



**Norbrook Laboratories Ltd - Levacide 7.5% injection -
VM 02000/4049
Res : 94011**

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Levacide 7.5% injection - VM 02000/4049
Res : 94011
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Norbrook Laboratories Ltd
Cambane Industrial Estate
BT35 6QQ Newry - Northern Ireland
Phone.: +44 (0)28 3026 4435 -
Fax: +44 (0)28 3026 5060
<http://www.norbrook.com>
- 1.4 Emergency telephone number:** +44 (0)28 3026 4435

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) n° 1272/2008:
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**
This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly
CLP Regulation (EC) n° 1272/2008:
None
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Injectable Solution
Components:
In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 16595-80-5 EC: 240-654-6 Index: Non-applicable REACH: Non-applicable	Levamisole hydrochloride Regulation 1272/2008 Acute Tox. 3: H301 - Danger	Proprietary
CAS: 77-92-9 EC: 201-069-1 Index: Non-applicable REACH: 01-2119457026-42-XXX X	Citric Acid Regulation 1272/2008 Eye Irrit. 2: H319 - Warning	Proprietary

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures:**
The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.
By inhalation:

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SECTION 4: FIRST AID MEASURES (continued)

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spill product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Maximum Temp.: 25 °C

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity, light and contact with food. For additional information see subsection 10.5

Other information:

Keep container in outer carton

7.3 Specific end use(s):

Levacide injection is a broad spectrum anthelmintic for use in the treatment and control of nematode infections in cattle and sheep.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

There are no occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Identification				
Citric Acid CAS: 77-92-9 EC: 201-069-1	STP	1000 mg/L	Fresh water	0.44 mg/L
	Soil	33.1 mg/kg	Marine water	0.044 mg/L
	Intermittent	Non-applicable	Sediment (Fresh water)	34.6 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	3.46 mg/kg

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection



The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

D.- Ocular and facial protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			
	Anti-slip work shoes		EN ISO 20347:2012	

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Undefined
Color:	Yellow

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Odor:	Undefined
Volatility:	
Boiling point at atmospheric pressure:	100 °C
Vapour pressure at 20 °C:	2350 Pa
Vapour pressure at 50 °C:	12381 Pa (12 kPa)
Evaporation rate at 20 °C:	Non-applicable *
Product description:	
Density at 20 °C:	1041 kg/m ³
Relative density at 20 °C:	1.041
Dynamic viscosity at 20 °C:	1.08 cP
Kinematic viscosity at 20 °C:	1.04 cSt
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Autoignition temperature:	1010 °C
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
9.2 Other information:	
Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
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SECTION 10: STABILITY AND REACTIVITY (continued)

Not applicable	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases
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10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, however it does contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

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Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Levamisole hydrochloride CAS: 16595-80-5 EC: 240-654-6	180 mg/kg	>2000 mg/kg	Rat
Citric Acid CAS: 77-92-9 EC: 201-069-1	LC50 inhalation	Non-applicable	
	LD50 oral	5400 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	>5 mg/L (4 h)	

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Identification	Acute toxicity		Species	Genus
	LC50	EC50		
Citric Acid CAS: 77-92-9 EC: 201-069-1	1516 mg/L (96 h)		Lepomis macrochirus	Fish
	160 mg/L (48 h)		N/A	Crustacean
	Non-applicable			

12.2 Persistence and degradability:

Identification	Degradability		Biodegradability	
	BOD5	COD	Concentration	Period
Citric Acid CAS: 77-92-9 EC: 201-069-1	Non-applicable	Non-applicable	10 mg/L	28 days
			% Biodegradable	97 %

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential	
	BCF	Pow Log
Citric Acid CAS: 77-92-9 EC: 201-069-1	3	-1.55
		Potential
		Low

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
	Koc	Conclusion	Henry	Dry soil
Citric Acid CAS: 77-92-9 EC: 201-069-1	Non-applicable	Non-applicable	Non-applicable	Non-applicable
			Moist soil	Non-applicable
		2.045E-2 N/m (350.93 °C)		

