

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	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 irritation : 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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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 reuse.
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	1-561

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

Methyl salicylate	119-36-8	3	3-1585
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	$\geq 1 - < 2.5$	3-3082
(+)-Bornan-2-one	464-49-3	$\geq 1 - < 10$	4-308, 4-601

4. FIRST AID MEASURES

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: May cause an allergic skin reaction. Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
-

7. HANDLING AND STORAGE**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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

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.

Avoidance of contact : Oxidizing agents
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 / Concentration standard / Permissible concentration	Basis
Petrolatum	8009-03-8	OEL-M (Mist)	3 mg/m ³	JP OEL JSOH
	Further information: Group 1: carcinogenic to humans			
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
Zinc oxide	1314-13-2	8h-OEL-M (As respiratory particles)	0.1 mg/m ³	JP ISHL OEL 577-2(2)
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH
		STEL (Respirable particulate matter)	10 mg/m ³	ACGIH

Methyl Salicylate / Diclofenac Formulation

Version 13.0 Revision Date: 2024/09/28 SDS Number: 656966-00020 Date of last issue: 2024/04/06
 Date of first issue: 2016/05/02

Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
(+)-Bornan-2-one	464-49-3	8h-OEL-M	2 ppm	JP ISHL OEL 577-2(2)
		TWA	2 ppm	ACGIH
		STEL	3 ppm	ACGIH

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

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

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.

Impermeable protective gloves

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

Methyl Salicylate / Diclofenac Formulation

Version 13.0	Revision Date: 2024/09/28	SDS Number: 656966-00020	Date of last issue: 2024/04/06 Date of first issue: 2016/05/02
-----------------	------------------------------	-----------------------------	---

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 / Upper flammability limit	:	No data available
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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

	Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

Methyl salicylate:

Acute oral toxicity	: LD50 (Rat): 890 mg/kg
---------------------	-------------------------

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

Acute oral toxicity	: LD50 (Rat): 55 - 240 mg/kg LD50 (Mouse): 170 - 389 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 97 - 161 mg/kg Application Route: Intravenous LD50 (Mouse): 92 - 147 mg/kg Application Route: Intravenous

(+)-Bornan-2-one:

Acute oral toxicity	: LD50 (Mouse): > 300 - 2,000 mg/kg Remarks: Based on data from similar materials Acute toxicity estimate (Humans): > 50 - 500 mg/kg Method: Expert 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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

Zinc oxide:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Methyl salicylate:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

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

Result	: irritating
--------	--------------

(+)-Bornan-2-one:

Species	: Rabbit
Result	: No skin irritation
Remarks	: Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**Petrolatum:**

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

Zinc oxide:

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405

Methyl salicylate:

Species	: Tissue Culture
Method	: OECD Test Guideline 491
Result	: Irreversible effects on the eye

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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
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
-----------------------	--

Methyl Salicylate / Diclofenac Formulation

Version 13.0	Revision Date: 2024/09/28	SDS Number: 656966-00020	Date of last issue: 2024/04/06 Date of first issue: 2016/05/02
-----------------	------------------------------	-----------------------------	---

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

Zinc oxide:

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

Methyl salicylate:

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: CHO Result: negative

(+)-Bornan-2-one:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Skin contact Result: negative Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:**Petrolatum:**

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

Zinc oxide:

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 1 Years
Result	: negative
Remarks	: Based on data from similar materials

Methyl salicylate:

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

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

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

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**Petrolatum:**

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

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

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:

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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

Components:**Zinc oxide:**

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

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

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

Repeated dose toxicity**Components:****Petrolatum:**

Species : Rat
NOAEL : 5,000 mg/kg
Application Route : Ingestion
Exposure time : 2 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 : Rat
NOAEL : 50 mg/kg

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

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 Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Zinc oxide:

Toxicity to fish	: LC50 : > 0.1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.136 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l Exposure time: 72 h Remarks: Based on data from similar materials
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to fish (Chronic toxicity)	: NOEC (Jordanella floridae (flagfish)): > 0.01 - 0.1 mg/l Exposure time: 14 Weeks Remarks: Based on data from similar materials
Toxicity to daphnia and other	: NOEC (Ceriodaphnia dubia (water flea)): > 0.01 - 0.1 mg/l

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

aquatic invertebrates (Chronic toxicity)	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
	NOEC (Desmodesmus subspicatus (green algae)): 0.79 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC10 (Pseudomonas putida): 140 mg/l
	Exposure time: 16 h

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

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l
	Exposure time: 96 h
	Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 80.1 mg/l
	Exposure time: 48 h
	Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
	Exposure time: 32 d
	Method: OECD Test Guideline 210
Toxicity to daphnia and other	: NOEC (Daphnia magna (Water flea)): 10 mg/l

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d
Method: OECD Test Guideline 211

(+)-Bornan-2-one:

Toxicity to fish

: LC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants

: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms

: EC50: > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

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

Biodegradability

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

Methyl salicylate:

Biodegradability

: Result: Readily biodegradable.
Biodegradation: 98.4 %
Exposure time: 28 d

(+)-Bornan-2-one:

Biodegradability

: Result: Readily biodegradable.
Method: OECD Test Guideline 301F

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
13.0	2024/09/28	656966-00020	2024/04/06
			Date of first issue: 2016/05/02

Remarks: Based on data from similar materials

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

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

Methyl salicylate:

Partition coefficient: n-octanol/water	:	log Pow: 2.55
--	---	---------------

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

Partition coefficient: n-octanol/water	:	log Pow: 4.51
--	---	---------------

(+)-Bornan-2-one:

Partition coefficient: n-octanol/water	:	log Pow: 2.3
--	---	--------------

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 handling 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	:	III

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

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

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

Not applicable for product as supplied.

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.

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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)

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	-

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Chemical name
Methyl 2-hydroxybenzoate

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

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

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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 (%)
Zinc compounds, soluble / Zinc	1	8.0
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)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

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:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
JP ISHL OEL 577-2(2)	:	Concentration standard (Value set by the Minister of Health, Labour and Welfare stipulated under the Ministerial Ordinance Article 577-2(2))
JP OEL JSOH	:	Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
JP ISHL OEL 577-2(2) / 8h-OEL-M	:	8-hour Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-M	:	Occupational Exposure Limit-Mean

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
13.0	2024/09/28	656966-00020	Date of first issue: 2016/05/02

stances 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