

Doramectin Formulation

Version 6.0	Revision Date: 06.07.2024		S Number: 91212-00014	Date of last issue: 06.04.2024 Date of first issue: 22.10.2019
	ON 1: IDENTIFICATION oduct name	:	Doramectin Form	nulation
Ма	nufacturer or supplier's	deta	ils	
	mpany	:		a Pty Limited (trading as MSD Animal Health)
Ad	dress	:	91-105 Harpin S Bendigo 3550, \	treet /ictoria Austrailia
Tel	lephone	:	1 800 033 461	
Em	nergency telephone number	er :	Poisons Informa	tion Centre: Phone 13 11 26
E-r	nail address	:	EHSDATASTEW	/ARD@msd.com
Re	commended use of the o	chem	ical and restriction	ons on use
	commended use strictions on use	:	Veterinary produ Not applicable	ict

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Reproductive toxicity	:	Category 1B
Specific target organ toxicity - single exposure (Oral)	:	Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Central nervous system, Liver, Kidney)
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360D May damage the unborn child. H371 May cause damage to organs (Central nervous system) if swallowed. H373 May cause damage to organs (Central nervous system, Liver, Kidney) through prolonged or repeated exposure if swal- lowed.
Precautionary statements	:	Prevention:





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		P202 Do not h and understood P260 Do not br P264 Wash ski P270 Do not ea	reathe mist or vapours. In thoroughly after handling. at, drink or smoke when using this product. Itective gloves/ protective clothing/ eye protec-
		Response: P308 + P311 IF CENTER/ doct	F exposed or concerned: Call a POISON or.
		Storage: P405 Store loc	ked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Oils, sesame	8008-74-0	>= 60 -<= 100
Doramectin	117704-25-3	>= 1 -< 10

SECTION 4. 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.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	 In case of contact, immediately flush skin with soap and 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	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
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.



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Methods and materials for

containment and cleaning up

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	Most important symptoms and effects, both acute and delayed		:	May damage the unborn child. May cause damage to organs if swallowed. May cause damage to organs through prolonged or repeated			
	Protect	ion of first-aiders	:	exposure if swallowed. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).			
	Notes t	o physician	:		cally and supportively.		
SEC	TION 5	. FIREFIGHTING MEA	SU	RES			
	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical			
	Unsuita media	able extinguishing	:	None known.			
	Specific fighting	c hazards during fire- I	:	Exposure to com	oustion products may be a hazard to health.		
	Hazard ucts	lous combustion prod-	:	Carbon oxides			
	Specifie ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do		
	for firef	l protective equipment ighters em Code	:	In the event of fire	e, wear self-contained breathing apparatus. rective equipment.		
SEC	TION 6	. ACCIDENTAL RELE	ASI	EMEASURES			
	Person tive equ	al precautions, protec- uipment and emer- procedures		Use personal pro Follow safe handl	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).		
	Enviror	nmental precautions	:		he environment. akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil		

cannot be contained.

:

bent.

Retain and dispose of contaminated wash water.

Soak up with inert absorbent material.

Local authorities should be advised if significant spillages

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-





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		posal of this ma employed in the mine which reg Sections 13 an	al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nical measures		ig measures under EXPOSURE ERSONAL PROTECTION section.
Local	/Total ventilation		tilation is unavailable, use with local exhaust
	e on safe handling	: Do not get on s Do not breathe Do not swallow Avoid contact v Wash skin thor Handle in acco practice, based sessment Keep container Do not eat, drin Take care to pr environment.	mist or vapours. vith eyes. oughly after handling. rdance with good industrial hygiene and safety I on the results of the workplace exposure as- tightly closed. k or smoke when using this product. event spills, waste and minimize release to the
Hygie	ene measures	flushing system place. When using do Wash contamir The effective of engineering con appropriate deg	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls
Cond	itions for safe storage	: Keep in proper Store locked up Keep tightly clo	ly labelled containers.). sed.
Mater	rials to avoid		ance with the particular national regulations. th the following product types: g agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components CAS-No. Value type Control parame-Basis ters / Permissible (Form of exposure) concentration Oils, sesame 8008-74-0 AU OEL TWA (Mist) 10 mg/m3 Doramectin 117704-25-3 TWA 25 µg/m3 (OEB 3) Internal

Components with workplace control parameters



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I		Further inform	nation: Skin
			Wipe limit 250 µg/100 cm2 Internal
Engir	neering measures	technologies less quick co All engineerin design and o protect produ Containment are required	ing controls should be implemented by facility operated in accordance with GMP principles to ucts, workers, and the environment. t technologies suitable for controlling compounds to control at source and to prevent migration of nd to uncontrolled areas (e.g., open-face con- vices).
Perso	onal protective equip	oment	
Fil	iratory protection Iter type protection	sure assessr	local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. type
Ма	aterial	: Chemical-res	sistant gloves
	emarks protection	If the work er mists or aero Wear a faces	uble gloving. glasses with side shields or goggles. nvironment or activity involves dusty conditions, osols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or
Skin a	and body protection	: Work uniform Additional bo task being pe posable suits	n or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, dis- s) to avoid exposed skin surfaces. riate degowning techniques to remove potentially d clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	oily
Colour	:	light yellow
Odour	:	characteristic
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	-7 °C



