

according to the Hazardous Products Regulations

Doramectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
5.0	07/06/2024	5191200-00015	Date of first issue: 10/22/2019

SECTION 1. IDENTIFICATION

Product name	:	Doramectin Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations Reproductive toxicity : Category 1B					
Specific target organ toxicity - single exposure (Oral)	:	Category 1 (Central nervous system)			
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Central nervous system, Liver, Kidney)			
GHS label elements					
Hazard pictograms	:				
Signal Word	:	Danger			
Hazard Statements	:	 H360D May damage the unborn child. H370 Causes damage to organs (Central nervous system) if swallowed. H372 Causes damage to organs (Central nervous system, Liver, Kidney) through prolonged or repeated exposure if swallowed. 			
Precautionary Statements	:	 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 vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. 			



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		P280 Wear pro and face protec	tective gloves, protective clothing, eye protection tion.
		Response: P308 + P311 IF	exposed or concerned: Call a doctor.
		Storage: P405 Store lock	ked up.
		Disposal: P501 Dispose o disposal plant.	of contents and container to an approved waste
Othe	r hazards		
None	known.		

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Oils, sesame	Sesamum indi- cum oil	8008-74-0	79
Doramectin	No data availa- ble	117704-25-3	1

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.
Most important symptoms and effects, both acute and delayed	:	
Protection of first-aiders	:	First Aid responders should pay attention to self-protection,



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Notes	Notes to physician		when the poten	ommended personal protective equipment ial for exposure exists (see section 8). atically and supportively.
SECTION	5. FIRE-FIGHTING ME	ASL	IRES	
Suital	ole extinguishing media	:	Water spray Alcohol-resistar Carbon dioxide Dry chemical	
Unsui media	itable extinguishing	:	None known.	
Speci fightir	fic hazards during fire	:	Exposure to cor	nbustion products may be a hazard to health.
Hazaı ucts	rdous combustion prod-	:	Carbon oxides	
Speci ods	fic extinguishing meth-	:	cumstances and Use water spray	ng measures that are appropriate to local cir- d the surrounding environment. v to cool unopened containers. aged containers from fire area if it is safe to do
	al protective equipment e-fighters	:	In the event of f	ire, wear self-contained breathing apparatus. otective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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SECTION 7. HANDLING AND STORAGE

Technical measures Local/Total ventilation	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. If sufficient ventilation is unavailable, use with local exhaust
Advice on safe handling	:	ventilation. Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

	••••••• pa			
Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Oils, sesame	8008-74-0	TWAEV	10 mg/m ³	CA QC OEL
		(Mist)		
Doramectin	117704-25-3	TWA	25 µg/m3 (OEB 3)	Internal
	Further inform	ation: Skin		
		Wipe limit	250 µg/100 cm2	Internal

Ingredients with workplace control parameters

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 technologies suitable for controlling compounds



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		containment Minimize op	
Perso	onal protective equip	ment	
Resp	iratory protection	exposure as	local exhaust ventilation is not available or sessment demonstrates exposures outside the ed guidelines, use respiratory protection.
	lter type protection	: Particulates	
Ma	aterial	: Chemical-re	sistant gloves
Re	emarks	: Consider do	uble gloving.
Eye p	protection	: Wear safety If the work e mists or aero Wear a face	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	Additional be task being p disposable s	n or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, suits) to avoid exposed skin surfaces. riate degowning techniques to remove potentially d clothing.
Hygie	ene measures	: If exposure the eye flushing working place When using Wash conta The effective engineering appropriate industrial hy	to chemical is likely during typical use, provide systems and safety showers close to the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	oily
Color	:	light yellow
Odor	:	characteristic
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	-7 °C
Initial boiling point and boiling range	:	270 °C
Flash point	:	215.7 °C

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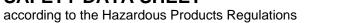


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	Evapor	ration rate	:	No data available)
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapor	pressure	:	No data available)
	Relativ	e vapor density	:	No data available)
	Relativ	e density	:	0.89 - 91	
	Density	/	:	No data available	9
	Solubil Wat	ity(ies) ter solubility	:	practically insolut	ble
	Partitio octano	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ity cosity, kinematic	:	31.7 - 32.1 m²/s (25 °C)
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available)
	Particle Particle	e characteristics e size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents





