

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
11.2	17.06.2025	1496904-00027	Date of first issue: 29.03.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Ivermectin (with Isopropyl Alcohol) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Germ cell mutagenicity, Category 2	H341: Suspected of causing genetic defects.
Specific target organ toxicity - single exposure, Category 3	H336: May cause drowsiness or dizziness.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

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Hazard pictograms :    

Signal word : Warning

Hazard statements :
 H226 Flammable liquid and vapour.
 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:
 P201 Obtain special instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
 P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
 P391 Collect spillage.

Hazardous components which must be listed on the label:

Propan-2-ol

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

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-(2-Butoxyethoxy)ethanol	112-34-5 203-961-6 603-096-00-8	Eye Irrit. 2; H319	>= 50 - < 70
Propan-2-ol	67-63-0	Flam. Liq. 2; H225	>= 30 - < 50

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	200-661-7 603-117-00-0	Eye Irrit. 2; H319 STOT SE 3; H336	
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	2386-87-0 219-207-4 607-773-00-9	Skin Sens. 1; H317 Muta. 2; H341 STOT RE 2; H373 (nasal cavity) Aquatic Chronic 3; H412	$\geq 1 - < 2,5$
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	$\geq 0,25 - < 1$
2,6-Di-tert-butyl-p-cresol	128-37-0 204-881-4	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	$\geq 0,25 - < 1$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).

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- | | | |
|-------------------------|---|--|
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|---|
| Risks | : | May cause an allergic skin reaction.
Causes serious eye irritation.
May cause drowsiness or dizziness.
Suspected of causing genetic defects. |
|-------|---|---|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures**5.1 Extinguishing media**

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| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
|------------------------------|---|--|

- | | | |
|--------------------------------|---|-----------------------|
| Unsuitable extinguishing media | : | High volume water jet |
|--------------------------------|---|-----------------------|

5.2 Special hazards arising from the substance or mixture

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|---------------------------------------|---|--|
| Specific hazards during fire-fighting | : | Do not use a solid water stream as it may scatter and spread fire.
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 products | : | Carbon oxides |

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5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- 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.
-

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- Personal precautions : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Non-sparking tools should be used.
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 absorbent.
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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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SECTION 7: Handling and storage**7.1 Precautions for safe handling**

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|-------------------------|---|---|
| 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 equipment. |
| 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 assessment
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. |
| 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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | 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. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases |

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Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-(2-Butoxyethoxy)ethanol	112-34-5	TWA	10 ppm 67,5 mg/m ³	2006/15/EC
		STEL	15 ppm 101,2 mg/m ³	2006/15/EC
Propan-2-ol	67-63-0	OEL-RL	400 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		OEL- RL STEL/C	800 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
Ivermectin	70288-86-7	TWA	30 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	300 µg/100 cm ²	Internal

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Propan-2-ol	67-63-0	Acetone: 40 mg/l (Urine)	End of shift at end of workweek	ZA BEI

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	Workers	Inhalation	Long-term systemic effects	0,18 mg/m ³
	Workers	Inhalation	Long-term local effects	0,18 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0,05 mg/kg bw/day
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m ³
	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day

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	Consumers	Inhalation	Long-term systemic effects	89 mg/m3
	Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	26 mg/kg bw/day
2-(2-Butoxyethoxy)ethanol	Workers	Inhalation	Long-term systemic effects	67,5 mg/m3
	Workers	Inhalation	Long-term local effects	67,5 mg/m3
	Workers	Inhalation	Acute local effects	101,2 mg/m3
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	40,5 mg/m3
	Consumers	Inhalation	Long-term local effects	40,5 mg/m3
	Consumers	Inhalation	Acute local effects	60,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	50 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day
2,6-Di-tert-butyl-p-cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m3
	Workers	Dermal	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,86 mg/m3
	Consumers	Dermal	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	Fresh water	0,024 mg/l
	Freshwater - intermittent	0,24 mg/l
	Marine water	0,0024 mg/l
	Sewage treatment plant	19,5 mg/l
	Fresh water sediment	0,211 mg/kg dry weight (d.w.)
	Marine sediment	0,0211 mg/kg dry weight (d.w.)
	Soil	0,0282 mg/kg dry weight (d.w.)
Propan-2-ol	Fresh water	140,9 mg/l
	Marine water	140,9 mg/l
	Intermittent use/release	140,9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry

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		weight (d.w.)
	Marine sediment	552 mg/kg dry weight (d.w.)
	Soil	28 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	160 mg/kg food
2-(2-Butoxyethoxy)ethanol	Fresh water	1,1 mg/l
	Freshwater - intermittent	11 mg/l
	Marine water	0,11 mg/l
	Sewage treatment plant	200 mg/l
	Fresh water sediment	4,4 mg/kg dry weight (d.w.)
	Marine sediment	0,44 mg/kg dry weight (d.w.)
	Soil	0,32 mg/kg dry weight (d.w.)
	Secondary Poisoning	56 mg/kg food
Ivermectin	Fresh water	0,000004 mg/l
	Marine water	0,000004 mg/l
2,6-Di-tert-butyl-p-cresol	Fresh water	0,199 µg/l
	Intermittent use/release	0,02 µg/l
	Marine water	0,02 µg/l
	Sewage treatment plant	0,17 mg/l
	Fresh water sediment	0,0996 mg/kg dry weight (d.w.)
	Marine sediment	0,00996 mg/kg dry weight (d.w.)
	Soil	0,04769 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	8,33 mg/kg food

8.2 Exposure controls

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 containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face 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.

