

# SAFETY DATA SHEET



## Methyl Salicylate / Diclofenac Formulation

Version  
11.0

Revision Date:  
14.04.2025

SDS Number:  
657427-00019

Date of last issue: 30.09.2023  
Date of first issue: 02.05.2016

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### SECTION 1. 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

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Category 3

Serious eye damage/eye  
irritation : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 2

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

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|                          |   |  |
|--------------------------|---|--|
| Hazard pictograms        | : |  |
| Signal Word              | : | Danger   |
| Hazard Statements        | : | <p>H303 May be harmful if swallowed.<br/>H316 Causes mild skin irritation.<br/>H317 May cause an allergic skin reaction.<br/>H318 Causes serious eye damage.<br/>H361d Suspected of damaging the unborn child.<br/>H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.<br/>H411 Toxic to aquatic life with long lasting effects.</p>  |
| Precautionary Statements | : | <p><b>Prevention:</b><br/>P201 Obtain special instructions before use.<br/>P202 Do not handle until all safety precautions have been read and understood.<br/>P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.<br/>P272 Contaminated work clothing should not be allowed out of the workplace.<br/>P273 Avoid release to the environment.<br/>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p><b>Response:</b><br/>P302 + P352 IF ON SKIN: Wash with plenty of water.<br/>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/ doctor.<br/>P312 Call a POISON CENTER/ doctor if you feel unwell.<br/>P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.<br/>P362 + P364 Take off contaminated clothing and wash it before reuse.<br/>P391 Collect spillage.</p> <p><b>Storage:</b><br/>P405 Store locked up.</p> <p><b>Disposal:</b><br/>P501 Dispose of contents/ container to an approved waste disposal plant.</p> |

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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|                 |                              |                             |   |
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|-----------------|------------------------------|-----------------------------|---|

**Components**

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

**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.

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 be harmful if swallowed.  
Causes mild skin irritation.  
May cause an allergic skin reaction.  
Causes serious eye damage.  
Suspected of damaging the unborn child.  
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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

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|  |   |
|--|---|
| Hazardous combustion products                  | : Carbon oxides<br>Chlorine compounds<br>Nitrogen oxides (NOx)<br>Sodium oxides   |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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## SECTION 6. ACCIDENTAL RELEASE MEASURES

|   |   |
|---|---|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

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## 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.<br>Avoid breathing dust, fume, gas, mist, vapors or spray.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the |

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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

| Components  | CAS-No.    | Value type (Form of exposure)                                    | Control parameters / Permissible concentration | Basis    |
|---|------------|--|--|----------|
| Petrolatum  | 8009-03-8  | CMP (Mist)   | 5 mg/m <sup>3</sup>                            | AR OEL   |
|   |            | CMP - CPT (Mist)   | 10 mg/m <sup>3</sup>                           | AR OEL   |
|   |            | TWA (Inhalable particulate matter)                               | 5 mg/m <sup>3</sup>                            | ACGIH    |
| Zinc oxide  | 1314-13-2  | CMP (Fumes)  | 5 mg/m <sup>3</sup>                            | AR OEL   |
|   |            | CMP (Dust)   | 10 mg/m <sup>3</sup>                           | AR OEL   |
|   |            | CMP - CPT (Fumes)  | 10 mg/m <sup>3</sup>                           | AR OEL   |
|   |            | TWA (Respirable particulate matter)                              | 2 mg/m <sup>3</sup>                            | ACGIH    |
|   |            | STEL (Respirable particulate matter)                             | 10 mg/m <sup>3</sup>                           | ACGIH    |
|   |            | TWA  | 100 µg/m <sup>3</sup> (OEB 2)                  | Internal |
| Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate | 15307-79-6 | Further information: Skin  |  |          |
|   |            | 464-49-3   | CMP  | 2 ppm    |
|   |            | Further information: A4 - Not classifiable as a human carcinogen |  |          |
|   |            | CMP - CPT  | 4 ppm  | AR OEL   |
| (+)-Bornan-2-one                                    |            | Further information: A4 - Not classifiable as a human carcinogen |  |          |
|   |            | TWA  | 2 ppm  | ACGIH    |
|   |            | STEL   | 3 ppm  | ACGIH    |

### Engineering measures

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

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Date of first issue: 02.05.2016**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:<br>Chemical resistant goggles must be worn.<br>If splashes are likely to occur, wear:<br>Face-shield  |
| Skin and body protection | : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.<br>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.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>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 |

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|  |  |
|--|--|
| 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 characteristics                         |  |
| Particle size                                    | : No data available  |

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## 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. |

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Skin contact

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exposure Ingestion  
Eye contact

### Acute toxicity

May be harmful if swallowed.

### Product:

|                           |   |  |
|---------------------------|---|--|
| Acute oral toxicity       | : | Acute toxicity estimate: 4.005 mg/kg<br>Method: Calculation method   |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 10 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |

### Components:

#### **Petrolatum:**

|                       |   |  |
|-----------------------|---|--|
| Acute oral toxicity   | : | LD50 (Rat): > 5.000 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: Based on data from similar materials  |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity<br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity |
| Acute dermal toxicity     | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>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<br>LD50 (Mouse): 170 - 389 mg/kg  |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 97 - 161 mg/kg<br>Application Route: Intravenous |

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LD50 (Mouse): 92 - 147 mg/kg  
Application Route: Intravenous

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

|                           |  |
|---------------------------|--|
| Acute oral toxicity       | : LD50 (Mouse): > 300 - 2.000 mg/kg<br>Remarks: Based on data from similar materials   |
|                           | Acute toxicity estimate (Humans): > 50 - 500 mg/kg<br>Method: Expert judgment<br>Remarks: Based on data from similar materials |
| Acute inhalation toxicity | : LC50 (Rat): > 0,5 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: Based on data from similar materials  |
| Acute dermal toxicity     | : LD50 (Rat): > 2.000 mg/kg<br>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:

|        |              |
|--------|--------------|
| 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.

