

according to the Hazardous Products Regulations

Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	6097531-00016	Date of first issue: 06/30/2020

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details

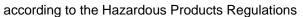
Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

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					
Specific target organ toxicity : - single exposure (Oral)	Category 1 (Central nervous system)				
Specific target organ toxicity : - repeated exposure (Oral)	Category 1 (Central nervous system)				
GHS label elements					
Hazard pictograms :					
Signal Word :	Danger				
Hazard Statements :	H370 Causes damage to organs (Central nervous system) if swallowed. H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.				
Precautionary Statements :	Prevention:				
	P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.				
	Response: P308 + P311 IF exposed or concerned: Call a doctor.				
	Storage: P405 Store locked up.				





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Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Oils, sesame	Sesamum indi- cum oil	8008-74-0	81.3
Ivermectin	No data availa- ble	70288-86-7	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 if symptoms occur.
In case of skin contact	:	
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.
Most important symptoms	:	Causes damage to organs if swallowed.
and effects, both acute and delayed		Causes damage to organs through prolonged or repeated exposure if swallowed.
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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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



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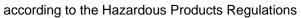
Ver 6.0	sion Revision Date: 07/06/2024	•	DS Number:)97531-00016	Date of last issue: 04/06/2024 Date of first issue: 06/30/2020
	Specific hazards during fi fighting Hazardous combustion pr ucts		·	pustion products may be a hazard to health.
Specific extinguishing meth- ods		th- :	cumstances and t Use 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
	Special protective equipm for fire-fighters	ent :	In the event of fire	e, wear self-contained breathing apparatus. tective 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.

SECTION 7. HANDLING AND STORAGE

Technical measures		ineering measures under EXPOSURE DLS/PERSONAL PROTECTION section.
Local/Total ventilation	Use only	with adequate ventilation.
Advice on safe handling	Do not b	reathe mist or vapors.
	Do not s	wallow.
	Avoid co	ntact with eyes.
	Avoid pro	blonged or repeated contact with skin.
	Wash sk	in thoroughly after handling.





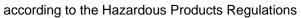
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		practice, based assessment Do not eat, drink	dance with good industrial hygiene and safety on the results of the workplace exposure or smoke when using this product. event spills, waste and minimize release to the		
Conditions for safe storage		: Keep in properly labeled containers. Store locked up.			
Mater	ials to avoid	: Do not store with Strong oxidizing	ostances and mixtures		

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Oils, sesame	8008-74-0	TWAEV (Mist)	10 mg/m ³	CA QC OEL
Ivermectin	70288-86-7	TWA	30 µg/m3 (OEB 3)	Internal
	Further informa	ation: Skin		
		Wipe limit	300 µg/100 cm2	Internal

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 equipmer	t
Respiratory protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type
Material :	Chemical-resistant gloves
Remarks : Eye protection :	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions,



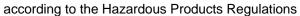


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Skin and body protection		 mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. Work uniform or laboratory coat. Additional 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. 				
Hygiene measures		eye flushing syst working place. When using do r Wash contamina The effective ope engineering cont appropriate dego	emical is likely during typical use, provide tems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the ative controls.			

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	:	No data available
Initial boiling point and boiling range	:	167.5 °C
Flash point	:	219.2 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available





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Relative vapor density		:	No data available	2	
Relative density		:	0.88 - 0.92		
	Density		:	No data available	9
	Solubili Wate	ty(ies) er solubility	:	practically insolu	ble
	Partition octanol	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available	9
	Decomposition temperature		:	No data available	9
	Viscosity Viscosity, kinematic		:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
	Particle characteristics Particle size		:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products		None known. Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

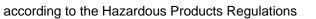
Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:





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	Acute o	oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method
	Acute o	lermal toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2,000 mg/kg on method
	Compo	onents:			
	Oils, se	esame:			
	Acute o	oral toxicity	:	LD50 (Rat): > 2,00 Remarks: Based of	00 mg/kg on data from similar materials
	Acute o	dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
	lverme	ctin:			
	Acute o	oral toxicity	:	LD50 (Rat): 50 mg	g/kg
				LD50 (Mouse): 25	5 mg/kg
				Symptoms: Vomit	 24 mg/kg entral nervous system ing, Dilatation of the pupil tality observed at this dose.
	Acute i	nhalation toxicity	:	LC50 (Rat): 5.11 Exposure time: 1 Test atmosphere:	h
	Acute of	lermal toxicity	:	LD50 (Rabbit): 40	6 mg/kg
				LD50 (Rat): > 660) mg/kg
		orrosion/irritation ssified based on availa	able	information.	
	Compo	onents:			
	Oils, se	esame:			
	Specie: Result	S	:	Rabbit No skin irritation	
	lverme	ctin:			
	Specie: Result	S	:	Rabbit No skin irritation	

Serious eye damage/eye irritation

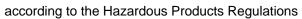
Not classified based on available information.