Hand protection

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Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
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/cm ³
Solubility(ies)	:	
Water solubility	:	No data available

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Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition 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.

9.2 Other information

Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 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

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
Method: OECD Test Guideline 436
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

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.

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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

Not classified based on available information.

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

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

Species : Rabbit
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.

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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

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

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

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

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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.

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

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

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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

Carcinogenicity

Not classified based on available information.

Components:**Propan-2-ol:**

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 104 weeks
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
Exposure time : 29 Months
Result : negative

Ivermectin:

Species : Rat
Application Route : Oral
NOAEL : 1,5 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

Species : Mouse
Application Route : Oral
NOAEL : 2,0 mg/kg body weight
Result : negative
Remarks : Based on data from similar materials

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

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

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tion**

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Reproductive toxicity

Not classified based on available information.

Components:**2-(2-Butoxyethoxy)ethanol:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 415
Result: negative

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

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tion**

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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
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
ment Species: Rat
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.

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tion**

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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 concentrations of 100 mg/kg bw or less.
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Repeated dose toxicity**Components:****2-(2-Butoxyethoxy)ethanol:**

Species	:	Rat
NOAEL	:	250 mg/kg
LOAEL	:	1.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408

Species	:	Rat
NOAEL	:	>= 0,094 mg/l
Application Route	:	inhalation (vapour)
Exposure time	:	90 Days
Method	:	OECD Test Guideline 413

Species	:	Rat
NOAEL	:	>= 2.000 mg/kg
Application 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
LOAEL	:	50 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408

Ivermectin:

Species	:	Dog
NOAEL	:	0,5 mg/kg
LOAEL	:	1 mg/kg

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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
 Remarks : No significant adverse effects were reported

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, Vomiting, anorexia, Lack of coordination

SECTION 12: Ecological information

12.1 Toxicity

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

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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
Exposure time: 30 min

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10.000 mg/l
aquatic invertebrates Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1.050 mg/l
Exposure time: 16 h

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 : EC50 (Daphnia magna (Water flea)): 40 mg/l
aquatic invertebrates Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 110 mg/l
plants 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

Toxicity to microorganisms : EC10 (activated sludge): 409 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): $0,003$ mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): $0,0048$ mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): $0,000025$ mg/l

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aquatic invertebrates	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 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 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.
Toxicity to daphnia and other aquatic invertebrates	: 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 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50 : > 10.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	: NOEC: 0,053 mg/l Exposure time: 30 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,316 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	: 1

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toxicity)

12.2 Persistence and degradability**Components:****2-(2-Butoxyethoxy)ethanol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 85 %
Exposure time: 28 d
Method: OECD Test Guideline 301C
Remarks: The test was conducted according to guideline

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

12.3 Bioaccumulative potential**Components:****2-(2-Butoxyethoxy)ethanol:**

Partition coefficient: n- : log Pow: 1
octanol/water

Propan-2-ol:

Partition coefficient: n- : log Pow: 0,05
octanol/water

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

Partition coefficient: n- : log Pow: 1,34

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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 - 1.800Partition coefficient: n-
octanol/water : log Pow: 5,1**12.4 Mobility in soil**

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling 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.

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SECTION 14: Transport information

14.1 UN number

ADN	: UN 1993
ADR	: UN 1993
RID	: UN 1993
IMDG	: UN 1993
IATA	: UN 1993

14.2 UN proper shipping name

ADN	: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
ADR	: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
RID	: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)
IMDG	: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol, Ivermectin, 2,6-Di-tert-butyl-p-cresol)
IATA	: Flammable liquid, n.o.s. (Propan-2-ol)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 3	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: F1
Hazard Identification Number	: 30
Labels	: 3
ADR	
Packing group	: III
Classification Code	: F1
Hazard Identification Number	: 30
Labels	: 3
Tunnel restriction code	: (D/E)
RID	
Packing group	: III

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Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

Packing group : III
Labels : 3
EmS Code : F-E, S-E

IATA (Cargo)

Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 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

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IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H225	: Highly flammable liquid and vapour.
H300	: Fatal if swallowed.
H311	: Toxic in contact with skin.
H317	: May cause an allergic skin reaction.
H319	: Causes serious eye irritation.
H336	: May cause drowsiness or dizziness.
H341	: Suspected of causing genetic defects.
H370	: Causes damage to organs if swallowed.
H372	: Causes damage to organs through prolonged or repeated exposure if swallowed.
H373	: May cause damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H412	: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Irrit.	: Eye irritation
Flam. Liq.	: Flammable liquids
Muta.	: Germ cell mutagenicity
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
2006/15/EC	: Europe. Indicative occupational exposure limit values
ZA BEI	: South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices
ZA OEL	: South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
2006/15/EC / TWA	: Limit Value - eight hours
2006/15/EC / STEL	: Short term exposure limit
ZA OEL / OEL-RL	: Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
ZA OEL / OEL- RL STEL/C	: Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

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ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

Further information

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

Classification of the mixture:

Flam. Liq. 3	H226
Eye Irrit. 2	H319
Skin Sens. 1	H317
Muta. 2	H341
STOT SE 3	H336
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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 mate-

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rial 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.

ZA / EN