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### 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 |

#### **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                |

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

**Zinc oxide:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: equivocal<br><br>Test Type: Chromosome aberration test in vitro<br>Result: equivocal |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: inhalation (dust/mist/fume)<br>Method: OECD Test Guideline 474<br>Result: negative  |

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|--|---|---|
|  |   | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Application Route: inhalation (dust/mist/fume)<br>Result: positive                                  |
|  |   | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Method: OECD Test Guideline 474<br>Result: negative               |
| Germ cell mutagenicity - Assessment  | : | Weight of evidence does not support classification as a germ cell mutagen.  |
| <b>Methyl salicylate:</b><br>Genotoxicity in vitro                                   | : | Test Type: Chromosome aberration test in vitro<br>Result: negative  |
|  |   | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
| <b>Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:</b><br>Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
|  |   | Test Type: Mouse Lymphoma<br>Result: negative   |
| Genotoxicity in vivo   | : | Test Type: Chromosomal aberration<br>Species: CHO<br>Result: negative   |
| <b>(+)-Bornan-2-one:</b><br>Genotoxicity in vitro                                    | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials   |
|  |   | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br>Remarks: Based on data from similar materials   |
|  |   | Test Type: Chromosome aberration test in vitro<br>Result: negative  |
| Genotoxicity in vivo   | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |

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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 |

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:****Petrolatum:**

|                      |   |   |
|----------------------|---|---|
| Effects on fertility | : | Test Type: Reproduction/Developmental toxicity screening test<br>Species: Rat |
|----------------------|---|---|

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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

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

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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

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

### Components:

#### Zinc oxide:

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

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

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Petrolatum:

Species : Rat  
NOAEL : 5.000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

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### 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 |
|-----------|---|--|

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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Petrolatum:**

|  |   |
|--|---|
| Toxicity to fish   | : <p>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l<br/>Exposure time: 96 h<br/>Test substance: Water Accommodated Fraction<br/>Method: OECD Test Guideline 203<br/>Remarks: Based on data from similar materials</p>           |
| Toxicity to daphnia and other aquatic invertebrates                    | : <p>EC50 (Daphnia magna (Water flea)): &gt; 10.000 mg/l<br/>Exposure time: 48 h<br/>Test substance: Water Accommodated Fraction<br/>Remarks: Based on data from similar materials</p>  |
| Toxicity to algae/aquatic plants                                       | : <p>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l<br/>Exposure time: 72 h<br/>Test substance: Water Accommodated Fraction<br/>Method: OECD Test Guideline 201<br/>Remarks: Based on data from similar materials</p> |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : <p>NOEC (Daphnia magna (Water flea)): 10 mg/l<br/>Exposure time: 21 d<br/>Test substance: Water Accommodated Fraction<br/>Remarks: Based on data from similar materials</p>   |

##### **Zinc oxide:**

|  |  |
|--|--|
| Toxicity to fish   | : <p>LC50 : &gt; 0,1 - 1 mg/l<br/>Exposure time: 96 h<br/>Remarks: Based on data from similar materials</p>  |
| Toxicity to algae/aquatic plants                                       | : <p>ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,136 mg/l<br/>Exposure time: 72 h<br/><br/>NOEC (Pseudokirchneriella subcapitata (green algae)): &gt; 0,01 - 0,1 mg/l<br/>Exposure time: 72 h<br/>Remarks: Based on data from similar materials</p> |
| M-Factor (Acute aquatic toxicity)                                      | : <p>1</p>   |
| Toxicity to fish (Chronic toxicity)                                    | : <p>NOEC (Jordanella floridae (flagfish)): &gt; 0,01 - 0,1 mg/l<br/>Exposure time: 14 Weeks<br/>Remarks: Based on data from similar materials</p>   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : <p>NOEC (Ceriodaphnia dubia (water flea)): &gt; 0,01 - 0,1 mg/l<br/>Exposure time: 7 d<br/>Remarks: Based on data from similar materials</p>   |

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M-Factor (Chronic aquatic toxicity) : 1

### 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  
Remarks: Based on data from similar materials

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

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|   |   |  |
|---|---|--|
|   |   | Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: Based on data from similar materials  |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: Based on data from similar materials                        |
| Toxicity to algae/aquatic plants                    | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials    |
|   |   | NOEC (Pseudokirchneriella subcapitata (green algae)): > 0,01 - 0,1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms                          | : | EC50: > 100 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209<br>Remarks: Based on data from similar materials   |

**Persistence and degradability****Components:****Petrolatum:**

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

**Methyl salicylate:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 98,4 %<br>Exposure time: 28 d |
|------------------|---|---|

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

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Method: OECD Test Guideline 301F<br>Remarks: Based on data from similar materials |
|------------------|---|---|

**Bioaccumulative potential****Components:****Zinc oxide:**

|                 |   |  |
|-----------------|---|--|
| Bioaccumulation | : | Species: Oncorhynchus mykiss (rainbow trout) |
|-----------------|---|--|

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Bioconcentration factor (BCF): 78 - 2.060

### Methyl salicylate:

Partition coefficient: n-octanol/water : log Pow: 2,55

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

Partition coefficient: n-octanol/water : log Pow: 4,51

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

Partition coefficient: n-octanol/water : log Pow: 2,3

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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  
Environmentally hazardous : yes

#### 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) : 956

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ger aircraft)

Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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## 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

### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

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Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

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|                    |   |
|--------------------|---|
| 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)           |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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 - 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; 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; 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; WHMIS - Workplace Hazardous Materials Information System

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.

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