

## Methyl Salicylate / Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 11.2 2023/09/30 656966-00018 Date of first issue: 2016/05/02

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Methyl Salicylate / Diclofenac Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irri-

tation

Category 1

Skin sensitisation : 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

Hazard pictograms





Signal word : Danger



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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 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or

repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

P391 Collect spillage.

### Storage:

P405 Store locked up.

### Disposal:

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

#### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Petrolatum	8009-03-8	>= 80 - < 90	
Zinc oxide	1314-13-2	>= 10 - < 20	1-561



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Methyl salicylate	119-36-8	3	3-1585
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	>= 1 - < 2.5	3-3082
(+)-Bornan-2-one	464-49-3	>= 1 - < 2.5	4-308, 4-601

### 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 contact, immediately flush skin with plenty of water. In case of skin contact

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, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

Causes serious eye damage.

delayed

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).

Treat symptomatically and supportively.

Notes to physician

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

ucts

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-Carbon oxides

Chlorine compounds

Nitrogen oxides (NOx)



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Sodium oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

so.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

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 as-

sessment

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.

Avoidance of contact : Oxidizing agents



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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.

**Storage** 

Conditions for safe storage : Keep in properly labelled 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

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Petrolatum	8009-03-8	OEL-M (Mist)	3 mg/m3	JP OEL JSOH
	Further information: Group 1: carcinogenic to humans			
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH
Zinc oxide	1314-13-2	OEL-M	0.5 mg/m3	JP OEL JSOH
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
		STEL (Respirable particulate matter)	10 mg/m3	ACGIH
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			
(+)-Bornan-2-one	464-49-3	TWA	2 ppm	ACGIH
		STEL	3 ppm	ACGIH

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.



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Minimize workplace exposure concentrations.

Personal protective equipment

If adequate local exhaust ventilation is not available or expo-Respiratory protection

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type 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.

Eye protection Wear the following personal protective equipment:

Chemical resistant goggles must be worn.

If splashes are likely to occur, wear:

Face-shield

Skin and body protection Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state ointment

Colour light red

Odour aromatic

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not classified as a flammability hazard

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit



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Lower explosion limit / Lower flammability limit

No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : 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

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : 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

### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

ions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : Oxidizing the composition : No haz

products

No hazardous decomposition products are known.



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#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 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:** 

Petrolatum:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: Based on data from similar materials

Zinc oxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.7 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion 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:



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Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg

LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 97 - 161 mg/kg

Application Route: Intravenous

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

(+)-Bornan-2-one:

Acute oral toxicity : LD50 (Mouse): > 300 - 2,000 mg/kg

Remarks: Based on data from similar materials

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

Method: Expert 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:**

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



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(+)-Bornan-2-one:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye damage.

**Components:** 

Petrolatum:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Zinc oxide:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Methyl salicylate:

Species : Tissue Culture

Method : OECD Test Guideline 491

Result : Irreversible effects on the eye

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:** 

Petrolatum:

Test Type : Buehler Test Exposure routes : Skin contact



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Species : Guinea pig Result : negative

Remarks : Based on data from similar materials

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

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Petrolatum:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Zinc oxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative



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Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: equivocal

Test Type: Chromosome aberration test in vitro

Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: inhalation (dust/mist/fume)

Method: OECD Test Guideline 474

Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: inhalation (dust/mist/fume)

Result: positive

Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Methyl salicylate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: CHO Result: negative

(+)-Bornan-2-one:



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Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

### **Components:**

#### Petrolatum:

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

### Zinc oxide:

Species : Mouse
Application Route : Ingestion
Exposure time : 1 Years
Result : negative

Remarks : Based on data from similar materials

### Methyl salicylate:

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



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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:**

Petrolatum:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

ment

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



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Effects on foetal develop-

ment

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 - As-

sessment

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 foetal develop-

ment

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 - As-

sessment

Suspected of damaging the unborn child.

(+)-Bornan-2-one:

Effects on foetal develop-

ment

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



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#### 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 concentra-

tions 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 yr

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: RatNOAEL: 50 mg/kgLOAEL: 250 mg/kgApplication Route: IngestionExposure 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



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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

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Petrolatum:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

NOEL (Pseudokirchneriella subcapitata (green algae)): >=

100 mg/l



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Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Zinc oxide:

Toxicity to fish : LC50 :> 0.1 - 1 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136

mg/l

Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01

- 0.1 mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

icity)

: 1

Toxicity to fish (Chronic tox-

icity)

NOEC (Jordanella floridae (flagfish)): > 0.01 - 0.1 mg/l

Exposure time: 14 Weeks

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): > 0.01 - 0.1 mg/l

Exposure time: 7 d

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



## Methyl Salicylate / Diclofenac Formulation

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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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

(+)-Bornan-2-one:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 -

10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials



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NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01

- 0.1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Persistence and degradability

**Components:** 

Petrolatum:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

Methyl salicylate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.4 % Exposure time: 28 d

(+)-Bornan-2-one:

Biodegradability : Result: Readily biodegradable.

Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Zinc oxide:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)

Bioconcentration factor (BCF): 78 - 2,060

Methyl salicylate:

Partition coefficient: n- :

octanol/water

log Pow: 2.55

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

Partition coefficient: n-

: log Pow: 4.51

octanol/water

(+)-Bornan-2-one:

Partition coefficient: n- : log Pow: 2.3



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octanol/water

Mobility in soil No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 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 Ш 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 Ш

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

956

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956



## Methyl Salicylate / Diclofenac Formulation

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(Zinc oxide, Sodium [2-[(2,6-

dichlorophenyl)aminolphenyllacetate)

Class Packing group Ш Labels 9 **EmS Code** F-A, S-F Marine pollutant

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

yes

Not applicable for product as supplied.

### **National Regulations**

Refer to section 15 for specific national regulation.

### 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.

**ERG Code** 171

#### 15. REGULATORY INFORMATION

#### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

### Industrial Safety and Health Law

### **Harmful Substances Prohibited from Manufacture**

Not applicable

### **Harmful Substances Required Permission for Manufacture**

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable

### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)



## Methyl Salicylate / Diclofenac Formulation

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Chemical name	Concentration (%)	Remarks
Petrolatum	>=80 - <90	From April 1st, 2026
Zinc oxide	>=10 - <20	-
Camphor	>=1 - <10	-

### **Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Petrolatum	From April 1st, 2026
Zinc oxide	-
Camphor	-

#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

### **Ordinance on Prevention of Lead Poisoning**

Not applicable

### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### **Poisonous and Deleterious Substances Control Law**

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

### **Class I Designated Chemical Substances**

Chemical name	Administration number	Concentration (%)
Methyl salicylate	624	3.0

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)



## Methyl Salicylate / Diclofenac Formulation

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#### Marine Pollution and Sea Disaster Prevention etc Law

**Bulk transportation** : Not classified as noxious liquid substance

: Classified as marine pollutant Pack transportation

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

not determined **AICS** 

DSL not determined

**IECSC** not determined

#### **16. OTHER INFORMATION**

#### **Further information**

Sheet

Sources of key data used to

compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Date format : yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH Japan. The Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average ACGIH / STEL Short-term exposure limit

Occupational Exposure Limit-Mean JP OEL JSOH / OEL-M

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



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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.

JP / EN