Commission Regulation (EU) 2020/878



## Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

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

1.1 Product id Trade nar			Ivermectin Formulation
1.2 Relevant i	dentified uses of the	รเ	ubstance or mixture and uses advised against
Use of the stance/Mi			Veterinary product
Recomme on use	ended restrictions :		Not applicable
1.3 Details of	the supplier of the sa	lfe	ety data sheet
Company	:		MSD Kilsheelan Clonmel Tipperary, IE
Telephone	e :		353-51-601000
E-mail add	dress of person :		EHSDATASTEWARD@msd.com

#### **1.4 Emergency telephone number**

responsible for the SDS

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - single exposure, Category 2 Specific target organ toxicity - repeated exposure, Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1

H371: May cause damage to organs.

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.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





## **Ivermectin Formulation**

Version 5.1	Revision Date: 28.09.2024	-	DS Number: 100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020	
Signa	ll word	:	Warning		
Haza	rd statements	:	H373 May caus repeated exposur	e damage to organs. e damage to organs through prolonged or e. to aquatic life with long lasting effects.	
Precautionary statements		:	Prevention:		
			P270 Do not ea	n thoroughly after handling. t, drink or smoke when using this product. ase to the environment.	
			Response: P308 + P311 IF CENTER/ doctor. P391 Collect sp	exposed or concerned: Call a POISON	
			<b>Storage:</b> P405 Store lock	·	

Hazardous components which must be listed on the label: Ivermectin

#### 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.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 1 - < 2,5



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

# **Ivermectin Formulation**

		SDS Number: 6100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
			(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
2,6-D	i-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

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, 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 if symptoms occur.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.



## **Ivermectin Formulation**

Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : 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

Treatment	: Treat symptomatically and supportive	ely.
-----------	----------------------------------------	------

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

5.3

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical	
Unsuitable extinguishing	:	None known.	

media			

#### 5.2 Special hazards arising from the substance or mixture

opecial nazarus arising irom the substance of mixture							
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.					
Hazardous combustion prod- ucts	:	Carbon oxides					
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-	:	Use extinguishing measures that are appropriate to local cir-					

Specific extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir-
ods		cumstances and the surrounding environment.
		Use water spray to cool unopened containers.
		Remove undamaged containers from fire area if it is safe to do
		S0.
		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.



## Ivermectin Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
		Prevent spread barriers). Retain and disp	leakage or spillage if safe to do so. ling over a wide area (e.g. by containment or oil pose of contaminated wash water. es should be advised if significant spillages ained.
6.3 Metho	ods and material for	containment and clea	ning up
Methods for cleaning up		For large spills, ment to keep m be pumped, sto Clean up remai bent. Local or nationa	hert absorbent material. provide dyking or other appropriate contain- material from spreading. If dyked material can pre recovered material in appropriate container. ining materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items
		employed in the mine which reg	e cleanup of releases. You will need to deter- julations 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.

#### **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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe mist or vapours.
C		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		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
		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.



## Ivermectin Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
7.2 Condi	tions for safe storage,	, including any inc	ompatibilities
	irements for storage and containers		erly labelled containers. Store locked up. Store in ith the particular national regulations.
Advice on common storage		Strong oxidizi	substances and mixtures
7 3 Spaci	fic and usa(s)		

#### 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.		Control parameters	Basis
		of exposure)		
Ivermectin	70288-86-7	TWA	30 µg/m3 (OEB 3)	Internal
	Further inform	nation: Skin		
		Wipe limit	300 µg/100 cm2	Internal

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

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
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
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.)

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



## **Ivermectin Formulation**

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017	Date of last issue: 0 Date of first issue: 3	
		Soil		0,04769 mg/kg dry weight (d.w.)
		Oral (Seconda	ary 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.

#### 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 Skin and body protection	:	Consider double gloving. 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 143
Filter type	:	Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state	:	oily
Colour	:	light yellow
Odour	:	characteristic
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available

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



# **Ivermectin Formulation**

Ver 5.1	sion	Revision Date: 28.09.2024		S Number: 00564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
	Initial b range	oiling point and boiling	:	167,5 °C	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	219,2 °C	
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	practically insolu	ble
	Partitio octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	No data available	9
	Relative	e density	:	0,88 - 0,92	
	Density	1	:	No data available	9
	Relative	e vapour density	:	No data available	9
		e characteristics icle size	:	Not applicable	
9.2	<b>Other ir</b> Explosi	formation ves	:	Not explosive	
	Oxidizii	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	9
	Molecu	lar weight	:	No data available	

