according to the OSHA Hazard Communication Standard



Doramectin Formulation

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SECTION 1. IDENTIFICATION

Product name **Doramectin Formulation**

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

Veterinary product Recommended use Restrictions on use Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity Category 1B

Specific target organ toxicity

- single exposure (Oral)

Category 1 (Central nervous system)

- repeated exposure (Oral)

Specific target organ toxicity : 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. P280 Wear protective gloves, protective clothing, eye protection

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and face protection.

Response:

P307 + P311 IF exposed: Call a doctor.

Storage:

P405 Store locked up.

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	CAS-No.	Concentration (% w/w)
Oils, sesame	8008-74-0	79
Doramectin	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

May damage the unborn child.

Causes damage to organs if swallowed.

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.

according to the OSHA Hazard Communication Standard



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SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Hazardous combustion prod- :

ucts

g fire : Exposure to combustion products may be a hazard to health.

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective 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

according to the OSHA Hazard Communication Standard



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Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : 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 : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

mground with workplace control parameters						
Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Oils, sesame	8008-74-0	TWA (mist - total)	10 mg/m³	NIOSH REL		
		TWA (mist - respirable)	5 mg/m³	NIOSH REL		
Doramectin	117704-25-3	TWA	25 μg/m3 (OEB 3)	Internal		
	Further inform	Further information: Skin				
		Wipe limit	250 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).

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Minimize open handling.

Personal protective equipment

Respiratory protection General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are

unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material Chemical-resistant gloves

Remarks Consider double gloving.

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Work uniform or laboratory coat. Skin and body protection

> 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.

If exposure to chemical is likely during typical use, provide Hygiene measures

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance oily

Color light yellow

Odor characteristic

Odor Threshold No data available

No data available pН

according to the OSHA Hazard Communication Standard



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Melting point/freezing point : 19 °F / -7 °C

Initial boiling point and boiling

range

518 °F / 270 °C

Flash point : 420.3 °F / 215.7 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : 0.89 - 91

Density : No data available

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 31.7 - 32.1 m²/s (77 °F / 25 °C)

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

according to the OSHA Hazard Communication Standard



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Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

ions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : Oxidizing agents

No hazardous decomposition products are known.

products

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:

Acute oral toxicity : Acute toxicity estimate: 5,000 mg/kg

Method: Calculation method

Components:

Oils, sesame:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Doramectin:

Acute oral toxicity : LD50 (Rat): 500 mg/kg

Target Organs: Central nervous system

LD50 (Mouse): > 2,000 mg/kg

Target Organs: Central nervous system

LD50 (Rat): 50 mg/kg

Target Organs: Central nervous system

LD50 (Mouse): 75 mg/kg

Target Organs: Central nervous system

Acute toxicity (other routes of :

administration)

LD50 (Rat): > 300 mg/kg

Application Route: Intraperitoneal Target Organs: Central nervous system

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Oils, sesame:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact Result : negative

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

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

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Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Doramectin:

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child.

Components:

Doramectin:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Embryo-fetal toxicity.: NOAEL: 0.3 mg/kg body weight

Symptoms: Reduced body weight

Test Type: Embryo-fetal development

Species: Mouse Application Route: Oral

Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight

Symptoms: Embryolethal effects.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: NOAEL: 0.75 mg/kg body weight

Symptoms: Maternal effects., Embryotoxic effects.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

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Components:

Doramectin:

Routes of exposure : Oral

Target Organs : Central nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations of 300 mg/kg bw or less.

STOT-repeated exposure

Causes damage to organs (Central nervous system, Liver, Kidney) through prolonged or repeated exposure if swallowed.

Components:

Doramectin:

Routes of exposure : Oral

Target Organs : Central nervous system, Liver, Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Doramectin:

Species : Rat
LOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 3 Months

Target Organs : Central nervous system

Species : Rat

NOAEL : 2 mg/kg

Application Route : Oral

Exposure time : 3 Months

Target Organs : Central nervous system, Liver, Kidney

Species : Dog
NOAEL : 2 mg/kg
Application Route : Oral
Exposure time : 36 d
Target Organs : Eye

Symptoms : Dilatation of the pupil

Species : Dog
NOAEL : 0.1 mg/kg
Application Route : Oral
Exposure time : 92 d

Target Organs : Central nervous system, Eye

Symptoms : Dilatation of the pupil

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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Doramectin:

Skin contact : Target Organs: Gastro-intestinal system

Symptoms: Nausea, Diarrhea

Target Organs: Central nervous system Symptoms: Dizziness, Headache

Target Organs: Eye Symptoms: Irritation Target Organs: Skin Symptoms: Irritation

Target Organs: Respiratory system Symptoms: Breathing difficulties

Ingestion : Target Organs: Gastro-intestinal system

Symptoms: Nausea, Abdominal pain, Diarrhea

Target Organs: Central nervous system

Symptoms: Dizziness

SECTION 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

LC50 (Oncorhynchus mykiss (rainbow trout)): 5.1 µg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.1 μg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Persistence and degradability

Components:

Oils, sesame:

Biodegradability : Result: Readily biodegradable.

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Bioaccumulative potential

Components:

Doramectin:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 71 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.5

pH: 7

Mobility in soil

Components:

Doramectin:

Distribution among environ-

mental compartments

: log Koc: 4.94

Other adverse effects

Components:

Doramectin:

Results of PBT and vPvB

assessment

Substance is not very persistent and very bioaccumulative

(vPvB).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste

handling 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

UN/ID No. : UN 3082

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Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Doramectin)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen- : 964

ger aircraft)

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
Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Doramectin)

Class : 9
Packing group : III
Labels : CLAS

Labels : CLASS 9 ERG Code : 171

Marine pollutant : yes(Doramectin)

Remarks : Above applies only to containers over 119 gallons or 450

liters.

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

 Oils, sesame
 8008-74-0

 Ethyl oleate
 111-62-6

California Permissible Exposure Limits for Chemical Contaminants

Oils, sesame 8008-74-0

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

AICS : not determined

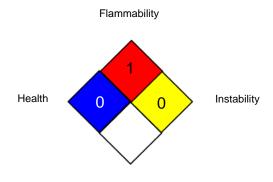
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

according to the OSHA Hazard Communication Standard



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NIOSH REL USA. NIOSH Recommended Exposure Limits

NIOSH REL / TWA Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 07/06/2024

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 quidance 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

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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.

US / Z8