SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Niclosamide (50%) Formulation

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SECTION 1. IDENTIFICATION

Product name : Niclosamide (50%) Formulation
Product code : Aquabosso™ Molu,Aquabosso Molu

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Acute toxicity (Oral) : Category 4

Skin irritation : Category 2

Eye irritation : Category 2A

Specific target organ toxicity - repeated exposure : Category 2 (Respiratory Tract)

Other hazards

None known.

Hazards associated with a change in physical form:

Conditions	Hazards
If small particles are generated during further processing, handling or by other means.	May form combustible dust concentrations in air.

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, eye protection and face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical attention if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Niclosamide ethanolamine salt	1420-04-8*	>= 45 - <= 70	TSC
Kaolin	1332-58-7*	>= 10 - <= 30	TSC
Silica gel, precipitated, crystalline free	112926-00-8*	>= 7 - <= 13	TSC
Disodium EDTA, dihydrate	6381-92-6*	>= 1 - <= 5	TSC
Ethanolamine	141-43-5*	>= 0.5 - <= 1.5	TSC

* Indicates that the identifier is a CAS No.
TSC- the actual concentration or concentration range is withheld as a trade secret

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 contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

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 and effects, both acute and delayed : No information available.
Harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.
May cause damage to organs through prolonged or repeated exposure.

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.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Chlorine compounds
Metal oxides
Sulfur oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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, protective equipment and emergency 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.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in 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
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.
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 in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust

50 Million particles per cubic foot
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

15 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

5 mg/m³
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Niclosamide ethanolamine salt	1420-04-8	TWA	>= 10 < 100 µg/m3 (OEB 3)	Internal
Kaolin	1332-58-7	TWA (Respirable particulate matter)	2 mg/m³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1

Silica gel, precipitated, crystalline free	112926-00-8	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m³ (Silica)	NIOSH REL
Ethanolamine	141-43-5	TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH
		TWA	3 ppm 8 mg/m³	NIOSH REL
		ST	6 ppm 15 mg/m³	NIOSH REL
		TWA	3 ppm 6 mg/m³	OSHA Z-1

Engineering measures : 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 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.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the

Hygiene measures	:	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 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	:	powder
Color	:	yellow
Odor	:	characteristic
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available

Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 817.06 mg/kg Method: Calculation method

Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Niclosamide ethanolamine salt:

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

Kaolin:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 (Rat): > 5,000 mg/kg

Silica gel, precipitated, crystalline free:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute inhalation toxicity	:	LC50 (Rat): > 0.69 mg/l Exposure time: 4 h Test atmosphere: dust/mist Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Acute oral toxicity	:	LD50 (Rat): 2,800 mg/kg
Acute inhalation toxicity	:	LC50 (Rat, male): > 1 mg/l Exposure time: 6 h Test atmosphere: dust/mist Method: OECD Test Guideline 412

Ethanolamine:

Acute oral toxicity	:	LD50 (Rat): 1,089 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: 11 mg/l Exposure time: 4 h Test atmosphere: vapor Method: Expert judgment Remarks: Based on national or regional regulation. Assessment: Not corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Kaolin:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Silica gel, precipitated, crystalline free:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Ethanolamine:

Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Kaolin:

Species : Rabbit
Result : No eye irritation

Silica gel, precipitated, crystalline free:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Disodium EDTA, dihydrate:

Species : Rabbit
Result : No eye irritation

Ethanolamine:

Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Disodium EDTA, dihydrate:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Ethanolamine:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Niclosamide ethanolamine salt:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative

Silica gel, precipitated, crystalline free:

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Test Type: In vitro mammalian cell gene mutation test Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Ethanolamine:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Silica gel, precipitated, crystalline free:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative
Remarks	:	Based on data from similar materials

Disodium EDTA, dihydrate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative
Remarks	:	Based on data from similar materials

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.

OSHA No 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

Not classified based on available information.

Components:

Niclosamide ethanolamine salt:

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Silica gel, precipitated, crystalline free:

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Effects on fertility	:	Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative

Ethanolamine:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

STOT-single exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment	:	May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure.