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<u>Comp</u>	oonents:					
Oils,	sesame:					
Speci		: Rabbit				
Resul	t	: No eye irritation				
lverm	ectin:					
Speci Resul		: Rabbit : Mild eye irritation				
Respi	iratory or skin sens	ization				
Skin	sensitization					
Not cl	assified based on ava	ilable information.				
Resp	iratory sensitization					
Not cl	assified based on ava	ilable information.				
<u>Comp</u>	oonents:					
Oils, s	sesame:					
Test 7		: Human repeat insult patch test (HRIPT)				
Route Resul	es of exposure	: Skin contact				
Resul	l	: negative				
lverm	ectin:					
	es of exposure	: Dermal				
Speci Resul		: Humans : Does not cause skin sensitization.				
Resul	l	: Does not cause skin sensitization.				
	cell mutagenicity					
Not cl	assified based on available	ilable information.				
Comp	<u>oonents:</u>					
Oils, s	sesame:					
Geno	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AM	/IES)			
		Result: negative				
lverm	ectin:					
Geno	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AM	/IES)			
		Result: negative				
		Test Type: DNA damage and repair, unschedule	ed DNA sv			
			-			
		thesis in mammalian cells (in vitro)				
		Test system: human diploid fibroblasts Result: negative				
		Test system: human diploid fibroblasts				





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	Not cla	ogenicity assified based on availa	able	information.	
	<u>Comp</u>	onents:			
	lverme	ectin:			
	Specie Applica NOAE Result Remar	ation Route L	: : : : : : : : : : : : : : : : : : : :	Rat Oral 1.5 mg/kg body w negative Based on data fro	reight om similar materials
	Specie Applica NOAE Result Remar	ation Route L	:	Mouse Oral 2.0 mg/kg body w negative Based on data fro	reight om similar materials
	Repro	ductive toxicity			
	Not cla	assified based on availa	able	information.	
	<u>Comp</u>	onents:			
	lverme	ectin:			
	Effects	s on fertility	:		-
	Effects	on fetal development	:	Result: Teratoger	
				Result: Embryoto offspring were de	e: Oral oxicity: LOAEL: 0.4 mg/kg body weight xic effects and adverse effects on the

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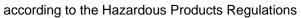


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стот	-single exposure		
Cause	es damage to organs	(Central nervous system	m) if swallowed.
Comp	onents:		
lverm	ectin:		
Targe	t Organs	: Central nervous	system
-	sment	: Causes damage	
стот	-repeated exposure		
	es damage to organs		m) through prolonged or repeated exposure if
Comp	oonents:		
lverm	ectin:		
•	t Organs sment	: Central nervous : Causes damage exposure.	s system e to organs through prolonged or repeated
Repea	ated dose toxicity		
Comp	oonents:		
lverm	ectin:		
Specie	es	: Dog	
NOAE		: 0.5 mg/kg	
LOAE	—	: 1 mg/kg	
	ation Route	: Oral	
	sure time	: 14 Weeks	
	t Organs	: Central nervous	
Symp	loms	Dilatation of the	pupil, Tremors, Lack of coordination, anorex
Specie		: Monkey	
NOAE		: 1.2 mg/kg	
	ation Route	: Oral	
Expos Rema	sure time	: 2 Weeks	duaraa offacto wara rapartad
Rema	IKS	: No significant a	dverse effects were reported
Specie		: Rat	
NOAE		: 0.4 mg/kg	
LOAE		: 0.8 mg/kg	
	ation Route	: Oral	
	sure time	: 3 Months	arrow Kidpov
rarge	t Organs	: spleen, Bone m	anow, Nuney
Aspir	ation toxicity		
-	assified based on av		

Components:

Ivermectin:





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Skin contact Eye contact Ingestion		 Remarks: Can be absorbed through skin. Remarks: May irritate eyes. Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vor iting, anorexia, Lack of coordination 			
	ECOLOGICAL INFO	ORN	IATION		
Ecotoxic	-				
Compone	<u>ents:</u>				
Ivermect Toxicity to		:	LC50 (Oncorhyn Exposure time: 9	chus mykiss (rainbow trout)): 0.003 mg/l 6 h	
			LC50 (Lepomis r Exposure time: 9	nacrochirus (Bluegill sunfish)): 0.0048 mg/l 6 h	
	o daphnia and other vertebrates	:	EC50 (Daphnia r Exposure time: 4	nagna (Water flea)): 0.000025 mg/l 8 h	
Toxicity to plants	o algae/aquatic	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 9.1 2 h est Guideline 201	
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 9.1 2 h Test Guideline 201	
Persister	nce and degradabil	ity			
Compone	ents:				
Oils, ses Biodegrad		:	Result: Readily b	iodegradable.	
lvermect Biodegrad		:	Result: Not readi Biodegradation: Exposure time: 2	50 %	
Bioaccur	nulative potential				
Bioaccur <u>Compon</u> e					
	ents: in:	:	Bioconcentration	factor (BCF): 74	

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	lity in soil ata available				
Othe	Other adverse effects				
No da	No data available				
SECTION	13. DISPOSAL CON	SIDEF	RATIONS		
Disp	osal methods				
Wast	e from residues	:	•	of waste into sewer. cordance with local regulations.	
Conta	aminated packaging	:	Empty container handling site for	s should be taken to an approved waste recycling or disposal. specified: Dispose of as unused product.	

SECTION 14. TRANSPORT INFORMATION

International Regulations

-		
UNRTDG UN number	:	
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin, 2,6-Di-tert-butyl-p-cresol)
Class Packing group	:	9 III
Labels	:	9
Environmentally hazardous	:	yes
UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin, 2,6-Di-tert-butyl-p-cresol)
Class	:	9
Packing group	:	
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.
Class		(Ivermectin, 2,6-Di-tert-butyl-p-cresol)
Class Decking group	÷	9 III
Packing group Labels	:	9
EmS Code	:	5 F-A, S-F
Marine pollutant	:	yes
nanno ponatarit	•	,



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Not a	applicable for product a	-	ARPOL 73/78 and the IBC Code
	nestic regulation		
	i number ber shipping name	N.O.S.	NTALLY HAZARDOUS SUBSTANCE, LIQUID, 2,6-Di-tert-butyl-p-cresol)
Labe ERG	king group	: 9 : III : 9 : 171	in, 2,6-Di-tert-butyl-p-cresol)

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-
CA QC OEL / TWAEV	:	borne contaminants 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International



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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