1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

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:
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

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May 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 fire- : Exposure to combustion products may be a hazard to health.
fighting
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/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

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

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>PEL (long term) (Mist)</td>
<td>5 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m3</td>
<td>SG 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>PEL (long term) (Dust)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (long term) (Fumes)</td>
<td>5 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Fumes)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

- Wipe limit: 1000 µg/100 cm² Internal

| (+)-Bornan-2-one                         | 464-49-3    | PEL (short term)              | 3 ppm, 19 mg/m3                               | SG OEL   |
|                                        |             | PEL (long term)               | 2 ppm, 12 mg/m3                               | SG OEL   |
|                                        |             | TWA                           | 2 ppm                                          | ACGIH    |
|                                        |             | STEL                          | 3 ppm                                          | ACGIH    |

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

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type
Hand protection : Combined particulates and organic vapour type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment: Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment
Colour : light red
Odour : aromatic
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not classified as a flammability hazard
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Zinc oxide:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

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

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

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

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

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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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
- Species: Mouse
- Result: negative

(+) - Bornan-2-one:
- Test Type: Buehler Test
- Exposure routes: Skin contact
- Species: Guinea pig
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
- Genotoxicity in vitro:
  - Test Type: Chromosome aberration test in vitro
  - Result: negative
  - Remarks: Based on data from similar materials

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

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

- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Inhalation (dust/mist/fume)
  - Method: OECD Test Guideline 474
  - Result: negative
  - Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Rat
  - Application Route: Inhalation (dust/mist/fume)
  - Result: positive
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative

Germ cell mutagenicity - : Weight of evidence does not support classification as a germ
Assessment

cell mutagen.

**Methyl salicylate:**

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

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

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

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

(+) Bornan-2-one:

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
  - Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  - Result: negative

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

**Carcinogenicity**

Not classified based on available information.
Components:

Petrolatum:

<table>
<thead>
<tr>
<th>Species</th>
<th>Species</th>
<th>Application Route</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Exposure time</th>
<th>Result</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Zinc oxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Species</th>
<th>Application Route</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Exposure time</th>
<th>Result</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Ingestion</td>
<td>1 Years</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Methyl salicylate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Species</th>
<th>Application Route</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Exposure time</th>
<th>Result</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Species</th>
<th>Application Route</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Exposure time</th>
<th>Result</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
<td></td>
<td></td>
<td></td>
<td></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
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Zinc oxide:
<table>
<thead>
<tr>
<th>Substance</th>
<th>Effects on fertility</th>
<th>Exposure Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl salicylate</td>
<td>Test Type: Two-generation reproduction toxicity study</td>
<td>Species: Rat</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Rat</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Application Route: inhalation (dust/mist/fume)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 414</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>Test Type: Three-generation reproduction toxicity study</td>
<td>Species: Rat, male and female</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fertility: NOAEL: 4 mg/kg body weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Development</td>
<td>Species: Rat</td>
<td>LOAEL: 1 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Development</td>
<td>Species: Rabbit</td>
<td>LOAEL: 5 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Developmental Toxicity: LOAEL: 5 mg/kg body weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reproductive toxicity - Assessment</td>
<td></td>
<td></td>
<td>Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Rat</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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
Exposure time: 98 w
Target Organs: Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate
SAFETY DATA SHEET
Methyl Salicylate / Diclofenac Formulation

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, 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)): >= 100 mg/l
<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Zinc oxide:</th>
<th>Methyl salicylate:</th>
</tr>
</thead>
</table>
|                          | Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials | Toxicity to fish: LC50: > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials | Toxicity to fish: LC50: (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203 |
|                          | NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
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 | 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 |
|                          | NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials | M-Factor (Acute aquatic toxicity): 1                                                                 | M-Factor (Chronic aquatic toxicity): 1                                                                |
|                          | M-Factor (Chronic toxicity): NOEC (Jordanella floridae (flagfish)): > 0.01 - 0.1 mg/l
Exposure time: 14 Weeks
Remarks: Based on data from similar materials | | |
|                          | NOEC (Ceriodaphnia dubia (water flea)): > 0.01 - 0.1 mg/l
Exposure time: 7 d
Remarks: Based on data from similar materials | | |
|                          | NOEC (Desmodesmus subspicatus (green algae)): 6.25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 | | |
|                          | NOEC (Desmodesmus subspicatus (green algae)): 27 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201 | | |
|                          | EC10 (Pseudomonas putida): 140 mg/l | | |

**Method**

- OECD Test Guideline 201
- OECD Test Guideline 203
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
  - 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Persistence and degradability

Components:

Petrolatum:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 209
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 Sheet.
Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: 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

Sources of key data used to compile the Safety Data Sheet:


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

Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with
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.

SG / EN