according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Ivermectin Liquid Formulation

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

Use of the Sub-: Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company **MSD**

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

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)

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation. Reproductive toxicity, Category 1B H360D: May damage the unborn child. Specific target organ toxicity - single ex-H371: May cause damage to organs.

posure, Category 2

Specific target organ toxicity - single ex-

posure, Category 3

Specific target organ toxicity - repeated

exposure, Category 2

Short-term (acute) aquatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-

egory 1

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H335: May cause respiratory irritation.

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 : Danger

Hazard statements : H315 Causes skin irritation.

H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H360D May damage the unborn child.
 H371 May cause damage to organs.

H373 May cause damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor. P391 Collect spillage.

Hazardous components which must be listed on the label:

N-Methyl-2-pyrrolidone

Ivermectin

Restricted to professional users.

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.

Ecological information: 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.

Toxicological information: 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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N-Methyl-2-pyrrolidone	872-50-4 212-828-1 606-021-00-7	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D STOT SE 3; H335 ———————————————————————————————————	>= 10 - < 20
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	>= 1 - < 2,5
		M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	

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 ad-

vice 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,

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

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

for at least 15 minutes while removing 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.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks Causes skin irritation.

> Causes serious eye irritation. May cause respiratory irritation. May damage the unborn child. May cause damage to organs.

May cause damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

: Treat symptomatically and supportively. Treatment

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

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 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective 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 : Soak up with inert absorbent material.

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.

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

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

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

Keep container tightly closed.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

Do not eat, drink or smoke when using this product.

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. Wash contami-

nated 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.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
N-Methyl-2-	872-50-4	TWA	14,4 mg/m3	FOR-2011-	
pyrrolidone				12-06-1358	
	Further inforn	Further information: Substances considered to be reprotoxic, Chemicals that			
	can be absort	can be absorbed through the skin.			
		STEL	20 ppm	FOR-2011-	
			80 mg/m3	12-06-1358	
	Further inforn	Further information: Substances considered to be reprotoxic, Chemicals that			
1		can be absorbed through the skin.			
		TWA	10 ppm	2009/161/EU	
			40 mg/m3		
	Further inforn	Further information: Identifies the possibility of significant uptake through the			
	skin, Indicativ	, , , , , , , , , , , , , , , , , , , ,			
	,	STEL	20 ppm	2009/161/EU	
			80 mg/m3		
		Further information: Identifies the possibility of significant uptake through the skin, Indicative			
	,	TWA	10 ppm	2004/37/EC	
			40 mg/m3		
	Further inforn	Further information: Skin, Carcinogens or mutagens			
		STEL	20 ppm	2004/37/EC	
			80 mg/m3		
	Further inforn	Further information: Skin, Carcinogens or mutagens			
Ivermectin	70288-86-7	TWA	30 µg/m3 (OEB 3)	Internal	
	Further inforn	Further information: Skin			
		Wipe limit	300 μg/100 cm2	Internal	
			1 3		

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

Substance name	End Use	Exposure routes	Potential health effects	Value
N-Methyl-2- pyrrolidone	Workers	Inhalation	Long-term systemic effects	14,4 mg/m3
	Workers	Inhalation	Long-term local ef- fects	40 mg/m3
	Workers	Skin contact	Long-term systemic effects	4,8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3,6 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	4,5 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2,4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,85 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
N-Methyl-2-pyrrolidone	Fresh water	0,25 mg/l
	Freshwater - intermittent	5 mg/l
	Marine water	0,025 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,09 mg/kg dry weight (d.w.)
	Marine sediment	1,09 mg/kg dry weight (d.w.)
	Soil	0,07 mg/kg dry weight (d.w.)

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.

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

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Physical state : liquid

Colour : light yellow

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : $> 100 \, ^{\circ}\text{C}$

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : 0,90 - 0,92 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

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9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation 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 dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

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Components:

N-Methyl-2-pyrrolidone:

Acute oral toxicity : LD50 (Rat): 4.150 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

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

Skin corrosion/irritation

Causes skin irritation.

