

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier's details

Company : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : +1-908-740-4000
Emergency telephone number : +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

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

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0	Revision Date: 2025/04/14	SDS Number: 11498550-00002	Date of last issue: 2024/12/23 Date of first issue: 2024/12/23
-------------	---------------------------	----------------------------	---

Hazard statements	: H302 Harmful if swallowed. 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 Labelling

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Niclosamide ethanolamine salt	1420-04-8	>= 30 -< 60
Calcium carbonate	471-34-1	>= 30 -< 60
Cristobalite	14464-46-1	>= 1 -< 10

4. FIRST AID MEASURES

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0	Revision Date: 2025/04/14	SDS Number: 11498550-00002	Date of last issue: 2024/12/23 Date of first issue: 2024/12/23
----------------	------------------------------	-------------------------------	---

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	: 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.

5. FIREFIGHTING 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 Sulphur 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.

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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.

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0 Revision Date: 2025/04/14 SDS Number: 11498550-00002 Date of last issue: 2024/12/23 Date of first issue: 2024/12/23

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 labelled containers.
Store locked up.
Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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
Calcium carbonate	471-34-1	NAB (Inhalable)	10 mg/m ³ (Calcium carbonate)	ID OEL
Cristobalite	14464-46-1	NAB (Respirable particulate matter)	0.025 mg/m ³	ID OEL
Further information: Suspected human carcinogen				
		TWA (Respirable particulate matter)	0.025 mg/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.

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

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. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : yellow

Odour : characteristic

Odour 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

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0 Revision Date: 2025/04/14 SDS Number: 11498550-00002 Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

flammability limit

Vapour pressure : Not applicable
Relative vapour 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
Auto-ignition 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

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion

Niclosamide (50%) FormulationVersion
2.0Revision Date:
2025/04/14SDS Number:
11498550-00002Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,000 mg/kg
		Method: Calculation method

Components:**Niclosamide ethanolamine salt:**

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

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 420 Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	LC50 (Rat): > 3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

Cristobalite:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Remarks: Based on data from similar materials
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Skin corrosion/irritation

Not classified based on available information.

Components:**Calcium carbonate:**

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

Serious eye damage/eye irritation

Not classified based on available information.

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

Components:

Calcium carbonate:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Calcium carbonate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
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

Calcium carbonate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
		Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
		Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

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)

Reproductive toxicity

Not classified based on available information.

Components:

Niclosamide ethanolamine salt:

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

Calcium carbonate:

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 foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 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.

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

Components:

Cristobalite:

Exposure routes	: 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

Calcium carbonate:

Species	: Rat
NOAEL	: > 1,000 mg/kg
Application Route	: Ingestion
Exposure time	: 28 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.

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

Niclosamide (50%) FormulationVersion
2.0Revision Date:
2025/04/14SDS Number:
11498550-00002Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

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

Calcium carbonate:

Toxicity to fish	:	LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201
		EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC: 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
		EC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

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

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0 Revision Date: 2025/04/14 SDS Number: 11498550-00002 Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

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

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.

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

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0 Revision Date: 2025/04/14 SDS Number: 11498550-00002 Date of last issue: 2024/12/23 Date of first issue: 2024/12/23

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined
DSL : not determined

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version 2.0	Revision Date: 2025/04/14	SDS Number: 11498550-00002	Date of last issue: 2024/12/23 Date of first issue: 2024/12/23
----------------	------------------------------	-------------------------------	---

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

Sources of key data used to compile the 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.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ID OEL / NAB : Long term exposure limit

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 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 Recom-

SAFETY DATA SHEET



Niclosamide (50%) Formulation

Version
2.0

Revision Date:
2025/04/14

SDS Number:
11498550-00002

Date of last issue: 2024/12/23
Date of first issue: 2024/12/23

mendations 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.

ID / EN