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	Initial bo range	iling point and boiling	:	270 °C	
	Flash po	pint	:	215.7 °C	
	Evapora	tion rate	:	No data available	9
	Flamma	bility (solid, gas)	:	Not applicable	
	Flamma	bility (liquids)	:	Not applicable	
		xplosion limit / Upper bility limit	:	No data available	
		xplosion limit / Lower bility limit	:	No data available)
	Vapour	pressure	:	No data available)
	Relative	vapour density	:	No data available)
	Relative	density	:	0.89 - 91	
	Density		:	No data available)
	Solubilit Wate	y(ies) er solubility	:	practically insolut	ble
	Partition octanol/	coefficient: n-	:	Not applicable	
		ition temperature	:	No data available)
	Decomp	osition temperature	:	No data available	9
	Viscosity Visco	y osity, kinematic	:	31.7 - 32.1 m2/s	(25 °C)
	Explosiv	e properties	:	Not explosive	
	Oxidizin	g properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecula	ar weight	:	No data available)
	Particle Particle	characteristics size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity

: Not classified as a reactivity hazard.



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Poss tions Cond Incor	nical stability ibility of hazardous reac- litions to avoid npatible materials rdous decomposition ucts	:	Can react with None known. Oxidizing agent	ormal conditions. strong oxidizing agents. ts decomposition products are known.
SECTION	11. TOXICOLOGICAL I	NFC	ORMATION	
Ехро	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	lassified based on availa	ble	information.	
Prod Acute	e oral toxicity	:	Acute toxicity es Method: Calcula	stimate: > 2,000 mg/kg ation method
<u>Com</u>	ponents:			
Oils,	sesame:			
Acute	e oral toxicity	:	LD50 (Rat): > 2, Remarks: Based	000 mg/kg d on data from similar materials
Acute	e dermal toxicity	:	LD50 (Rabbit): >	> 2,000 mg/kg
Dora	mectin:			
Acute	e oral toxicity	:	LD50 (Rat): 500 Target Organs: 0	mg/kg Central nervous system
			LD50 (Mouse): = Target Organs: (> 2,000 mg/kg Central nervous system
			LD50 (Rat): 50 r Target Organs:	ng/kg Central nervous system
			LD50 (Mouse): 7 Target Organs: 0	75 mg/kg Central nervous system
	e toxicity (other routes of nistration)	:		00 mg/kg te: Intraperitoneal Central nervous system
<u>.</u>				

Skin corrosion/irritation

Not classified based on available information.



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Components:

Oils, sesame:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Oils, sesame:

Species	:	Rabbit
Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Oils, sesame:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Oils, sesame:

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

Doramectin:

Genotoxicity in vitro : Test Type: Ames test Result: negative Test Type: Mouse Lymphoma Result: negative

Test Type: unscheduled DNA synthesis assay Result: negative



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Genot	toxicity in vivo	:	Test Type: Micro Species: Mouse Result: negative	nucleus test
	cell mutagenicity -	:	Weight of eviden cell mutagen.	ce does not support classification as a gerr
	nogenicity assified based on avail	lable	information.	
Comp	oonents:			
	nectin: nogenicity - Assess-	:	Weight of eviden cinogen	ce does not support classification as a car-
-	oductive toxicity lamage the unborn chil	d.		
Comp	oonents:			
Dorar	nectin:			
Effect ment	s on foetal develop-	:	Species: Rat Application Route	kicity: NOAEL: 0.3 mg/kg body weight
			Species: Mouse Application Route Embryo-foetal to:	kicity: NOAEL: 3 mg/kg body weight
			Symptoms: Emb	yolethal effects
			Species: Rabbit Application Route General Toxicity	yo-foetal development e: Oral Maternal: NOAEL: 0.75 mg/kg body weight rnal effects, Embryotoxic effects.
Repro sessm	oductive toxicity - As- nent	:	Clear evidence o animal experime	f adverse effects on development, based o nts.
STOT	- single exposure			
	ause damage to organ	is (Ce	entral nervous syst	tem) if swallowed.
-	oonents:			
Dorar	nectin:			
			Oral	