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 05*	Organic wastes containing dangerous substances	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Dangerous for the environment: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Non-applicable |
| Tunnel restriction code: | Non-applicable |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Non-applicable |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

Transport of dangerous goods by sea:

With regard to IMDG 37-14:

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Dangerous for the environment: | No |
| 14.6 Special precautions for user | |
| Special regulations: | Non-applicable |
| EmS Codes: | |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Non-applicable |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

- | | |
|---|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group: | Non-applicable |
| 14.5 Dangerous for the environment: | No |
| 14.6 Special precautions for user | |
| Physico-Chemical properties: | see section 9 |
| 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: | Non-applicable |

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SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Citric Acid (Product-type 1)

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) n° 1272/2008:

Acute Tox. 3: H301 - Toxic if swallowed

Eye Irrit. 2: H319 - Causes serious eye irritation

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:



Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

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SECTION 16: OTHER INFORMATION (continued)

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol-water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -



**Norbrook Laboratories Ltd - Levacide Low Volume 7.5% -
VM 02000/4081
Res : 94008**

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Levacide Low Volume 7.5% - VM 02000/4081
Res : 94008
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Norbrook Laboratories Ltd
Cambane Industrial Estate
BT35 6QQ Newry - Northern Ireland
Phone.: +44 (0)28 3026 4435 -
Fax: +44 (0)28 3026 5060
<http://www.norbrook.com>
- 1.4 Emergency telephone number:** +44 (0)28 3026 4435

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) n° 1272/2008:
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**
This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly
CLP Regulation (EC) n° 1272/2008:
None
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Oral Drench
Components:
In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 16595-80-5 EC: 240-654-6 Index: Non-applicable REACH: Non-applicable	Levamisole hydrochloride Regulation 1272/2008: Acute Tox. 3: H301 - Danger	Proprietary
CAS: 77-92-9 EC: 201-069-1 Index: Non-applicable REACH: 01-2119457026-42-XXX	Citric Acid Regulation 1272/2008: Eye Irrit. 2: H319 - Warning	Proprietary

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures:**
The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.
By inhalation:

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Res : 94008**

SECTION 4: FIRST AID MEASURES (continued)

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

- CONTINUED ON NEXT PAGE -



**Norbrook Laboratories Ltd - Levacide Low Volume 7.5% -
VM 02000/4081
Res : 94008**

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Maximum Temp.: 25 °C

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity, light and contact with food. For additional information see subsection 10.5

Other information:

Keep container in outer carton

7.3 Specific end use(s):

Levacide Low Volume is a broad spectrum anthelmintic for use in the treatment and control of nematode infections in cattle and sheep.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

There are no occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Identification				
Citric Acid CAS: 77-92-9 EC: 201-069-1	STP	1000 mg/L	Fresh water	0.44 mg/L
	Soil	33.1 mg/kg	Marine water	0.044 mg/L
	Intermittent	Non-applicable	Sediment (Fresh water)	34.6 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	3.46 mg/kg

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.



B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

D.- Ocular and facial protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			
	Anti-slip work shoes		EN ISO 20347:2012	

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Undefined
Color:	Yellow

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Odor:	Undefined
Volatility:	
Boiling point at atmospheric pressure:	100 °C
Vapour pressure at 20 °C:	2350 Pa
Vapour pressure at 50 °C:	12381 Pa (12 kPa)
Evaporation rate at 20 °C:	Non-applicable *
Product description:	
Density at 20 °C:	1039 kg/m ³
Relative density at 20 °C:	1.039
Dynamic viscosity at 20 °C:	1.07 cP
Kinematic viscosity at 20 °C:	1.03 cSt
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Autoignition temperature:	1010 °C
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

9.2 Other information:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
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SECTION 10: STABILITY AND REACTIVITY (continued)

Not applicable	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases
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10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, however it does contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