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



### **Ivermectin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

#### **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 exposure	:	Inhalation Skin contact
CAPUGUIC		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
Components:		
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

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



# **Ivermectin Formulation**

\_

Remarks

ersion 1	Revision Date: 28.09.2024	SDS Nu 6100564		Date of last issue: 06.07.2024 Date of first issue: 30.06.2020	
		Rem	arks: No mo	ortality observed at this dose.	
Acute	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		06 mg/kg			
		LD5	0 (Rat): > 66	60 mg/kg	
2,6-D	)i-tert-butyl-p-cresol:				
Acute	e oral toxicity		0 (Rat): > 6. nod: OECD	000 mg/kg Test Guideline 401	
Acute	e dermal toxicity	Meth Asse	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 c	lassified based on ava	ilable inforr	nation.		
<u>Com</u>	ponents:				
lvern	nectin:				
Spec Resu			Rabbit No skin irritation		
2,6-D	)i-tert-butyl-p-cresol:				
Spec		: Rab	• • •		
Meth Resu			D Test Guid		
Rem				rom similar materials	
Serio	ous eye damage/eye i	rritation			
	lassified based on ava		nation.		
<u>Com</u>	ponents:				
lvern	nectin:				
Spec		: Rab			
Resu	ılt	: Mild	eye irritatior	1	
2,6-D	)i-tert-butyl-p-cresol:				
Spec		: Rab	oit		
Meth	od		: OECD Test Guideline 405		
Resu			No eye irritation Based on data from similar materials		
Rem	arks	· Base	n on data tr	om similar materials	

: Based on data from similar materials

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



## **Ivermectin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### 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

Not classified based on available information.

#### Components:

#### 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	

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



## **Ivermectin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

#### **Result: negative**

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

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

#### **Reproductive toxicity**

Not classified based on available information.

#### Components:

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.

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



# **Ivermectin Formulation**

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
		Remarks: Th vant in huma	e mechanism or mode of action may not be rele- ns.
			bbit
2.6-D	i-tert-butyl-p-cresol:		
	ts on fertility	Species: Rat	Route: Ingestion
Effect ment	ts on foetal develop-	Species: Rat	Route: Ingestion
	Γ - single exposure cause damage to orgar	IS.	
Com	ponents:		
lverm	nectin:		
	et Organs ssment	: Central nervo : Causes dam	ous system age to organs.
	<b>- repeated exposure</b>		d or repeated exposure.
	ponents:	ie uneugn protonge	
	nectin:		
Targe	et Organs ssment	<ul> <li>Central nervo</li> <li>Causes dam exposure.</li> </ul>	ous system age to organs through prolonged or repeated
2.6-D	i-tert-butyl-p-cresol:		
	ssment		t health effects observed in animals at concentra- ng/kg bw or less.
Repe	ated dose toxicity		
Com	ponents:		
lverm	nectin:		
Speci NOAI		: Dog : 0,5 mg/kg	

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



## Ivermectin Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
Expo Targe Symp Spec NOAI Applie	cation Route sure time et Organs otoms ies EL cation Route sure time	: Monkey : 1,2 mg/kg : Oral : 2 Weeks	us system ne pupil, Tremors, Lack of coordination, anorexia adverse effects were reported
Expo	ΞL	: Rat : 0,4 mg/kg : 0,8 mg/kg : Oral : 3 Months : 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.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### Product:

Assessment : 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.

#### 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



# **Ivermectin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

#### **SECTION 12: Ecological information**

### 12.1 Toxicity

Components:		
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 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 mg/l 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.
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 tox- icity)	:	1

