SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details

Company : MSD
Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 5
Skin irritation : Category 3
Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms : 

Signal Word : Warning
Hazard Statements : H303 May be harmful if swallowed.
H316 Causes mild skin irritation.
H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
Precautionary Statements

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

Response:
P312 Call a POISON CENTER/ doctor if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
<td>&gt;= 2,5 - &lt; 5</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

Most important symptoms and effects, both acute and delayed : May be harmful if swallowed.
Causes mild skin irritation.
May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Sodium oxides
Metal oxides

Specific extinguishing methods:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

SECTION 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 spills 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.

SECTION 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, vapors 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 labeled containers.
- Store in accordance with the particular national regulations.

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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>CMP (Mist)</td>
<td>5 mg/m³ AR OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³ AR OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³ AR OEL</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>CMP (Fumes)</td>
<td>5 mg/m³ AR OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP (Dust)</td>
<td>10 mg/m³ AR OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Fumes)</td>
<td>10 mg/m³ AR OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung, metal fever</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³ AR OEL</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable particulate matter)</td>
<td>10 mg/m³ AR OEL</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</th>
<th>15307-79-6</th>
<th>TWA</th>
<th>100 µg/m³ (OEB 2)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further information: Skin Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(+)-Bornan-2-one</th>
<th>464-49-3</th>
<th>CMP</th>
<th>2 ppm</th>
<th>AR OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further information: A4 - Not classifiable as a human carcinogen, anosmia, irritation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMP - CPT</td>
<td>4 ppm</td>
<td>AR OEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: A4 - Not classifiable as a human carcinogen, anosmia, irritation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TWA</td>
<td>2 ppm</td>
<td>ACGIH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEL</td>
<td>3 ppm</td>
<td>ACGIH</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Combined particulates and organic vapor type

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Choose gloves to protect hands against chemicals depending on the concentration 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: ointment

**Color**: light red

**Odor**: aromatic
Odor 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
Vapor pressure : No data available
Relative vapor 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
   Autoignition temperature : No data available
   Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
    Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
May be harmful if swallowed.

Product:
- Acute oral toxicity: Acute toxicity estimate: 4.003 mg/kg
  Method: Calculation method
- Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:

Petrolatum:
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
- Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity
  Remarks: Based on data from similar materials

Zinc oxide:
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 5.7 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity
Methyl salicylate:
Acute oral toxicity : LD50 (Rat): 887 mg/kg

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg
LD50 (Mouse): 170 - 389 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg
Application Route: Intravenous
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 judgment
Remarks: Based on data from similar materials
Acute inhalation toxicity : LC50 (Rat): > 0,5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Causes mild skin irritation.

Components:

Petrolatum:
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:

Species : Rabbit
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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials
Zinc oxide:

| Test Type | Maximization Test |
| Routes of exposure | Skin contact |
| Species | Guinea pig |
| Method | OECD Test Guideline 406 |
| Result | negative |

Methyl salicylate:

| Test Type | Local lymph node assay (LLNA) |
| Routes of exposure | Skin contact |
| Species | Mouse |
| Result | negative |

(+) - Bornan-2-one:

| Test Type | Buehler Test |
| Routes of exposure | 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:

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 |

Genotoxicity in vivo:

| 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:

<p>| Test Type | Mammalian erythrocyte micronucleus test (in vivo |</p>
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>positive</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Mouse Lymphoma</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
</tbody>
</table>
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:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Zinc oxide:
Species: Mouse
Application Route: Ingestion
Exposure time: 1 Year
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:

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 fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Skin contact
- Result: negative
- Remarks: Based on data from similar materials

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

- Test Type: Development
- Species: Rabbit
- Application Route: Oral
- Developmental Toxicity: LOAEL: 5 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

Reproductive toxicity - Assessment

(+) - Bornan-2-one:

Effects on fetal development

Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

Components:

(+) - Bornan-2-one:

Assessment
May cause respiratory irritation.
Remarks
Based on data from similar materials

STOT-repeated exposure
May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

Components:

Zinc oxide:

Assessment
No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Sodium [2-[(2,6-dichlorophenyl)aminophenyl]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 y

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 y

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, Diarrhea

(+)-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, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 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)): > 10000 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
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Zinc oxide:

Toxicity to fish: LC50: > 0,1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,136 mg/l
Exposure time: 72 h
NOEC (Pseudokirchneriella subcapitata (green algae)): > 0,01 - 0,1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 1
Toxicity to fish (Chronic toxicity): NOEC (Jordanella floridai (flagfish)): > 0,01 - 0,1 mg/l
Exposure time: 14 Weeks
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): > 0,01 - 0,1 mg/l
Exposure time: 7 d
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity): 1

Methyl salicylate:

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
### Toxicity Data

#### Methyl Salicylate / Diclofenac Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 27 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Desmodesmus subspicatus (green algae)): 6,25 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC10 (Pseudomonas putida): 140 mg/l</td>
<td>16 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 71,9 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 49,2 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0,32 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 80,1 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 - 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>NOEC (Daphnia magna (Water flea)): &gt; 10 - 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 - 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0,32 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 10 - 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 1 - 10 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 - 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
plants

Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 0,01 - 0,1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Petrolatum:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Methyl salicylate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98,4 %
Exposure time: 28 d

(+)-Bornan-2-one:

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Zinc oxide:

Bioaccumulation : Species: Onchorhynchus 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 8.0  Revision Date: 10.10.2020  SDS Number: 657427-00011  Date of last issue: 23.03.2020  Date of first issue: 02.05.2016

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 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
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
AR OEL / CMP: TLV (Threshold Limit Value)
AR OEL / CMP - CPT: STEL (Short Term Limit Value)
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.