Version

6.0



Date of last issue: 2024/04/06

Date of first issue: 2019/10/22

Doramectin Formulation

Revision Date:

2024/07/06

Hazard statements

1. PRODUCT AND COMPANY IDE	NT	IFICATION
Product name	:	Doramectin Formulation
Manufacturer or supplier's de Company	etai :	ils MSD
Address	:	126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone number	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions on use	:	Veterinary product Not applicable
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)
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements		H360D May damage the upborn child

SDS Number:

5191214-00014

: H360D May damage the unborn child. H371 May cause damage to organs (Central nervous system) if





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		Liver, Kidney) lowed.	through prolonged	ans (Central nervous system, I or repeated exposure if swal- ith long lasting effects.				
Preca	autionary statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P270 Do not e P273 Avoid rel	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protec- 					
		Response: P308 + P311 I CENTER/ doct P391 Collect s	tor.	cerned: Call a POISON				
		Storage: P405 Store loc	ked up.					
		Disposal:	of contents/ conta	iner to an approved waste				
	r hazards which do known.	not result in classifica	tion					
3. COMPO	OSITION/INFORMAT	ION ON INGREDIENTS	3					
	tance / Mixture	: Mixture						
	ponents nical name		CAS-No.	Concentration (% w/w)				
Onen			117704-25-3	>= 1 -< 2.5				

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes.



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If swa Most and e delay Prote	se of eye contact allowed important symptoms effects, both acute and red ection of first-aiders s to physician	: : : :	Flush eyes with w Get medical atter If swallowed, DO Get medical atter Rinse mouth thor Never give anythi May damage the May cause dama May cause dama exposure if swalld First Aid respond and use the recon when the potentia	fore reuse. shoes before reuse. vater as a precaution. ntion if irritation develops and persists. NOT induce vomiting. ntion. oughly with water. ing by mouth to an unconscious person. unborn child. ge to organs if swallowed. ge to organs through prolonged or repeated
	GHTING MEASURES	•		
Unsu media Spec fightir	ific hazards during fire-	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical None known. Exposure to comi Carbon oxides	
ucts				
ods Spec	ific extinguishing meth- ial protective equipment efighters	:	cumstances and Use water spray Remove undama so. Evacuate area. In the event of fire	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to d e, wear self-contained breathing apparatus. tective equipment.
. ACCID	ENTAL RELEASE MEAS	SUF	RES	
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envir	onmental precautions	:	Prevent spreadin barriers). Retain and dispos	eakage or spillage if safe to do so. g over a wide area (e.g. by containment or o se of contaminated wash water. should be advised if significant spillages

cannot be contained.



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	nods and materials for ainment and cleaning up	For large spills, ment to keep m be pumped, sto Clean up remai bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	ert absorbent material. provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. ning materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items a cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
7. HAND	LING AND STORAGE		
Tech	nnical measures		g measures under EXPOSURE ERSONAL PROTECTION section.
Loca	al/Total ventilation		ilation is unavailable, use with local exhaust
Advi	ce on safe handling	: Do not get on s Do not breathe Do not swallow. Avoid contact w Wash skin thoro Handle in accor practice, based sessment Keep container Do not eat, drin	mist or vapours. with eyes. bughly after handling. dance with good industrial hygiene and safety on the results of the workplace exposure as-
Cond	ditions for safe storage	: Keep in properl Store locked up Keep tightly clo	sed.
Mate	erials to avoid		ance with the particular national regulations. In the following product types: g agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Doramectin	117704-25-3	TWA	25 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	250 µg/100 cm2	Internal



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Engineering measures		technologie less quick c All engineer design and protect prod Containmer are required the compou tainment de	riate engineering controls and manufacturing s to control airborne concentrations (e.g., drip- onnections). ing controls should be implemented by facility operated in accordance with GMP principles to lucts, workers, and the environment. It 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	ment	
Resp	iratory protection	sure assess	local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection.
	ter type protection	: Particulates	
Ma	aterial	: Chemical-re	sistant gloves
	emarks protection	: Wear safety If the work e mists or aer Wear a face	puble gloving. glasses with side shields or goggles. environment or activity involves dusty conditions, osols, wear the appropriate goggles. eshield or other full face protection if there is a direct contact to the face with dusts, mists, or
Skin a	and body protection	: Work unifor Additional b task being p posable suit	m or laboratory coat. ody garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, dis- is) to avoid exposed skin surfaces. riate degowning techniques to remove potentially ed clothing.
Hygie	ene measures	eye flushing ing place. When using Wash conta The effectiv engineering appropriate industrial hy	to chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, rgiene monitoring, medical surveillance and the nistrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	oily
Colour	:	light yellow
Odour	:	characteristic



