According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Niclosamide (50%) Formulation

Product code : Aquabosso™ Molu,Aquabosso Molu

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

# Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Carcinogenicity, Category 1A H350i: May cause cancer by inhalation.

Specific target organ toxicity - repeated

exposure, Category 2

H373: May cause damage to organs through pro-

longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

gory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

#### 2.2 Label elements

# Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :







Signal word : Danger

Hazard statements : H302 Harmful if swallowed.

H350i May cause cancer by inhalation.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Niclosamide ethanolamine salt

Cristobalite

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

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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**

### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

	EC-No. Index-No. Registration number		(% w/w)
Niclosamide ethanolamine salt	1420-04-8 215-811-7	Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ———— M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 50 - < 70
Cristobalite	14464-46-1 238-455-4	Carc. 1A; H350i STOT RE 1; H372 (Lungs)	>= 1 - < 10
Substances with a workplace exposure limit :			
Calcium carbonate	471-34-1 207-439-9		>= 30 - < 50

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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.

#### 4.2 Most important symptoms and effects, both acute and delayed

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

Risks 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.

4.3 Indication of any immediate medical attention and special treatment needed

: Treat symptomatically and supportively. **Treatment** 

### SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

#### 5.2 Special hazards arising from the substance or mixture

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 prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx) Chlorine compounds Sulphur oxides Metal oxides

### 5.3 Advice for firefighters

Special protective equipment :

for firefighters

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

Use personal protective equipment.

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

Evacuate area.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

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 as-

sessment

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

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.

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 contami-

nated 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.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Store in

accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

#### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

#### **Occupational Exposure Limits**

dust of any kind 10 mg/m3

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

	Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
	Niclosamide etha- nolamine salt	1420-04-8	TWA	>= 10 < 100 μg/m3 (OEB 3)	Internal
	Calcium carbonate	471-34-1	TWA (inhalable dust)	10 mg/m3	GB EH40
П			TWA (Respirable	4 mg/m3	GB EH40

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

		dust)		
Cristobalite	14464-46-1	TWA (Respirable fraction)	0.1 mg/m3 (Silica)	GB EH40
	Further inforrage.	Further information: Capable of causing cancer and/or heritable genetic dam-		
		TWA (Respirable dust)	0.1 mg/m3	2004/37/EC
	Further inforn	Further information: Carcinogens or mutagens		

### **Derived No Effect Level (DNEL)**

-				
Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Calcium carbonate	Workers	Inhalation	Long-term systemic	6.36 mg/m3
			effects	
	Consumers	Ingestion	Acute systemic ef-	6.1 mg/kg
			fects	bw/day
	Consumers	Inhalation	Long-term systemic	1.06 mg/m3
			effects	
	Consumers	Ingestion	Long-term systemic	6.1 mg/kg
			effects	bw/day

#### **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Calcium carbonate	Sewage treatment plant	100 mg/l

### 8.2 Exposure controls

### **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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to BS EN 143

Filter type : Particulates type (P)

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic 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, han-

dling 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

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- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Molecular weight : No data available

Particle size : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

### 11.1 Information on toxicological effects

Information on likely routes of : Inhalation exposure Skin contact

Ingestion

Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,000 mg/kg

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

Method: Calculation method

#### **Components:**

Niclosamide ethanolamine salt:

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

Cristobalite:

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

Remarks: Based on data from similar materials

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 tox-

icity

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 inhala-

tion 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

#### 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.

#### Components:

#### Calcium carbonate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

#### 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

#### Carcinogenicity

May cause cancer by inhalation.

#### **Components:**

#### Cristobalite:

Species : Humans

Application Route : inhalation (dust/mist/fume)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

Result : positive

Carcinogenicity - Assess-

ment

Positive evidence from human epidemiological studies (inhala-

tion)

#### Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### Niclosamide ethanolamine salt:

Effects on foetal develop- : Test T

ment

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 develop-

ment

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 through prolonged or repeated exposure.

### **Components:**

### Cristobalite:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Lungs

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

centrations of 0.02 mg/l/6h/d or less.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

#### Repeated dose toxicity

#### **Components:**

#### Niclosamide ethanolamine salt:

Species Rat

NOAEL > 100 mg/kgApplication Route Ingestion Exposure time 90 Days

Remarks Based on data from similar materials

Cristobalite:

Species Humans LOAEL 0.053 mg/m3

Application Route inhalation (dust/mist/fume)

Calcium carbonate:

Species Rat

NOAEL > 1,000 mg/kg Application Route : Ingestion Exposure time 28 Days

Method OECD Test Guideline 422

**Aspiration toxicity** 

Not classified based on available information.

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

### **Components:**

#### Niclosamide ethanolamine salt:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0179 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia longispina (water flea)): 0.0164 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

: ErC50 (Skeletonema costatum (marine diatom)): 0.071 mg/l

Exposure time: 96 h

M-Factor (Acute aquatic tox- :

icity)

plants

10

Toxicity to daphnia and other : NOEC: 0.032 mg/l aguatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic : 10

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

toxicity)

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

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

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

**Components:** 

Niclosamide ethanolamine salt:

Bioaccumulation : Species: Fish

Bioconcentration factor (BCF): < 500

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

log Pow: 3.86

Remarks: Calculation

### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

### **Product:**

Endocrine disrupting poten-

tial

This substance/mixture does not contain components consid-

ered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

### **SECTION 13: Disposal considerations**

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

N.O.S.

(Niclosamide ethanolamine salt)

**ADR** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Niclosamide ethanolamine salt)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, **RID** 

(Niclosamide ethanolamine salt)

**IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Niclosamide ethanolamine salt)

**IATA** Environmentally hazardous substance, solid, n.o.s.

(Niclosamide ethanolamine salt)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN 9 **ADR** 9 **RID** 9 **IMDG** 9 IATA 9

14.4 Packing group

**ADN** 

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels 9

**ADR** 

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels 9 Tunnel restriction code (-)

**RID** 

Packing group Ш Classification Code M7 Hazard Identification Number 90 Labels 9

**IMDG** 

Packing group Ш Labels 9 **EmS Code** 

F-A, S-F

IATA (Cargo)

Packing instruction (cargo 956

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

rid

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

**SECTION 15: Regulatory information** 

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EU) No 2024/590 on substances that de: Not a

plete the ozone layer

: Not applicable

Not applicable

Not applicable

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.12.2024 2.0 14.04.2025 11498572-00002 Date of first issue: 23.12.2024

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : 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 H-Statements** 

H302 : Harmful if swallowed.

H350i : May cause cancer by inhalation.

H372 : Causes damage to organs through prolonged or repeated

exposure if inhaled.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity

STOT RE : Specific target organ toxicity - repeated exposure

2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers

from the risks related to exposure to carcinogens, mutagens

or reprotoxic substances at work - Annex III

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

2004/37/EC / TWA : Long term exposure limit

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

#### **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/

#### Classification of the mixture:

# Classification procedure:

H302	Calculation method
H350i	Calculation method
H373	Calculation method
H400	Calculation method
H410	Calculation method
	H350i H373 H400

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Niclosamide (50%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.12.2024

 2.0
 14.04.2025
 11498572-00002
 Date of first issue: 23.12.2024

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.

GB / EN