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Ivermectin (with Isopropyl Alcohol) Formulation

 Version
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 SDS Number:
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 9.0
 28.09.2024
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin (with Isopropyl Alcohol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Highly flammable liquids

GHS Classification

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 5

Acute toxicity (Dermal) : Category 5

Skin corrosion/irritation : Category 3

Serious eye damage/eye irri-

tation

Category 2A

Skin sensitisation : Category 1

Germ cell mutagenicity : Category 2

Specific target organ toxicity -

single exposure

Category 3

Short-term (acute) aquatic

hazard

Category 1

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Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms









Signal word Warning

Hazard statements H226 Flammable liquid and vapour.

H303 + H313 May be harmful if swallowed or in contact with

H316 Causes mild skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H341 Suspected of causing genetic defects.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements Prevention:

> P203 Obtain, read and follow all safety instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames

and other ignition sources. No smoking. P261 Avoid breathing mist or vapours.

P264+P265 Wash hands thoroughly after handling. Do not

P271 Use only outdoors or with adequate ventilation.

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 protec-

tion/ face protection.

Response:

P301 + P333 + P317 IF SWALLOWED or if skin irritation or

rash occurs: Get medical help.

P303 + P361 + P353 + P317 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Get medical help.

P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

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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

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (%
		w/w)
2-(2-Butoxyethoxy)ethanol	112-34-5	>= 50 - < 70
Propan-2-ol	67-63-0	>= 30 - < 50
Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-	642443-86-5	>= 10 - < 20
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	2386-87-0	>= 1 - < 2.5
Ivermectin	70288-86-7	>= 0.25 - < 1
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.25 - < 1

4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of 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.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms : May be harmful if swallowed or in contact with skin.

and effects, both acute and Causes mild skin irritation.

delayed May cause an allergic skin reaction.

Causes serious eye irritation.

May cause drowsiness or dizziness.

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Suspected of causing genetic defects.

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread

tire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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

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

SO.

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Remove all sources of ignition.

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for : Non-sparking tools should be used.

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containment and cleaning up Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition.

Materials to avoid : Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

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> Poisonous gases Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
2-(2-Butoxyethoxy)ethanol	112-34-5	TWA (Inhalable fraction and vapor)	10 ppm	ACGIH	
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH	
		STEL	400 ppm	ACGIH	
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH	
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	300 μg/100 cm2	Internal	

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face contain-

ment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Organic vapour type

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Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : yellow

Odour : solvent-like

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 28 °C

Evaporation rate : No data available

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Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure No data available

Relative vapour density No data available

Relative density No data available

Density 0.855 - 0.905 g/cm3

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size Not applicable

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

Flammable liquid and vapour.

Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

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11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

Acute toxicity

May be harmful if swallowed or in contact with skin.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,985 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 4,924 mg/kg

Method: Calculation method

Components:

2-(2-Butoxyethoxy)ethanol:

Acute oral toxicity : LD50 (Mouse): 2,410 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 2,764 mg/kg

Propan-2-ol:

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

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l

Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

Acute oral toxicity : LD50 (Rat): > 16,000 mg/kg

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Acute oral toxicity : LD50 (Rat, male): > 2,959 - 5,000 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): >= 5.19 mg/l

Exposure time: 4 h
Test atmosphere: dust/mist

Mathadi OFCD Toot Cuidalina

Method: OECD Test Guideline 436

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

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toxicity

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

LD50 (Rat): > 660 mg/kg

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg

Method: OECD Test Guideline 401

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Causes mild skin irritation.

Components:

2-(2-Butoxyethoxy)ethanol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

Species : Rabbit

Result : Mild skin irritation

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species : Rabbit

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Method : OECD Test Guideline 404

Result : No skin irritation

Ivermectin:

Species : Rabbit

Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-(2-Butoxyethoxy)ethanol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

Species : Rabbit

Result : No eye irritation

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Ivermectin:

Species : Rabbit

Result : Mild eye irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

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Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig Result : negative

Propan-2-ol:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity

Suspected of causing genetic defects.

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Components:

2-(2-Butoxyethoxy)ethanol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

Propan-2-ol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

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

Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

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

Method: OECD Test Guideline 471

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: positive

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Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 486

Result: negative

Test Type: Micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Transgenic rodent somatic cell gene mutation as-

say

Species: Mouse

Application Route: Ingestion

Method: OECD Test Guideline 488

Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Ivermectin:

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

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts

Result: negative

Test Type: Mouse Lymphoma

Result: negative

2,6-Di-tert-butyl-p-cresol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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: Rat

Application Route: Ingestion

Result: negative

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Carcinogenicity

Not classified based on available information.