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Hazar produ	rdous decomposition cts	:	No hazardous	decomposition products are known.
ECTION	11. TOXICOLOGICAL	INF	ORMATION	
Inform	nation on likely route	s of	exposure	
Inhala Skin o Ingest	ation contact	3 01	exposure	
•	e toxicity			
Not cl	assified based on avail	lable	information.	
<u>Produ</u> Acute	uct: oral toxicity	:	Acute toxicity e Method: Calcul	stimate: > 2,000 mg/kg ation method
Comp	oonents:			
Oils,	sesame:			
Acute	oral toxicity	:	LD50 (Rat): > 2 Remarks: Base	,000 mg/kg d on data from similar materials
Acute	dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
Dorar	mectin:			
Acute	oral toxicity	:	LD50 (Rat): 50 Target Organs:) mg/kg Central nervous system
			LD50 (Mouse): Target Organs:	> 2,000 mg/kg Central nervous system
			LD50 (Rat): 50 Target Organs:	mg/kg Central nervous system
			LD50 (Mouse): Target Organs:	75 mg/kg Central nervous system
	toxicity (other routes on istration)	of :	Application Rou	00 mg/kg ute: Intraperitoneal Central nervous system
-	corrosion/irritation assified based on avail	lable	information.	
Comp	oonents:			
Oils,	sesame:			
Speci Resul		:	Rabbit No skin irritatio	n



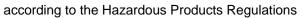
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Not cl	us eye damage/eye i lassified based on ava			
Comp	oonents:			
Oils, Speci Resul		:	Rabbit No eye irritation	
	iratory or skin sensit	Hizatio		
-	-	lizatio		
-	sensitization lassified based on ava	ilable	information.	
-	iratory sensitization			
Not cl	lassified based on ava	ilable	information.	
<u>Comp</u>	<u>ponents:</u>			
Oils,	sesame:			
Test Route Resul	es of exposure	:	Human repeat in Skin contact negative	sult patch test (HRIPT)
Not cl	n cell mutagenicity lassified based on ava ponents:	ilable	information.	
	sesame: toxicity in vitro	:	Test Type: Bacte Result: negative	erial reverse mutation assay (AMES)
			Ũ	
	mectin:			
Geno	toxicity in vitro	:	Test Type: Ames Result: negative	s test
			Test Type: Mous Result: negative	e Lymphoma
			Test Type: unsch Result: negative	neduled DNA synthesis assay
Geno	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 germ

Carcinogenicity

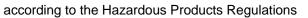
Not classified based on available information.





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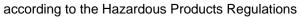
sion	Revision Date: 07/06/2024		OS Number: 91200-00015	Date of last issue: 04/06/2024 Date of first issue: 10/22/2019
<u>Comp</u>	oonents:			
Dorar	nectin:			
Carcir ment	nogenicity - Assess-	:	Weight of evide cinogen	nce does not support classification as a car
-	oductive toxicity lamage the unborn chi	ld.		
Comp	oonents:			
Dorar	mectin:			
Effect	s on fetal developmen	t :	Species: Rat Application Rou Embryo-fetal to	ryo-fetal development te: Oral kicity.: NOAEL: 0.3 mg/kg body weight luced body weight
				ryo-fetal development
			Species: Mouse Application Rou	
			Embryo-fetal to	kicity.: NOAEL: 3 mg/kg body weight bryolethal effects.
			Species: Rabbi Application Rou General Toxicit	
Repro sessn	oductive toxicity - As- nent	:		of adverse effects on development, based
STOT	-single exposure			
	es damage to organs (Centi	al nervous svste	m) if swallowed.
	oonents:		,	,
	nectin:			
	es of exposure	:	Oral	
•	t Organs ssment	:		system ce significant health effects in animals at co 00 mg/kg bw or less.
6 707	wonootod owe o over			
Cause	r-repeated exposure es damage to organs (posure if swallowed.	Centi	al nervous syste	n, Liver, Kidney) through prolonged or repe
	oonents:			
Dorar	nectin:			
	s of exposure	:	Oral	
rtouto				system, Liver, Kidney