Components:

Disodium EDTA, dihydrate:

Routes of exposure	:	inhalation (dust/mist/fume)
Target Organs	:	Respiratory Tract
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Ethanolamine:

Assessment	:	No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Repeated dose toxicity

Components:

Niclosamide ethanolamine salt:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Silica gel, precipitated, crystalline free:

Species	:	Rat
NOAEL	:	> 4,500 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Disodium EDTA, dihydrate:

Species	:	Rat
NOAEL	:	500 mg/kg
Application Route	:	Ingestion

Exposure time	:	13 Weeks

Species	:	Rat
LOAEL	:	0.03 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

Ethanolamine:

Species	:	Rat
NOAEL	:	> 120 mg/kg
Application Route	:	Ingestion
Exposure time	:	> 75 Days
Remarks	:	Based on data from similar materials

Species	:	Rat
NOAEL	:	>= 0.15 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Niclosamide ethanolamine salt:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0179 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia longispina (Water flea)): 0.0164 mg/l Exposure time: 96 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 0.071 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.032 mg/l Exposure time: 21 d

Silica gel, precipitated, crystalline free:

Toxicity to fish	:	LL50 (Danio rerio (zebra fish)): > 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other	:	EL50 (Daphnia magna (Water flea)): > 1,000 mg/l

aquatic invertebrates		Exposure time: 24 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EL50 (Scenedesmus subspicatus): > 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials

Disodium EDTA, dihydrate:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 140 mg/l Exposure time: 48 h Method: DIN 38412
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials EC10 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10 (activated sludge): > 500 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

Ethanolamine:

Toxicity to fish	:	LC50 (Cyprinus carpio (Carp)): 349 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 65 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2.
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l

		Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l Exposure time: 41 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.85 mg/l Exposure time: 21 d
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

Persistence and degradability

Components:

Disodium EDTA, dihydrate:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 2 % Exposure time: 28 d Method: OECD Test Guideline 301D

Ethanolamine:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: > 90 % Exposure time: 21 d Method: OECD Test Guideline 301A

Bioaccumulative potential

Components:

Niclosamide ethanolamine salt:

Bioaccumulation	:	Species: Fish Bioconcentration factor (BCF): < 500 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water	:	log Pow: 3.86 Remarks: Calculation

Disodium EDTA, dihydrate:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): < 500 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water	:	log Pow: -4.3

Ethanolamine:

Partition coefficient: n-	:	log Pow: -2.3

octanol/water	Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects

No data available

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 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Niclosamide ethanolamine salt)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Niclosamide ethanolamine salt)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes
Remarks	:	This product can be subject to exemptions when packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids, or having a net mass of 5 kg or less for solids.

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Niclosamide ethanolamine salt)
Class	:	9

Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes
Remarks	:	This product can be subject to exemptions when packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids, or having a net mass of 5 kg or less for solids.

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Niclosamide ethanolamine salt)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Niclosamide ethanolamine salt)
Remarks	:	Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. 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.

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	:	Acute toxicity (any route of exposure) Specific target organ toxicity (single or repeated exposure) Skin corrosion or irritation Serious eye damage or eye irritation
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

Niclosamide ethanolamine salt	1420-04-8
Kaolin	1332-58-7
Silica gel, precipitated, crystalline free	112926-00-8
Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt	9084-06-4
Disodium EDTA, dihydrate	6381-92-6
Ethanolamine	141-43-5

California List of Hazardous Substances

Niclosamide ethanolamine salt	1420-04-8
Polyvinyl pyrrolidone	9003-39-8
Ethanolamine	141-43-5

California Permissible Exposure Limits for Chemical Contaminants

Kaolin	1332-58-7
Silica gel, precipitated, crystalline free	112926-00-8
Ethanolamine	141-43-5

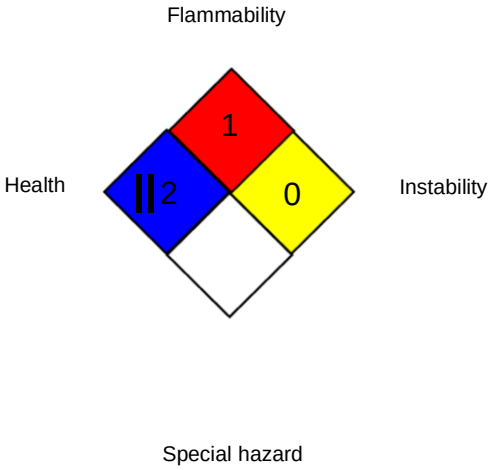
The ingredients of this product are reported in the following inventories:

AICS	:	not determined
CA. DSL	:	not determined
IECSC	:	not determined

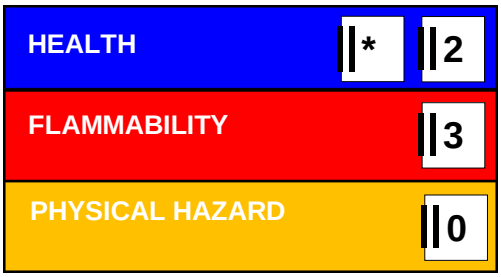
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

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 Standardization; 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 Organization 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, Authorization 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 Agency, http://echa.europa.eu/
Revision Date	:	01/15/2026

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.

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