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



# **Ivermectin Formulation**

Ver 5.1	sion	Revision Date: 28.09.2024		DS Number: 00564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020	
	Toxicity	to microorganisms	:	EC50 : > 10.000 r Exposure time: 3 Method: OECD Te	h	
	Toxicity icity)	to fish (Chronic tox-	:	NOEC: 0,053 mg/ Exposure time: 30 Species: Oryzias Method: OECD Te	) d latipes (Japanese medaka)	
		invertebrates (Chron-	:	NOEC: 0,316 mg/ Exposure time: 21 Species: Daphnia		
	M-Facto toxicity)	or (Chronic aquatic	:	1		
12.2	12.2 Persistence and degradability					
	<u>Compo</u>	nents:				
	lverme	ctin:				
	Biodegr	adability	:	Result: Not readily Biodegradation: 5 Exposure time: 24	50 %	
	2.6-Di-t	ert-butyl-p-cresol:				
		adability	:	Result: Not readily Biodegradation: 4 Exposure time: 28 Method: OECD To	4,5 %	
12.3	12.3 Bioaccumulative potential					
	Compo	nents:				
	lverme	ctin:				
		imulation	:	Bioconcentration	factor (BCF): 74	
	Partitior octanol/	n coefficient: n- /water	:	log Pow: 3,22		
	2,6-Di-t	ert-butyl-p-cresol:				
	Bioaccu	Imulation	:	Species: Cyprinus Bioconcentration	s carpio (Carp) factor (BCF): 330 - 1.800	
	Partitior octanol/	n coefficient: n- /water	:	log Pow: 5,1		
12.4	<b>4 Mobilit</b> No data	<b>y in soil</b> available				



## Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

:

#### 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 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.

#### 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	:	

#### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
ΙΑΤΑ	:	UN 3082

#### 14.2 UN proper shipping name

ADN

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

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



# **Ivermectin Formulation**

Version 5.1	Revision Date: 28.09.2024		0S Number: 00564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
ADR		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID, Di-tert-butyl-p-cresol)
RID		:	ENVIRONMENTA N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
IMDG	6	:	ENVIRONMENTA N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
ΙΑΤΑ		:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin, 2,6-Di-tert-butyl-p-cresol)	
14.3 Tran	sport hazard class(es)			
			Class	Subsidiary risks
ADN		:	9	
ADR		:	9	
RID		:	9	
IMDO	6	:	9	
ΙΑΤΑ		:	9	
14.4 Pack	ing group			
Class	ing group sification Code rd Identification Number Is	:	III M6 90 9	
Class Haza Label	ing group sification Code rd Identification Number Is el restriction code	:	III M6 90 9 (-)	
Class	ing group sification Code rd Identification Number Is	:	III M6 90 9	
Labe	ing group	:	III 9 F-A, S-F	
Packi aircra Packi	(Cargo) ing instruction (cargo ift) ing instruction (LQ) ing group	:	964 Y964 III	



## Ivermectin Formulation

Vers 5.1	sion	Revision Date: 28.09.2024		DS Number: 00564-00017	Date of last issue: 06.07.2024 Date of first issue: 30.06.2020
	Labels		:	Miscellaneous	
		Passenger) g instruction (passen-	:	964	
	Packin	g instruction (LQ) g group	:	Y964 III Miscellaneous	
14.5 Environmental hazards		•	Miscellarieous		
	<b>ADN</b> Enviror	nmentally hazardous	:	yes	
	<b>ADR</b> Enviror	nmentally hazardous	:	yes	
	<b>RID</b> Enviror	nmentally hazardous	:	yes	
	<b>IMDG</b> Marine	pollutant	:	yes	
		Passenger) nmentally hazardous	:	yes	
		<b>Cargo)</b> nmentally 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) : Conditions of restriction for the following entries should be considered: Number on list 3

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.

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



## Ivermectin Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 6100564-00017		last issue: 06.07.2 first issue: 30.06.2	
	CH - Candidate List of S cern for Authorisation (A	, ,	h :	Not applicable	
REA	CH - List of substances ex XIV)		n :	Not applicable	
	ulation (EC) on substand	ces that deplete the ozo	one :	Not applicable	
•	lation (EU) 2019/1021 (recast)	on persistent organic p	ollu- :	Not applicable	
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import				Not applicable	
Seve	ngerous chemicals so III: Directive 2012/18 r-accident hazards invo	•		t and of the Counc	il on the control of
, E1		ENVIRONMENT		Quantity 1 100 t	Quantity 2 200 t

# 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:

HAZARDS

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.			
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 abbreviatio	Full text of other abbreviations				
Acute Tox.	:	Acute toxicity			



## Ivermectin Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.07.2024
5.1		6100564-00017	Date of first issue: 30.06.2020
	tic Acute	: Short-term (ac	ute) aquatic hazard

Aquatic Acute :	Short-term (acute) aquatic hazard
Aquatic Chronic :	Long-term (chronic) aquatic hazard
STOT RE :	Specific target organ toxicity - repeated exposure
STOT SE :	Specific target organ toxicity - single exposure

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 -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:	

STOT SE 2	H371
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure: Calculation method Calculation method Calculation method Calculation method



## Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	6100564-00017	Date of first issue: 30.06.2020

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