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ersion 0	Revision Date: 06.07.2024	SDS Number: 5191212-00014	Date of last issue: 06.04.2024 Date of first issue: 22.10.2019
A			
Asses	ssment		uce significant health effects in animals at co 00 mg/kg bw or less.
STOT	- repeated exposur	e	
	ause damage to orga d exposure if swallow		rstem, Liver, Kidney) through prolonged or re
<u>Com</u>	oonents:		
Dora	mectin:		
	sure routes	: Oral	
	et Organs ssment	: Shown to produ	s system, Liver, Kidney uce significant health effects in animals at co 0 mg/kg bw or less.
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Dora	mectin:		
Speci		: Rat	
LOAE		: 30 mg/kg	
	cation Route sure time	: Oral : 3 Months	
	et Organs	: Central nervous	s system
•	-		
Speci		: Rat	
NOAE	L cation Route	: 2 mg/kg : Oral	
	sure time	: 3 Months	
-	et Organs		s system, Liver, Kidney
Speci		: Dog	
NOAE		: 2 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 36 d : Eye	
Symp		: Dilatation of the	e pupil
Speci	es	: Dog	
NOAE	EL	: 0.1 mg/kg	
	cation Route	: Oral	
	sure time	: 92 d : Central nervou	
	et Organs		

Not classified based on available information.



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ersion .0	Revision Date: 06.07.2024		DS Number: 91212-00014	Date of last issue: 06.04.2024 Date of first issue: 22.10.2019
Expe	rience with human e	xposi	ure	
Com	ponents:			
Dora	mectin:			
Skin	contact	:	Symptoms: Na Target Organs: Symptoms: Diz Target Organs: Symptoms: Irrit Target Organs: Symptoms: Irrit	ation Skin
Inges	tion	:	Symptoms: Bre Target Organs: Symptoms: Na	eathing difficulties Gastro-intestinal system usea, Abdominal pain, Diarrhoea Central nervous system
	12. ECOLOGICAL IN	NFORI	MATION	
	ponents:			
	mectin:			
	ity to fish	:	Exposure time:	s macrochirus (Bluegill sunfish)): 11 μg/l 96 h 9 Test Guideline 203
			Exposure time:	rnchus mykiss (rainbow trout)): 5.1 μg/l 96 h 9 Test Guideline 203
	ity to daphnia and oth tic invertebrates	er :	Exposure time:	a magna (Water flea)): 0.1 μg/l 48 h 9 Test Guideline 202
	oxicology Assessme	ent :	Very toxic to ac	quatic life.
Persi	stence and degrada	bility		
	ponents:	-		
	sesame:			

Biodegradability

: Result: Readily biodegradable.



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Bioa	ccumulative potential			
Com	ponents:			
	mectin: ccumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 71 est Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4.5 pH: 7	
Mobi	lity in soil			
Com	ponents:			
Distri	mectin: bution among environ- al compartments	:	log Koc: 4.94	
Othe	r adverse effects			
Com	ponents:			
Resu	mectin: Its of PBT and vPvB ssment	:	Substance is not (vPvB).	very persistent and very bioaccumulative

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		



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UN/I	D No.	: UN 30)82	
Prop	er shipping name		onmentally h amectin)	azardous substance, liquid, n.o.s.
Clas	S	: 9	,	
Pack	king group	: 111		
Labe			llaneous	
	king instruction (cargo	: 964		
aircr		. 004		
	ting instruction (passen-	: 964		
	ronmentally hazardous	: yes		
		. ,00		
	G-Code number	: UN 30	201	
	er shipping name			ALLY HAZARDOUS SUBSTANCE, LIQUID,
FTOP	er snipping name	N.O.S		LET HAZARDOUS SUBSTAINCE, EIQUID,
			mectin)	
Clas	S	: 9	,	
Pack	ting group	: 111		
Labe		: 9		
-	Code	: F-A, S	S-F	
Mari	ne pollutant	: yes		
Tran	sport in bulk according	to Annex	II of MARP	OL 73/78 and the IBC Code
Not a	applicable for product as	supplied.		
Nati	onal Regulations	-		

National Regulations

ADG UN number Proper shipping name	:	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)
Class	:	9
Packing group	:	
Labels	:	9
Hazchem Code	:	•3Z
Environmentally hazardous	:	yes

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-	
ture	

Therapeutic Goods (Poisons	:	Schedule 7 (Please use the original publication to check for
Standard) Instrument		specific uses, specific conditions or threshold limits that might
		apply for this chemical)



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Prohibition/Licensing Requirements			: There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of the model WHS Act and Regula- tions.			
The components of this product are reported in the following inventories:						
AICS		: not determin	ed			
DSL		: not determin	ed			
IECSC)	: not determin	ed			

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

:	06.07.2024
:	Internal technical data, data from raw material SDSs, OECD
	eChem Portal search results and European Chemicals Agen-
	cy, http://echa.europa.eu/
	:

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

Date format	: dd.mm.yyyy
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Full text of other abbreviations

AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals: ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect



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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AU / EN