

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Methyl Salicylate / Diclofenac Formulation

Version 10.1      Revision Date: 30.09.2023      SDS Number: 657438-00018      Date of last issue: 04.04.2023  
Date of first issue: 02.05.2016

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Methyl Salicylate / Diclofenac Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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- Signal word : Danger
- Hazard statements : H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H411 Toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
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.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

### Hazardous components which must be listed on the label:

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

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Zinc oxide	1314-13-2	Aquatic Acute 1;	>= 10 - < 20

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	215-222-5 030-013-00-7	H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Methyl salicylate	119-36-8 204-317-7 607-749-00-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1B; H317 Repr. 2; H361d Aquatic Chronic 3; H412 <hr/> Acute toxicity estimate  Acute oral toxicity: 890 mg/kg	>= 3 - < 10
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6 239-346-4	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) Aquatic Chronic 2; H411	>= 1 - < 2.5
(+)-Bornan-2-one	464-49-3 207-355-2	Flam. Sol. 2; H228 Acute Tox. 3; H301 Acute Tox. 3; H331 Eye Irrit. 2; H319 STOT SE 3; H335 Aquatic Chronic 2; H411 <hr/> Acute toxicity estimate  Acute oral toxicity: > 50 - 500 mg/kg Acute inhalation toxicity (dust/mist): 0.5001 mg/l	>= 1 - < 2.5

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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 : 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
- 

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing : None known.
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### 5.2 Special hazards arising from the substance or mixture

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

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

### 5.3 Advice for firefighters

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

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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust, fume, gas, mist, vapours or spray.  
Do not swallow.  
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.
- 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.

#### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

#### 7.3 Specific end use(s)

- Specific use(s) : No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m <sup>3</sup>	IE OEL
Zinc oxide	1314-13-2	OELV - 8 hrs	2 mg/m <sup>3</sup>	IE OEL

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		(TWA) (fume, respirable)		
		OELV - 15 min (STEL) (Fumes)	10 mg/m <sup>3</sup>	IE OEL
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: Skin				
(+)-Bornan-2-one	464-49-3	OELV - 15 min (STEL)	3 ppm 18 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA)	2 ppm 12 mg/m <sup>3</sup>	IE OEL

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value	
Methyl salicylate	Workers	Inhalation	Long-term systemic effects	17.5 mg/m <sup>3</sup>	
	Workers	Inhalation	Acute systemic effects	285 mg/m <sup>3</sup>	
	Workers	Skin contact	Long-term systemic effects	6 mg/kg bw/day	
	Consumers	Inhalation	Long-term systemic effects	4 mg/m <sup>3</sup>	
	Consumers	Inhalation	Acute systemic effects	213 mg/m <sup>3</sup>	
	Consumers	Skin contact	Long-term systemic effects	3 mg/kg bw/day	
	Consumers	Ingestion	Long-term systemic effects	1 mg/kg bw/day	
	Consumers	Ingestion	Acute systemic effects	5 mg/kg bw/day	
	Zinc oxide	Workers	Inhalation	Long-term systemic effects	5 mg/m <sup>3</sup>
Workers		Inhalation	Long-term local effects	0.5 mg/m <sup>3</sup>	
Workers		Skin contact	Long-term systemic effects	83 mg/kg bw/day	
Consumers		Inhalation	Long-term systemic effects	2.5 mg/m <sup>3</sup>	
Consumers		Skin contact	Long-term systemic effects	83 mg/kg bw/day	
Consumers		Ingestion	Long-term systemic effects	0.83 mg/kg bw/day	
(+) -Bornan-2-one		Workers	Inhalation	Long-term systemic effects	17.632 mg/m <sup>3</sup>
		Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
		Consumers	Inhalation	Long-term systemic	4.348 mg/m <sup>3</sup>

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			effects	
	Consumers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Methyl salicylate	Fresh water	20 µg/l
	Marine water	2 µg/l
	Intermittent use/release	200 µg/l
	Sewage treatment plant	140 mg/l
	Fresh water sediment	0.33 mg/kg
	Marine sediment	0.033 mg/kg
	Soil	0.35 mg/kg
Petrolatum	Oral (Secondary Poisoning)	9.33 mg/kg food
Zinc oxide	Fresh water	20.6 µg/l
	Marine water	6.1 µg/l
	Sewage treatment plant	100 µg/l
	Fresh water sediment	117.8 mg/kg dry weight (d.w.)
	Marine sediment	56.5 mg/kg dry weight (d.w.)
	Soil	35.6 mg/kg dry weight (d.w.)
(+) -Bornan-2-one	Fresh water	1.71 µg/l
	Freshwater - intermittent	17.1 µg/l
	Marine water	0.171 µg/l
	Marine water - intermittent	1.71 µg/l
	Sewage treatment plant	1 mg/l
	Fresh water sediment	0.139 mg/kg dry weight (d.w.)
	Marine sediment	0.017 mg/kg dry weight (d.w.)
	Soil	0.013 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### Engineering measures