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	Odour ⁻	Threshold	:	No data available	3
	рН			No data available	
		point/freezing point	:	-7 °C	,
			•		
	range	oiling point and boiling	·	270 °C	
	Flash p	oint	:	215.7 °C	
	Evapor	ation rate	:	No data available	9
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available)
	Relative	e vapour density	:	No data available	9
	Relative	e density	:	0.89 - 91	
	Density	,	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	practically insolu	ble
		n coefficient: n-	:	Not applicable	
	octanol Auto-ig	/water nition temperature	:	No data available)
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	31.7 - 32.1 m2/s	(25 °C)
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	



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	le characteristics le size	:	Not applicable	
. STABI	LITY AND REACTIVITY	,		
Possi tions Condi Incom	nical stability bility of hazardous reac- itions to avoid npatible materials rdous decomposition	:	Stable under no Can react with s None known. Oxidizing agent	s a reactivity hazard. ormal conditions. strong oxidizing agents. s lecomposition products are known.
•		101	N	
Inform	nation on likely routes of	:	Inhalation Skin contact	
expos	sure		Ingestion Eye contact	
Acute	e toxicity	ble	Ingestion Eye contact	
Acute	e toxicity lassified based on availa	ble	Ingestion Eye contact	
Acute Not cl <u>Produ</u>	e toxicity lassified based on availa	ble :	Ingestion Eye contact information.	timate: > 2,000 mg/kg tion method
Acute Not cl <u>Produ</u> Acute	e toxicity lassified based on availa u <u>ct:</u>	ble :	Ingestion Eye contact information. Acute toxicity es	
Acute Not cl Produ Acute	e toxicity lassified based on availa u <u>ct:</u> e oral toxicity	ble :	Ingestion Eye contact information. Acute toxicity es	
Acute Not cl <u>Produ</u> Acute <u>Comp</u>	e toxicity lassified based on availa uct: oral toxicity ponents:	:	Ingestion Eye contact information. Acute toxicity es Method: Calcular LD50 (Rat): 500	tion method
Acute Not cl <u>Produ</u> Acute <u>Comp</u>	e toxicity lassified based on availa uct: oral toxicity <u>conents:</u> mectin:	:	Ingestion Eye contact information. Acute toxicity es Method: Calcular LD50 (Rat): 500 Target Organs: 0 LD50 (Mouse): >	tion method mg/kg Central nervous system
Acute Not cl <u>Produ</u> Acute <u>Comp</u>	e toxicity lassified based on availa uct: oral toxicity <u>conents:</u> mectin:	:	Ingestion Eye contact information. Acute toxicity est Method: Calculat LD50 (Rat): 500 Target Organs: C LD50 (Mouse): > Target Organs: C LD50 (Rat): 50 n	tion method mg/kg Central nervous system > 2,000 mg/kg Central nervous system
Acute Not cl <u>Produ</u> Acute <u>Comp</u>	e toxicity lassified based on availa uct: oral toxicity <u>conents:</u> mectin:	:	Ingestion Eye contact information. Acute toxicity es Method: Calcular LD50 (Rat): 500 Target Organs: C LD50 (Mouse): > Target Organs: C LD50 (Rat): 50 n Target Organs: C LD50 (Mouse): 7	tion method mg/kg Central nervous system > 2,000 mg/kg Central nervous system ng/kg Central nervous system



ersion 0	Revision Date: 2024/07/06		91214-00014	Date of last issue: 2024/04/06 Date of first issue: 2019/10/22
	us eye damage/eye ir			
	lassified based on avai iratory or skin sensiti			
Skin	sensitisation lassified based on avai			
-	iratory sensitisation lassified based on avai	lable	information.	
	cell mutagenicity lassified based on avai	lable	information.	
<u>Comp</u>	oonents:			
Dora	mectin:			
Geno	toxicity in vitro	:	Test Type: Ames Result: negative	s test
			Test Type: Mous Result: negative	se Lymphoma
			Test Type: unsc Result: negative	heduled DNA synthesis assay
Geno	toxicity in vivo	:	Test Type: Micro Species: Mouse Result: negative	onucleus test
Asses	cell mutagenicity -	:	Weight of evider cell mutagen.	nce does not support classification as a gern
	nogenicity lassified based on avai	labla	information	
	oonents:	lable		
	mectin: nogenicity - Assess-	:	Weight of evider cinogen	nce does not support classification as a car-
-	oductive toxicity damage the unborn chil	ld.		
Com	oonents:			
Dora	mectin:			
Effect ment	s on foetal develop-	:	Species: Rat Application Rout Embryo-foetal to	ryo-foetal development e: Oral xicity: NOAEL: 0.3 mg/kg body weight uced body weight
			8 / 14	