Components:

N-Methyl-2-pyrrolidone:

Result : Skin irritation

Ivermectin:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

N-Methyl-2-pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

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Ivermectin:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

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

thesis in mammalian cells (in vitro)

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

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Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Hamster

Application Route: Ingestion Method: OECD Test Guideline 475

Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

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

Species
Application Route Species Rat

inhalation (vapour)

Exposure time 2 Years Result negative

Ivermectin:

Species Rat Application Route
NOAEL Oral

NOAEL 1,5 mg/kg body weight

Result negative

Remarks Based on data from similar materials

Species Mouse Species
Application Route Oral

NOAEL 2,0 mg/kg body weight

Result negative

Remarks Based on data from similar materials

Reproductive toxicity

May damage the unborn child.

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Components:

N-Methyl-2-pyrrolidone:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Effects on foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: inhalation (vapour)

Result: positive

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

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.

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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

STOT - single exposure

May cause respiratory irritation. May cause damage to organs.

Components:

N-Methyl-2-pyrrolidone:

Assessment : May cause respiratory irritation.

Ivermectin:

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

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

N-Methyl-2-pyrrolidone:

Species : Rat, male

NOAEL : 169 mg/kg

LOAEL : 433 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Method : OECD Test Guideline 408

 Species
 : Rat

 NOAEL
 : 0,5 mg/l

 LOAEL
 : 1 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 96 Days

Method : OECD Test Guideline 413

Species : Rabbit NOAEL : 826 mg/kg

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LOAEL : 1.653 mg/kg
Application Route : Skin contact
Exposure time : 20 Days

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

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

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact : Symptoms: Skin irritation

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

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SECTION 12: Ecological information

12.1 Toxicity

Components:

N-Methyl-2-pyrrolidone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l

Exposure time: 24 h Method: DIN 38412

Toxicity to algae/aquatic

plants

: ErC50 (Desmodesmus subspicatus (green algae)): 600,5 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 92,6 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50 : > 600 mg/l

> Exposure time: 30 min Method: ISO 8192

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 12,5 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Ivermectin:

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

Toxicity to algae/aquatic

plants

Exposure time: 48 h

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9,1

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,1

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

city)

10.000

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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M-Factor (Chronic aquatic

toxicity)

10.000

12.2 Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 73 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

12.3 Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0,46

octanol/water Method: OECD Test Guideline 107

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

log Pow: 3,22

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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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12.7 Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Ivermectin)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ADR 9 RID 9 **IMDG** 9 **IATA** 9

14.4 Packing group

ADN

Packing group Ш Classification Code M6 Hazard Identification Number : 90 Labels 9

ADR

Packing group Ш Classification Code M6 Hazard Identification Number : 90 Labels 9 Tunnel restriction code (-)

RID

Packing group Ш Classification Code M6 Hazard Identification Number : 90 Labels

IMDG

Packing group Ш Labels 9

F-A, S-F EmS Code

IATA (Cargo)

Packing instruction (cargo 964

aircraft)

Packing instruction (LQ) Y964 Packing group Ш

Labels Miscellaneous

IATA (Passenger)

Packing instruction (passen-964

ger aircraft)

Packing instruction (LQ) Y964 Packing group Ш

Labels Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous yes

Environmentally hazardous yes

Environmentally hazardous yes

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : 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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) lowing entries should be considered: Number on list 3

Conditions of restriction for the fol-

Number on list 30: N-Methyl-2pyrrolidone

Number on list 71: N-Methyl-2pyrrolidone

Number on list 72: N-Methyl-2-pyrrolidone

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

N-Methyl-2-pyrrolidone

: Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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(Annex XIV)

Regulation (EC) on substances that deplete the ozone : Not applicable

laver

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

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

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin.
H315 : Causes skin irritation.

H319 : Causes serious eye irritation.
H335 : May cause respiratory irritation.
H360D : May damage the unborn child.

H370 : Causes damage to organs if swallowed.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure

2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers

from the risks related to exposure to carcinogens or mutagens

at work

2009/161/EU : Europe. COMMISSION DIRECTIVE 2009/161/EU establishing

a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending

Commission Directive 2000/39/EC

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

2004/37/EC / STEL : Short term exposure limit 2004/37/EC / TWA : Long term exposure limit 2009/161/EU / TWA : Limit Value - eight hours 2009/161/EU / STEL : Short term exposure limit FOR-2011-12-06-1358 / : Long term exposure limit

TWA

FOR-2011-12-06-1358 / : Short term exposure limit

STEL

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

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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

Sheet

Sources of key data used to compile the Safety Data

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: Classification procedure:

Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 1B	H360D	Calculation method
STOT SE 2	H371	Calculation method
STOT SE 3	H335	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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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.

NO / EN