SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

SECTION 1. IDENTIFICATION

Product name: Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
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
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage: Category 1
Skin sensitization: Category 1
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:
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
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 or spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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;= 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; 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>(+)-Boman-2-one</td>
<td>464-49-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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.
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In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

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 an allergic skin reaction. Causes serious eye damage. 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

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

Unsuitable extinguishing media: None known.

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

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

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 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.

**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.
Do not get in 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
Keep container tightly closed.
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 locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
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 (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Res-</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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TWA (Dust) 5 mg/m³ NIOSH REL
TWA (Fumes) 5 mg/m³ NIOSH REL
TWA (Fumes) 10 mg/m³ NIOSH REL
C (Dust) 15 mg/m³ NIOSH REL
TWA (Fumes) 5 mg/m³ OSHA Z-1
TWA (total dust) 15 mg/m³ OSHA Z-1
TWA (respirable fraction) 5 mg/m³ OSHA Z-1
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate 15307-79-6 TWA 100 µg/m³ (OEB 2) Internal
Further information: Skin
(+) Broman-2-one 464-49-3 TWA 2 mg/m³ OSHA Z-1
TWA 2 ppm ACGIH
STEL 3 ppm ACGIH
TWA 2 mg/m³ NIOSH REL

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

Personal protective equipment

Respiratory protection: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield
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. Contaminated work clothing should not be allowed out of the workplace. 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
### SECTION 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.

### 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: 4,005 mg/kg
Method: Calculation method

**Acute inhalation toxicity**

Acute toxicity estimate: 50.01 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): 890 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
Causes serious eye damage.

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 : Tissue Culture
Method : OECD Test Guideline 491
Result : Irreversible effects on the eye
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Date of first issue: 05/02/2016

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
May cause an allergic skin reaction.

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 : positive
Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

(+) -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)
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)
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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 Years
Result: negative
Remarks: Based on data from similar materials

Methyl salicylate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
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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: Ingestion
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: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Test Type: Embryo-fetal development
Species: Monkey
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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: Suspected of damaging the unborn child.

**(+-) 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**
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
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Revision Date: 04/04/2023
SDS Number: 656972-00017
Date of last issue: 10/01/2022
Date of first issue: 05/02/2016

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:
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<tr>
<td>8.3</td>
<td>04/04/2023</td>
<td>656972-00017</td>
<td>10/01/2022</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

### 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
  - Method: OECD Test Guideline 203
  - 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

#### Toxicity to fish (Chronic toxicity)

- **NOEC (Jordanella floridae (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

### Methyl salicylate:

#### Toxicity to fish

- **LC₅₀ (Pimephales promelas (fathead minnow)):** > 10 - 100 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials

#### Toxicity to daphnia and other aquatic invertebrates

- **EC₅₀ (Daphnia magna (Water flea)):** > 10 - 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 1.6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 0.79 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC10 (Pseudomonas putida): 140 mg/l
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
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: 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
octanol/water

**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. Do not dispose of waste into sewer.
- 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
- **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

49 CFR
UN/ID/NA 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 : CLASS 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide, Sodium [2-[(2,6-
dichlorophenyl)amino]phenyl]acetate)
Remarks : Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

<table>
<thead>
<tr>
<th>Component</th>
<th>U.S. EPA Registry Number</th>
<th>Reporting Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
<td>&gt;= 10 - &lt; 20 %</td>
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</tbody>
</table>

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Component</th>
<th>U.S. EPA Registry Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>1314-13-2</td>
</tr>
<tr>
<td>Methyl salicylate</td>
<td>119-36-8</td>
</tr>
</tbody>
</table>
California List of Hazardous Substances

- Petrolatum: 8009-03-8
- Zinc oxide: 1314-13-2
- Methyl salicylate: 119-36-8
- (+)-Bornan-2-one: 464-49-3

California Permissible Exposure Limits for Chemical Contaminants

- Petrolatum: 8009-03-8
- Zinc oxide: 1314-13-2
- (+)-Bornan-2-one: 464-49-3

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

NFPA 704:
- Flammability
- Health
- Instability

HMIS® IV:

- HEALTH: *
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

Version 8.3  Revision Date: 04/04/2023  SDS Number: 656972-00017  Date of last issue: 10/01/2022

Date of first issue: 05/02/2016

NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday

NIOSH REL / C : Ceiling value not be exceeded at any time.

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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


Revision Date : 04/04/2023

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.
# SAFETY DATA SHEET

Methyl Salicylate / Diclofenac Formulation

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US / Z8