Components:

Propan-2-ol:

Species Rat

Application Route : inhalation (vapour)

: 104 weeks Exposure time

Method : OECD Test Guideline 451

Result : negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species Mouse Application Route Skin contact : 29 Months Exposure time Result negative

Ivermectin:

Species : Rat Application Route
NOAEL : Oral

NOAEL : 1.5 mg/kg body weight

: negative Result

Remarks Based on data from similar materials

: Mouse Species Application Route Oral

NOAEL 2.0 mg/kg body weight

: negative Result

Based on data from similar materials Remarks

2,6-Di-tert-butyl-p-cresol:

Species : Rat Application Route : Ingestion Exposure time : 22 Months Result negative

Reproductive toxicity

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

Test Type: One-generation reproduction toxicity study Effects on fertility

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 415

Result: negative

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Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Effects on foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 0.2 mg/kg body weight Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 0.4 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Development

Species: Rabbit

Application Route: Oral

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Result: Teratogenic effects, Embryotoxic effects and adverse

effects on the offspring were detected only at high maternally

toxic doses

2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

 Test Type: Embryo-foetal development Species: Rat

ment

Application Route: Ingestion

Result: negative

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

Ivermectin:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure

Not classified based on available information.

Components:

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Exposure routes : Ingestion
Target Organs : nasal cavity

Assessment : Shown to produce significant health effects in animals at con-

centrations of >10 to 100 mg/kg bw.

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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Repeated dose toxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Species Rat NOAEL : 250 mg/kg LOAEL : 1,000 mg/kg : Ingestion Application Route : 90 Days Exposure time

Method : OECD Test Guideline 408

: Rat

Species NOAEL Application Route Exposure time Method >= 0.094 mg/linhalation (vapour)90 Days

: OECD Test Guideline 413 Method

Species

NOAEL >= 2,000 mg/kgApplication Route : Skin contact Exposure time : 90 Days

Propan-2-ol:

Species Rat NOAEL 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time 104 Weeks

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species Rat NOAEL 5 mg/kg อบ mg/kg : Ingestion : ๑๐ ฅ LOAEL 50 mg/kg Application Route Exposure time

: OECD Test Guideline 408 Method

Ivermectin:

Species : Dog NOAEL 0.5 mg/kg LOAEL 1 mg/kg Application Route : Oral Exposure time 14 Weeks

Target Organs Central nervous system

Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species Monkey NOAEL : 1.2 mg/kg Application Route Oral Exposure time 2 Weeks

No significant adverse effects were reported Remarks

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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Species : Rat

NOAEL : 0.4 mg/kg

LOAEL : 0.8 mg/kg

Application Route : Oral

Exposure time : 3 Months

Target Organs : spleen, Bone marrow, Kidney

2,6-Di-tert-butyl-p-cresol:

Species : Rat

NOAEL : 25 mg/kg

Application Route : Ingestion

Exposure time : 22 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, anorexia, Lack of coordination

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,300 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 100

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): >= 100

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10: > 1,995 mg/l

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Exposure time: 30 min

Propan-2-ol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h

Poly[oxy(methyl-1,2-ethanediyl)], α -(1-oxotetradecyl)- ω -(phenylmethoxy)-:

Toxicity to fish : LC50: 540 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 221 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Toxicity to algae/aquatic

plants

NOEC (Selenastrum capricornutum (fresh water algae)): 78

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 24 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 40 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

110 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 30

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

: EC10 (activated sludge): 409 mg/l Toxicity to microorganisms

Exposure time: 3 h

Method: OECD Test Guideline 209

Ivermectin:

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l Toxicity to fish

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

10,000

M-Factor (Chronic aquatic

toxicity)

10,000

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish LC50 (Danio rerio (zebra fish)): > 0.57 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.48 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): >

0.24 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 1

icity)

Toxicity to microorganisms : EC50: > 10,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox- : NOEC: 0.053 mg/l

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Ivermectin (with Isopropyl Alcohol) Formulation

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icity) Exposure time: 30 d

Species: Oryzias latipes (Japanese medaka)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.316 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

: 1

Persistence and degradability

Components:

2-(2-Butoxyethoxy)ethanol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 85 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)

COD: 2,23 BOD/COD: 53 %

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 71 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4.5 % Exposure time: 28 d

Method: OECD Test Guideline 301C

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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Bioaccumulative potential

Components:

2-(2-Butoxyethoxy)ethanol:

Partition coefficient: n-

octanol/water

: log Pow: 1

Propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0.05

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Partition coefficient: n- : log Pow: 1.34

octanol/water Method: OECD Test Guideline 107

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

: log Pow: 3.22

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-

octanol/water

: log Pow: 5.1

Mobility in soil

No data available

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

Class : 3
Packing group : III
Labels : 3
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1993

Proper shipping name : Flammable liquid, n.o.s.

(Propan-2-ol)

Class : 3 Packing group : III

Labels : Flammable Liquids

Packing instruction (cargo : 366

aircraft)

Packing instruction (passen-

ger aircraft)

IMDG-Code

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S.

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(Propan-2-ol, Ivermectin, 2,6-Di-tert-butyl-p-cresol)

Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-E
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

according to the Globally Harmonized System



Ivermectin (with Isopropyl Alcohol) Formulation

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IECSC : not determined

16. OTHER INFORMATION

Revision Date : 28.09.2024

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 Agen-

cy, 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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

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

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 Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

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mendations 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.

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