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Repr	oductive toxicity - As- ment	:	Species: Mouse Application Route Embryo-foetal tox Symptoms: Embry Test Type: Embry Species: Rabbit Application Route General Toxicity Symptoms: Mater	ticity: NOAEL: 3 mg/kg body weight yolethal effects vo-foetal development e: Oral Maternal: NOAEL: 0.75 mg/kg body weight rnal effects, Embryotoxic effects.
May	T - single exposure cause damage to organs ponents:	s (Ce	entral nervous syst	em) if swallowed.
Expo Targe	mectin: sure routes et Organs ssment	::		system e significant health effects in animals at con-) mg/kg bw or less.
May	T - repeated exposure cause damage to organs ed exposure if swallowed		entral nervous syst	em, Liver, Kidney) through prolonged or re-
Dora Expo Targe	ponents: mectin: sure routes et Organs ssment	: : :	Shown to produce	system, Liver, Kidney e significant health effects in animals at con- mg/kg bw or less.
-	eated dose toxicity ponents:			
Dora	mectin:			
Expo		:	Rat 30 mg/kg Oral 3 Months Central nervous s	system
Spec	ies	:	Rat	



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Expo	cation Route sure time	: Ora : 3 M	onths	
Spec NOA Appli Expo Targe		: Dog : 2 m : Ora : 36 c : Eye	l g/kg l	system, Liver, Kidney pupil
Expo Targe		: Ora : 92 (: Cer	mg/kg l d	system, Eye pupil
Not c	ration toxicity classified based on ava crience with human e		mation.	
	ponents:			
Skin	mectin: contact	Syn Tar Syn Tar Syn Tar Syn Tar	nptoms: Nau get Organs: nptoms: Dizz get Organs: nptoms: Irrita get Organs: nptoms: Irrita get Organs:	ation Skin
Inges	stion	: Tar Syn Tar	get Organs: hptoms: Nau	Gastro-intestinal system isea, Abdominal pain, Diarrhoea Central nervous system

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Doramectin:

Toxicity to fish

 LC50 (Lepomis macrochirus (Bluegill sunfish)): 11 μg/l Exposure time: 96 h Method: OECD Test Guideline 203



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П				
			Exposure time: 9	ichus mykiss (rainbow trout)): 5.1 μg/l 96 h Test Guideline 203
	city to daphnia and other atic invertebrates	:	Exposure time: 4	magna (Water flea)): 0.1 µg/l ł8 h Test Guideline 202
M-F toxic	actor (Chronic aquatic city)	:	10,000	
Eco	toxicology Assessment			
Acut	te aquatic toxicity	:	Very toxic to aqu	latic life.
	sistence and degradabili	ity		
Bioa	accumulative potential			
<u>Con</u>	nponents:			
Dora	amectin:			
Bioa	accumulation	:	Bioconcentration	is macrochirus (Bluegill sunfish) n factor (BCF): 71 Test Guideline 305
	ition coefficient: n- nol/water	:	log Pow: 4.5 pH: 7	
Mob	bility in soil			
<u>Con</u>	nponents:			
Dist	amectin: ribution among environ- ital compartments er adverse effects	:	log Koc: 4.94	
	nponents:			
Res	amectin: ults of PBT and vPvB essment	:	Substance is not (vPvB).	t very persistent and very bioaccumulative
13. DISP	OSAL CONSIDERATION	IS		
Dier	acal mothoda			
Disp	posal methods			• · · · · ·



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Conta	aminated packaging	:	dling site for recy	s should be taken to an approved waste han- /cling or disposal. specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION	l		
Interr	national Regulations			
	umber er shipping name	::	UN 3082 ENVIRONMENT N.O.S. (Doramectin) 9	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Label	ng group s onmentally hazardous	:	III 9 yes	
IATA∙ UN/ID Prope	-	:	UN 3082 Environmentally (Doramectin)	hazardous substance, liquid, n.o.s.
Label Packi aircra	ng group s ng instruction (cargo		9 III Miscellaneous 964 964	
	rcraft) onmentally hazardous	:	yes	
UN nu	-Code umber er shipping name	:	UN 3082	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Label EmS	ng group s		9 III 9 F-A, S-F yes	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.



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15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances
Hazardous to Health

Hazardous substances that must be registered	:	Not applicable
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Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	2024/07/06
Further information		
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

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

Date format

: yyyy/mm/dd



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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods: IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations 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.

ID / EN