SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 6.0  Revision Date: 09/16/2019  SDS Number: 656957-00009  Date of last issue: 04/24/2019
Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation
Other means of identification: No data available

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 1 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements
Hazard pictograms: ❒
Signal Word: Danger
Hazard Statements: H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
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;= 80 - &lt;= 100</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret

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 : Suspected of damaging the unborn child. Causes 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
### SECTION 1. IDENTIFICATION AND references

#### 1.1. Substance/technical name and CAS Number

<table>
<thead>
<tr>
<th>Substance/technical name</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Salicylate / Diclofenac Formulation</td>
<td></td>
</tr>
</tbody>
</table>

#### 1.2.Synonyms

- None known.

#### 1.3. Supplier identification

- Merck

#### 1.4. Other information

- None known.

### SECTION 2. HAZARDS IDENTIFICATION

#### 2.1. Emergency phrases

- Suitable extinguishing media: Water spray
- Unsuitable extinguishing media: None known.
- Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

#### 2.2. Other hazards

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

#### 2.3. 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 3. PREVENTIVE MEASURES

#### 3.1. Protection measures

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

### SECTION 4. FIRST AID MEASURES

#### 4.1. Description

- None known.

### SECTION 5. FIRE FIGHTING MEASURES

#### 5.1. Extinguishment

- 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, protective equipment and emergency procedures:
  - 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 materials for containment and cleaning up

- 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

#### 7.1. Technical measures

- Technical measures:
  - See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

#### 7.2. Local/Total ventilation

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

#### 7.3. Advice on safe handling

- 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.
assessments
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>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fume)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
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<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
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<tr>
<td></td>
<td></td>
<td>STEL (Respirable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Fume)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (to- tal dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Fume)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Respirable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate</td>
<td>15307-79-6</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>(+)-Bornan-2-one</td>
<td>464-49-3</td>
<td>TWA</td>
<td>2 ppm</td>
<td>CA AB OEL</td>
</tr>
</tbody>
</table>

Further information: Skin
Wipe limit 1000 µg/100 cm² Internal
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<table>
<thead>
<tr>
<th>STEL</th>
<th>3 ppm</th>
<th>12 mg/m³</th>
<th>CA AB OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>2 ppm</td>
<td>19 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>STEL</td>
<td>3 ppm</td>
<td>12 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>TWAEV</td>
<td>2 ppm</td>
<td>19 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>STEV</td>
<td>3 ppm</td>
<td>19 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>TWA</td>
<td>2 ppm</td>
<td>2 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>STEL</td>
<td>3 ppm</td>
<td>2 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Personal protective equipment

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

Filter type:
Combined particulates and organic 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
Methyl Salicylate / Diclofenac Formulation

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

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 : No data available
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
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.

SECTION 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: 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 / Diclofenac Formulation

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
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 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
- 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)
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 - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Methyl salicylate:
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Result: negative

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

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Test Type: Mouse Lymphoma Result: negative

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

(+)-Bornan-2-one:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity:
Not classified based on available information.

Components:

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:
Suspected of damaging the unborn child.
**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: Skin contact  
  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

- **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.

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

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

(+)-Boran-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:
(+)-Boran-2-one:

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

STOT-repeated exposure
Causes 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 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 / Diclofenac Formulation**

**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
  - NOAEL: 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

**Methyl salicylate**
- **LC50** (Danio rerio (zebra fish)): > 100 mg/l
- **Exposure time**: 96 h

**Zinc oxide**
- **LC50** (Oncorhynchus mykiss (rainbow trout)): > 0.1 - 1 mg/l
- **Exposure time**: 96 h

## Toxicity to daphnia and other aquatic invertebrates

**Methyl salicylate**
- **EC50** (Daphnia magna (Water flea)): > 10,000 mg/l
- **Exposure time**: 48 h

**Zinc oxide**
- **EC50** (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l
- **Exposure time**: 48 h

## Toxicity to algae/aquatic plants

**Methyl salicylate**
- **NOEL** (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
- **Exposure time**: 72 h

**Zinc oxide**
- **EC50** (Selenastrum capricornutum (green algae)): > 0.1 - 1 mg/l
- **Exposure time**: 96 h

## Chronic toxicity

**Methyl salicylate**
- **NOEC** (Danio rerio (zebra fish)): > 100 mg/l
- **Exposure time**: 96 h
<table>
<thead>
<tr>
<th>Substance: Methyl Salicylate / Diclofenac Formulation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance: Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance: (+)-Bornan-2-one</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>
Toxicity to algae/aquatic plants:
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

- NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

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

Persistence and degradability

Components:

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

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

(+)-Boren-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:
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)
(Zinc oxide)
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)
(Zinc oxide)
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)()
Class : 9
Packing group : III
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 6.0  Revision Date: 09/16/2019  SDS Number: 656957-00009  Date of last issue: 04/24/2019  Date of first issue: 05/02/2016

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.

Domestic regulation

TDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide) (Zinc oxide)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide)(Zinc oxide)

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.

SECTION 15. REGULATORY INFORMATION

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Quebec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA BC OEL / STEL : short-term exposure limit
CA QC OEL / TWAEV : Time-weighted average exposure value
CA QC OEL / STEV : Short-term exposure value
AICS - Australian Inventory of Chemical Substances; 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 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; ERG - Emergency Response Guide; 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 Chemicals 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 09/16/2019

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.

CA / Z8