

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage : Category 1
Skin sensitization : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 1 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

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, vapors or spray.
P264 Wash skin thoroughly after handling.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version 8.5 Revision Date: 09/28/2024 SDS Number: 656972-00019 Date of last issue: 09/30/2023
Date of first issue: 05/02/2016

P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

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

P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

In case of eye contact	: Thoroughly clean shoes before reuse. 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. Causes damage to organs through prolonged or repeated exposure.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
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
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 fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version 8.5 Revision Date: 09/28/2024 SDS Number: 656972-00019 Date of last issue: 09/30/2023
Date of first issue: 05/02/2016

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.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust, fume, gas, mist, vapors 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.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m ³	OSHA Z-1
		TWA (Inhal-	5 mg/m ³	ACGIH

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version 8.5 Revision Date: 09/28/2024 SDS Number: 656972-00019 Date of last issue: 09/30/2023
Date of first issue: 05/02/2016

		able particulate matter)		
		TWA (Mist)	5 mg/m ³	NIOSH REL
		ST (Mist)	10 mg/m ³	NIOSH REL
Zinc oxide	1314-13-2	TWA (Respirable particulate matter)	2 mg/m ³	ACGIH
		STEL (Respirable particulate matter)	10 mg/m ³	ACGIH
		TWA (Dust)	5 mg/m ³	NIOSH REL
		TWA (Fumes)	5 mg/m ³	NIOSH REL
		ST (Fumes)	10 mg/m ³	NIOSH REL
		C (Dust)	15 mg/m ³	NIOSH REL
		TWA (Fumes)	5 mg/m ³	OSHA Z-1
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
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	TWA	2 mg/m ³	OSHA Z-1
		TWA	2 ppm	ACGIH
		STEL	3 ppm	ACGIH
		TWA	2 mg/m ³	NIOSH REL

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

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment: 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).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment

Color : light red

Odor : aromatic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 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: 4,005 mg/kg
---------------------	---	--------------------------------------

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 50.01 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 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Remarks: Based on data from similar materials

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

Method: Expert judgment

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

(+)-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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

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

Zinc oxide:

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

Methyl salicylate:

Species	:	Tissue Culture
Method	:	OECD Test Guideline 491

Result	:	Irreversible effects on the eye
--------	---	---------------------------------

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

Result	:	Mild eye irritation
--------	---	---------------------

(+)-Bornan-2-one:

Result	:	Eye irritation
Remarks	:	Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Petrolatum:

Test Type	:	Buehler Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Zinc oxide:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Methyl salicylate:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Species	:	Mouse
Result	:	positive
Assessment	:	Probability or evidence of low to moderate skin sensitization rate in humans

(+)-Bornan-2-one:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Petrolatum:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

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:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

Species: Mouse

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Petrolatum:

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

Zinc oxide:

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

Methyl salicylate:

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

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

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

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

Zinc oxide:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

Methyl salicylate:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Test Type: Embryo-fetal development
Species: Monkey
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

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

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral
Fertility: NOAEL: 4 mg/kg body weight
Result: No effects on fertility.

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Embryo-fetal toxicity., No teratogenic effects.

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

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

(+)-Bornan-2-one:

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure

Not classified based on available information.

Components:

(+)-Bornan-2-one:

Assessment : May cause respiratory irritation.
Remarks : Based on data from similar materials

STOT-repeated exposure

Causes 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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Repeated dose toxicity

Components:

Petrolatum:

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

Zinc oxide:

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

Methyl salicylate:

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

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

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

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

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

(+)-Bornan-2-one:

Species	:	Rat
NOAEL	:	> 200 mg/kg
Application Route	:	Skin contact
Exposure time	:	13 Weeks

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

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

Ingestion : Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

SECTION 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

- 0.1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

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

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

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

(+)-Bornan-2-one:

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

(+)-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-octanol/water : log Pow: 4.51

(+)-Bornan-2-one:

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)
Class : 9

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger 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.

Domestic regulation

49 CFR

UN/ID/NA 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 : CLASS 9
ERG Code : 171
Marine pollutant : yes(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

Remarks : Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Zinc oxide	1314-13-2	>= 10 - < 20 %
------------	-----------	----------------

US State Regulations

Pennsylvania Right To Know

Petrolatum	8009-03-8
Zinc oxide	1314-13-2
Methyl salicylate	119-36-8
(+)-Bornan-2-one	464-49-3

California List of Hazardous Substances

Petrolatum	8009-03-8
Zinc oxide	1314-13-2
Methyl salicylate	119-36-8
(+)-Bornan-2-one	464-49-3

California Permissible Exposure Limits for Chemical Contaminants

Petrolatum	8009-03-8
Zinc oxide	1314-13-2
(+)-Bornan-2-one	464-49-3

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

AICS : not determined

DSL : not determined

IECSC : not determined

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



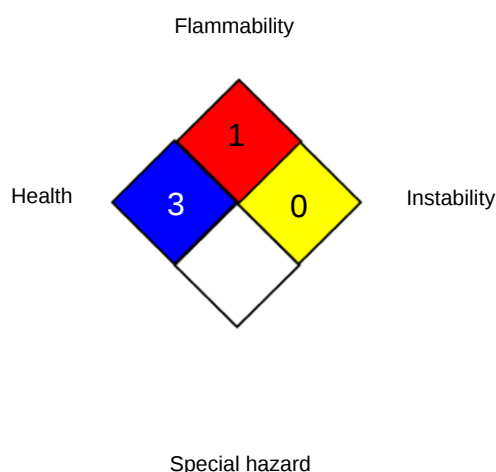
Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
NIOSH REL / C	:	Ceiling value not be exceeded at any time.
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Chemi-

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Methyl Salicylate / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
8.5	09/28/2024	656972-00019	Date of first issue: 05/02/2016

cals 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

Revision Date : 09/28/2024

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.

US / Z8