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

#### Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:  
Chemical resistant goggles must be worn.  
If splashes are likely to occur, wear:  
Face-shield  
Equipment should conform to I.S. EN 166

Hand protection

Material : Chemical-resistant gloves



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Remarks	: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
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).
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387
Filter type	: Combined particulates and organic vapour type (A-P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	: ointment
Colour	: light red
Odour	: aromatic
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: 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
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available

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pH : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### Components:

##### **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

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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 judgement  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 0.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **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:**

#### **Zinc oxide:**

Species : Rabbit  
Method : OECD Test Guideline 405

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Result : No eye irritation

### **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 sensitisation**

#### **Skin sensitisation**

May cause an allergic skin reaction.

#### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### **Zinc oxide:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

#### **Methyl salicylate:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : positive

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

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

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Zinc oxide:

- |                                    |   |   |
|------------------------------------|---|---|
| Genotoxicity in vitro              | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
|                                    |   | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: equivocal   |
|                                    |   | 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 |
|                                    |   | 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.  |

#### Methyl salicylate:

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

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

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

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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:**

#### **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

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### **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:**

#### **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 foetal development : Test Type: Embryo-foetal 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 foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive  
Remarks: Based on data from similar materials

Test Type: Embryo-foetal 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.



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

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

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

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

Effects on foetal development : Test Type: Embryo-foetal 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 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.

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### Repeated dose toxicity

#### Components:

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

Species : Rat, male  
NOAEL : 0.0015 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 3 Months  
Method : OECD Test Guideline 413

##### **Methyl salicylate:**

Species : Rat  
NOAEL : 50 mg/kg  
LOAEL : 250 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

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

Species : Rat  
LOAEL : 0.25 mg/kg  
Application Route : Oral  
Exposure time : 98 w  
Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog  
LOAEL : 1 mg/kg  
Application Route : Oral  
Exposure time : 12 w  
Target Organs : Blood

Species : Baboon  
NOAEL : 0.5 mg/kg  
LOAEL : 5 mg/kg  
Application Route : Oral  
Exposure time : 52 w  
Target Organs : Gastrointestinal tract, Blood  
Symptoms : constipation, Diarrhoea

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

Species : Rat  
NOAEL : > 200 mg/kg  
Application Route : Skin contact  
Exposure time : 13 Weeks  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

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### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### Experience with human exposure

##### Components:

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

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

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## SECTION 12: Ecological information

### 12.1 Toxicity

##### Components:

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

Toxicity to fish : LC50 : > 0.1 - 1 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l  
Exposure time: 72 h  
NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC: > 0.01 - 0.1 mg/l  
Exposure time: 14 Weeks  
Species: Jordanella floridae (flagfish)  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.01 - 0.1 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)  
Remarks: Based on data from similar materials

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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: 0.32 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

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### (+)-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

## 12.2 Persistence and degradability

### Components:

#### 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

## 12.3 Bioaccumulative potential

### Components:

#### Zinc oxide:

- Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)  
Bioconcentration factor (BCF): 78 - 2,060

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### 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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

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**ADN** : UN 3077  
**ADR** : UN 3077  
**RID** : UN 3077  
**IMDG** : UN 3077  
**IATA** : UN 3077

### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)  
**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)  
**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)  
**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)  
**IATA** : Environmentally hazardous substance, solid, n.o.s.  
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 9	

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9  
**ADR**  
Packing group : III  
Classification Code : M7

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Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

### RID

Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

## 14.6 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.

## 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.



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### SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75  
If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
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#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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### SECTION 16: Other information

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

#### Full text of H-Statements

H228 : Flammable solid.  
H301 : Toxic if swallowed.  
H302 : Harmful if swallowed.  
H315 : Causes skin irritation.  
H317 : May cause an allergic skin reaction.  
H318 : Causes serious eye damage.  
H319 : Causes serious eye irritation.  
H331 : Toxic if inhaled.  
H335 : May cause respiratory irritation.  
H361d : Suspected of damaging the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.  
H411 : Toxic to aquatic life with long lasting effects.  
H412 : Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Dam. : Serious eye damage  
Eye Irrit. : Eye irritation  
Flam. Sol. : Flammable solids  
Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
IE OEL : List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)  
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration

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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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 2	H361d
STOT RE 2	H373
Aquatic Chronic 2	H411

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

IE / EN