according to the Hazardous Products Regulations



Methyl Salicylate / Diclofenac Formulation

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SECTION 1. IDENTIFICATION

Product name : Methyl Salicylate / Diclofenac Formulation

Other means of identification : No data available

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 Hazardous Products Regulations

Serious eye damage : Category 1

Skin sensitization : Sub-category 1B

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 repeat-

ed 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.

according to the Hazardous Products Regulations



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P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should 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 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.

P362 + P364 Take off contaminated clothing and wash it 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 | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---|-----------------------------------|------------|-----------------------|
| Petrolatum | No data availa- ble | 8009-03-8 | >= 80 - <= 100 * |
| Zinc oxide | Zinc monoxide | 1314-13-2 | >= 10 - < 30 * |
| Methyl salicylate | Methyl 2- hydroxybenzo- ate | 119-36-8 | >= 1 - < 5 * |
| Sodium [2-[(2,6-dichloro-phe-nyl)amino]phenyl]aceta | No data availa- ble | 15307-79-6 | >= 1 - < 5 * |
| (+)-Bornan-2-one | D-Camphor | 464-49-3 | >= 1 - < 5 * |

^{*} Actual concentration or concentration range 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

according to the Hazardous Products Regulations



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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. May cause an allergic skin reaction. Causes serious eye damage.

Most important symptoms and effects, both acute and

delayed

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

ucts

Chlorine compounds Nitrogen oxides (NOx)

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

Evacuate area.

Special protective equipment:

for fire-fighters

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

Use personal protective equipment.

according to the Hazardous Products Regulations



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: :

tive equipment and emer-

gency 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.

SECTION 7. HANDLING AND STORAGE

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, 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

according to the Hazardous Products Regulations



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis | |
|-----------------------------|---------------------------|-------------------|--|--------------------|--|
| Components | OAO NO. | (Form of | ters / Permissible | Dasis | |
| | | exposure) | concentration | | |
| Petrolatum | 8009-03-8 | TWA (Mist) | 5 mg/m ³ | CA AB OEL | |
| Petrolatum | 0003-03-0 | STEL (Mist) | 10 mg/m³ | CA AB OEL | |
| | | TWAEV (Mist) | 5 mg/m ³ | CA QC OEL | |
| | | - Inhalable | 5 mg/m² | CA QC OEL | |
| | | | | | |
| | | dust) | 4 / 3 | CA DC OFI | |
| | | TWA (Mist) TWA | 1 mg/m ³ 5 mg/m ³ | CA BC OEL ACGIH | |
| | | | 5 mg/m² | ACGIH | |
| | | (Inhalable | | | |
| | | particulate | | | |
| 7in a svida | 4044400 | matter) | 0/2 | | |
| Zinc oxide | 1314-13-2 | TWA (Res- | 2 mg/m³ | CA AB OEL | |
| | | pirable) | 40/2 | 04 45 051 | |
| | | STEL (Res- | 10 mg/m ³ | CA AB OEL | |
| | | pirable) | | 04 00 05: | |
| | | TWA (Res- | 2 mg/m³ | CA BC OEL | |
| | | pirable) | | <u> </u> | |
| | | STEL (Res- | 10 mg/m³ | CA BC OEL | |
| | | pirable) | | | |
| | | TWAEV | 2 mg/m³ | CA QC OEL | |
| | | (respirable | | | |
| | | dust) | | | |
| | | STEV (res- | 10 mg/m³ | CA QC OEL | |
| | | pirable dust) | | | |
| | | TWA | 2 mg/m³ | ACGIH | |
| | | (Respirable | | | |
| | | particulate | | | |
| | | matter) | | | |
| | | STEL | 10 mg/m³ | ACGIH | |
| | | (Respirable | | | |
| | | particulate | | | |
| | | matter) | | | |
| Sodium [2-[(2,6- | 15307-79-6 | TWA | 100 μg/m3 (OEB | Internal | |
| dichloro- | | | 2) | | |
| phenyl)amino]phenyl]acetate | | | | | |
| | Further information: Skin | | | | |
| (+)-Bornan-2-one | 464-49-3 | STEL | 3 ppm | CA AB OEL | |
| | | | 19 mg/m³ | | |
| | | TWA | 2 ppm | CA AB OEL | |
| | | | 12 mg/m ³ | | |
| | | TWA | 2 ppm | CA BC OEL | |
| | | STEL | 3 ppm | CA BC OEL | |
| | | STEV | 3 ppm | CA QC OEL | |
| | | | 19 mg/m³ | | |
| | | TWAEV | 2 ppm | CA QC OEL | |
| | | | 12 mg/m³ | | |
| | 1 | 1 | _ · - · · · · · · · · · | I | |

according to the Hazardous Products Regulations



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| | 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 vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

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 : No data available

according to the Hazardous Products Regulations



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range

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

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 reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.

according to the Hazardous Products Regulations



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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: > 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

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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 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:

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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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 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

according to the Hazardous Products Regulations



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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:

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

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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

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

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

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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 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

according to the Hazardous Products Regulations



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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 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

Application Route. Oral

Developmental Toxicity: LOAEL: 5 mg/kg body weight Result: Embryo-fetal toxicity., No teratogenic effects.

Reproductive toxicity - As-

sessment

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 concentra-

tions of 0.2 mg/l/6h/d or less.

according to the Hazardous Products Regulations



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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 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

according to the Hazardous Products Regulations



Methyl Salicylate / Diclofenac Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 8.5 09/28/2024 656957-00019 Date of first issue: 05/02/2016

(+)-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, 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 (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

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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

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

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

according to the Hazardous Products Regulations



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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

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

according to the Hazardous Products Regulations



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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- : log Pow: 2.55

octanol/water

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

Partition coefficient: n- : log Pow: 4.51

octanol/water

(+)-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 : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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,

according to the Hazardous Products Regulations



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N.O.S.

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

dichlorophenyl)amino]phenyl]acetate)

Class : 9
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)

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

(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

TDG

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
ERG Code : 171

Marine pollutant : yes(Zinc oxide, Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate)

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

according to the Hazardous Products Regulations



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

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

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

CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average CA BC OEL / STEL : short-term exposure limit

CA QC OEL / TWAEV : Time-weighted average exposure value

CA QC OEL / STEV : Short-term exposure value

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 Develop-

according to the Hazardous Products Regulations



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ment; 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

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 Agen-

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

Revision Date : 09/28/2024 Date format : mm/dd/yyyy

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.

CA / Z8