

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 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
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

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 :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

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.

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	1314-13-2 215-222-5 030-013-00-7	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 10 - < 20
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	>= 3 - < 10

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

		Aquatic Chronic 3; H412	
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	>= 1 - < 2,5

For explanation of abbreviations see section 16.

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.

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

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 (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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 (NO_x)
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.

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).

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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.

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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

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
Zinc oxide	1314-13-2	OEL-RL (respirable fraction, fume)	4 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
		OEL- RL STEL/C (respirable fraction, fume)	20 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
(+)-Bornan-2-one	464-49-3	OEL-RL	4 ppm	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
		OEL- RL STEL/C	6 ppm	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

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 ³
	Workers	Inhalation	Acute systemic effects	285 mg/m ³
	Workers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4 mg/m ³
	Consumers	Inhalation	Acute systemic effects	213 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	3 mg/kg bw/day

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

	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 ³
	Workers	Inhalation	Long-term local effects	0,5 mg/m ³
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	2,5 mg/m ³
	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 ³
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4,348 mg/m ³
	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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

		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
- Hand protection
- Material : Chemical-resistant gloves
- 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.
- Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : ointment
 Colour : light red
 Odour : aromatic
 Odour 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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

Flammability (solid, gas)	:	Not classified as a flammability hazard
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	No data available

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.
---------------------	---	-------------

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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 : LD50 (Rat): 97 - 161 mg/kg

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

administration) Application Route: Intravenous

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

(+)-Bornan-2-one:

Acute oral toxicity : LD50 (Mouse): > 300 - 2.000 mg/kg
Remarks: Based on data from similar materials

Acute toxicity estimate (Humans): > 50 - 500 mg/kg
Method: Expert 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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

Method : OECD Test Guideline 405
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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

Germ cell mutagenicity

Not classified based on available information.

Components:

Zinc oxide:

- | | | |
|------------------------------------|---|--|
| Genotoxicity in vitro | : | <p>Test Type: Bacterial reverse mutation assay (AMES)
Result: negative</p> <p>Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: equivocal</p> <p>Test Type: Chromosome aberration test in vitro
Result: equivocal</p> |
| Genotoxicity in vivo | : | <p>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: inhalation (dust/mist/fume)
Method: OECD Test Guideline 474
Result: negative</p> <p>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: inhalation (dust/mist/fume)
Result: positive</p> <p>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative</p> |
| Germ cell mutagenicity- Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

Methyl salicylate:

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

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

- | | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | <p>Test Type: Bacterial reverse mutation assay (AMES)
Result: negative</p> <p>Test Type: Mouse Lymphoma
Result: negative</p> |
| Genotoxicity in vivo | : | Test Type: Chromosomal aberration |

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

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

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

Species : Rat
Application Route : Oral
Exposure time : 2 Years

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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.

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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.

Repeated dose toxicity**Components:****Zinc oxide:**

Species : Rat, male
NOAEL : 0,0015 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 3 Months

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

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.

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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

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
- 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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

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

(+)-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

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
Date of first issue: 02.05.2016

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

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 Other adverse effects**Product:**

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

Endocrine disrupting potential : 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 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.

SECTION 14: Transport information

14.1 UN number

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)

Methyl Salicylate / Diclofenac Formulation

Version 10.1 Revision Date: 30.09.2023 SDS Number: 656973-00018 Date of last issue: 04.04.2023
 Date of first issue: 02.05.2016

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 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
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	

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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.

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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
 ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
 ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
 ZA OEL / OEL- RL STEL/C : Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

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 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; 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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
10.1	30.09.2023	656973-00018	Date of first issue: 02.05.2016

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.

ZA / EN