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Asses	ssment	:		uce significant health effects in animals at con- I0 mg/kg bw or less.
Repe	ated dose toxicity			
Com	ponents:			
Dora	mectin:			
Speci		:	Rat	
LOAE		:	30 mg/kg	
	cation Route	:	Oral	
	sure time	:	3 Months	
large	et Organs	:	Central nervou	s system
Speci		:	Rat	
NOA		:	2 mg/kg	
	cation Route	:	Oral	
	sure time	:	3 Months	
Targe	et Organs	:	Central nervou	s system, Liver, Kidney
Speci	ies	:	Dog	
NOA		:	2 mg/kg	
-	cation Route		Oral	
	sure time	:	36 d	
	et Organs	:	Eye	
Symp		:	Dilatation of the	e pupil
Speci	ies		Dog	
NOA			0.1 mg/kg	
	cation Route		Oral	
	sure time	:	92 d	
	et Organs	:	Central nervou	s svstem. Eve
Symp		:	Dilatation of the	
• • • •				
-	r ation toxicity lassified based on ava	ailahla	information	
-	rience with human e	exposi	Ire	
<u>Com</u>	ponents:			
Dora	mectin:			
Skin	contact		Target Organs	Gastro-intestinal system
		•	Symptoms: Na	
				Central nervous system
				ziness, Headache
			Target Organs	
			Symptoms: Irri	
			Target Organs	
			Symptoms: Irrit	
				Respiratory system
				eathing difficulties
Inges	tion	:		Gastro-intestinal system
0				usea, Abdominal pain, Diarrhea
			7 T	





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			Target Organs: C Symptoms: Dizzir	entral nervous system ness
SECTION	12. ECOLOGICAL INFO	DRI	IATION	
Ecoto	oxicity			
Com	oonents:			
	mectin: ity to fish	:	Exposure time: 96	nacrochirus (Bluegill sunfish)): 11 μg/l δ h est Guideline 203
			Exposure time: 96	chus mykiss (rainbow trout)): 5.1 μg/l δ h est Guideline 203
	ity to daphnia and other ic invertebrates	:	Exposure time: 48	nagna (Water flea)): 0.1 μg/l 8 h est Guideline 202
	exicology Assessment	:	Very toxic to aqua	atic life.
Persi	stence and degradabili	ty		
Com	oonents:			
	sesame: gradability	:	Result: Readily bi	iodegradable.
Bioad	cumulative potential			
Com	oonents:			
Dora	mectin:			
Bioac	cumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 71 est Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 4.5 pH: 7	
Mobil	lity in soil			
Com	oonents:			
Dora	mectin:			
	oution among environ- al compartments	:	log Koc: 4.94	

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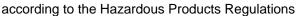


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rsion)	Revision Date: 07/06/2024		Number: 200-00015	Date of last issue: 04/06/2024 Date of first issue: 10/22/2019
Othe	r adverse effects			
Com	ponents:			
Dora	mectin:			
	Its of PBT and vPvB			ot very persistent and very bioaccumulative
asses	ssment	(\	/PvB).	
	13. DISPOSAL CON			
CTION				
CTION Dispe	13. DISPOSAL CONS	SIDERA	TIONS to not dispose	of waste into sewer. ccordance with local regulations.

International Regulations

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)
Class	:	9
Packing group	:	
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Doramectin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passen- ger aircraft)	:	964
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
		N.O.S. (Doramectin)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F





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Marine	pollutant	:	yes	
•	port in bulk according			OL 73/78 and the IBC Code
Domes	stic regulation			
TDG UN nu Proper	mber shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Labels ERG C		:	(Doramectin) 9 III 9 171 yes(Doramectin)	

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

The ingredients of this product are reported in the following inventories:
--

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

CA QC OEL	:	Québec. Regulation respecting occupational health and safe-
		ty, Schedule 1, Part 1: Permissible exposure values for air-
		borne contaminants
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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 Chemi-



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cal 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

Sources of key data used to compile the Material 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/
Revision Date Date format	-	07/06/2024 mm/dd/yyyy

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

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.

CA / Z8