

Niclosamide (50%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.12.2024
2.0	14.04.2025	11498316-00002	Date of first issue: 23.12.2024

SECTION 1. IDENTIFICATION

Product name : Niclosamide (50%) Formulation

Product code : Aquabosso™ Molu, Aquabosso Molu

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.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**

Acute toxicity (Oral) : Category 4

Carcinogenicity (Inhalation) : Category 1A

Specific target organ toxicity - repeated exposure (Inhalation) : Category 2 (Lungs)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :   

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.

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H350 May cause cancer by inhalation.
H373 May cause damage to organs (Lungs) through prolonged or repeated exposure if inhaled.
H410 Very toxic to aquatic life with long lasting effects.

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 dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Additional Labeling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2 %

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Niclosamide ethanolamine salt	1420-04-8	≥ 50 -< 70
Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt	9084-06-4	≥ 5 -< 10
Cristobalite	14464-46-1	≥ 5 -< 10

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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		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	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. 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 and effects, both acute and delayed	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Harmful if swallowed. May cause cancer by inhalation. May cause damage to organs through prolonged or repeated exposure if inhaled.
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 (CO ₂) 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 (NO _x) Chlorine compounds Sulfur oxides Metal 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.

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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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
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 locked up.

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Materials to avoid : Store in accordance with the particular national regulations.
 : 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Niclosamide ethanolamine salt	1420-04-8	TWA	$\geq 10 < 100$ $\mu\text{g}/\text{m}^3$ (OEB 3)	Internal
Cristobalite	14464-46-1	CMP (Respirable fraction)	$0,05 \text{ mg}/\text{m}^3$	AR OEL
		TWA (Respirable particulate matter)	$0,025 \text{ mg}/\text{m}^3$ (Silica)	ACGIH

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 : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

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 task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

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Hygiene measures : 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

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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
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Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 980,39 mg/kg Method: Calculation method
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Components:**Niclosamide ethanolamine salt:**

Acute oral toxicity	:	LD50 (Rat): 500 mg/kg
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Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:

Acute oral toxicity : LD50 (Rat): > 2.000 - 5.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Cristobalite:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:**

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:**

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:**

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
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)

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	Result: negative
Genotoxicity in vivo	: Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative

Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:

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

May cause cancer by inhalation.

Components:**Cristobalite:**

Species	: Humans
Application Route	: inhalation (dust/mist/fume)
Result	: positive

Carcinogenicity - Assessment	: Positive evidence from human epidemiological studies (inhalation)
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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

Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:

Effects on fertility	: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative
Effects on fetal development	: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat

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Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Lungs) through prolonged or repeated exposure if inhaled.

Components:**Cristobalite:**

Routes of exposure	: inhalation (dust/mist/fume)
Target Organs	: Lungs
Assessment	: Shown to produce significant health effects in animals at concentrations of 0.02 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

Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:

Species	: Rat
NOAEL	: >= 1.000 mg/kg
Application Route	: Ingestion
Exposure time	: 42 Days
Method	: OECD Test Guideline 422

Cristobalite:

Species	: Humans
LOAEL	: 0,053 mg/m ³
Application Route	: inhalation (dust/mist/fume)

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
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	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

M-Factor (Acute aquatic toxicity)	: 10
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0,032 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	: 10

Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt:

Toxicity to fish	: LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
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Cristobalite:

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 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)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Persistence and degradability

No data available

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

Mobility in soil

No data available

Other adverse effects

No data available

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SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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

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

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

Not applicable for product as supplied.

Special precautions for user

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

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SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Cristobalite

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

Further information

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/>

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit 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 Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

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centration 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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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