method:**

- OECD Test Guideline 203
- OECD Test Guideline 201
Methyl Salicylate / Diclofenac Formulation

Toxicity to microorganisms:

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

**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

**(+) 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
12.2 Persistence and degradability

**Components:**

- **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

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

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

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
</tbody>
</table>
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

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Methyl Salicylate / Diclofenac Formulation

Version 7.0 Revision Date: 16.09.2019 SDS Number: 657437-00009 Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

IATA (Cargo) Environmentally hazardous : yes

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

E1 ENVIRONMENTAL HAZARDS Quantity 1 Quantity 2
100 t 200 t

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
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
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: 657437-00009  Date of last issue: 24.04.2019
Date of first issue: 02.05.2016

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
GB EH40  : UK EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA  : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL  : Short-term exposure limit (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; AIS - 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; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median 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 - Organisation for Economic Co-operation and Development; OEL - Occupational Exposure Limit; ORL - Organism Readability Level; PEL - Permissible Exposure Level; PMF - Physicochemical Parameters; PNEC - Predicted No Effect Concentration; POP - Persistent Organic Pollutant; RAC - Responsible Authorised Contactor; RACR - Responsible Authorised Contact Route; RACR - Responsible Authorised Contact Route; RAS - Responsible Authorised Contactor Route; RTK - Ready-to-use; SAD - Specific Action Date; SC价钱- Standard Concentration; Sentinel - Sentinel Substance; TWA - Time-weighted Average; ULN - Upper Limit; VV - Volume Variation; WHO - World Health Organization; WLD - World Land Day; WLC - World Land Cap; XPO - Hazardous Goods Transporter; ZLD - Zero Land Day; ZLC - Zero Land Cap.
Further information


Classification of the mixture: Classification procedure:

<table>
<thead>
<tr>
<th>STOT RE 2</th>
<th>H373</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</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.

GB / EN