- CONTINUED ON NEXT PAGE -



Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
	Route	Dose	
Levamisole hydrochloride CAS: 16595-80-5 EC: 240-654-6	LD50 oral	180 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	Non-applicable	
Citric Acid CAS: 77-92-9 EC: 201-069-1	LD50 oral	5400 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	>5 mg/L (4 h)	

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Identification	Acute toxicity		Species	Genus
	Endpoint	Dose		
Citric Acid CAS: 77-92-9 EC: 201-069-1	LC50	1516 mg/L (96 h)	Lepomis macrochirus	Fish
	EC50	160 mg/L (48 h)	N/A	Crustacean
	EC50	Non-applicable		

12.2 Persistence and degradability:

Identification	Degradability		Biodegradability	
	Endpoint	Value	Parameter	Value
Citric Acid CAS: 77-92-9 EC: 201-069-1	BOD5	Non-applicable	Concentration	10 mg/L
	COD	Non-applicable	Period	28 days
	BOD5/COD	Non-applicable	% Biodegradable	97 %

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential	
	Parameter	Value
Citric Acid CAS: 77-92-9 EC: 201-069-1	BCF	3
	Pow Log	-1.55
	Potential	Low

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
	Parameter	Value	Parameter	Value
Citric Acid CAS: 77-92-9 EC: 201-069-1	Koc	Non-applicable	Henry	Non-applicable
	Conclusion	Non-applicable	Dry soil	Non-applicable
	Surface tension	2.045E-2 N/m (350.93 °C)	Moist soil	Non-applicable

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class. (Regulation (EU) No 1357/2014)
16 03 06	Organic wastes other than those mentioned in 16 03 05	Non dangerous

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
 - Special regulations: Non-applicable
 - Tunnel restriction code: Non-applicable
 - Physico-Chemical properties: see section 9
 - Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 37-14:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
 - Special regulations: Non-applicable
 - EmS Codes:
 - Physico-Chemical properties: see section 9
 - Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
 - Physico-Chemical properties: see section 9
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

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SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Citric Acid (Product-type 1)

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) n° 1272/2008:

Acute Tox. 3: H301 - Toxic if swallowed

Eye Irrit. 2: H319 - Causes serious eye irritation

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:



Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

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SECTION 16: OTHER INFORMATION (continued)

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol-water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -




**Norbrook Laboratories Ltd - Levafas Diamond Oral Suspension -
VM 02000/4080
Res : 94101**

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Levafas Diamond Oral Suspension - VM 02000/4080
Res : 94101
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Norbrook Laboratories Ltd
Cambane Industrial Estate
BT35 6QQ Newry - Northern Ireland
Phone.: +44 (0)28 3026 4435 -
Fax: +44 (0)28 3026 5060
<http://www.norbrook.com>
- 1.4 Emergency telephone number:** +44 (0)28 3026 4435

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) n° 1272/2008:
Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 1272/2008.
Aquatic Chronic 2: Hazardous to the aquatic environment, long-term hazard, Category 2, H411
- 2.2 Label elements:**
This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly
CLP Regulation (EC) n° 1272/2008:

Hazard statements:
Aquatic Chronic 2: H411 - Toxic to aquatic life with long lasting effects
Precautionary statements:
P101: If medical advice is needed, have product container or label at hand
P102: Keep out of reach of children
P273: Avoid release to the environment
P391: Collect spillage
P501: Dispose of contents and / or their container according to the separated collection system used in your municipality
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Oral Suspension
Components:
In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 2277-92-1 EC: 218-904-0 Index: Non-applicable REACH: Non-applicable	Oxyclozanide Regulation 1272/2008 Acute Tox. 4: H302; Aquatic Acute 1: H400; Aquatic Chronic 1: H410 - Warning	Proprietary

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**Norbrook Laboratories Ltd - Levafas Diamond Oral Suspension -
VM 02000/4080
Res : 94101**

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Identification	Chemical name/Classification	Concentration
CAS: 16595-80-5 EC: 240-654-6 Index: Non-applicable REACH: Non-applicable	Levamisole hydrochloride Regulation 1272/2008 Acute Tox. 3: H301 - Danger	Proprietary

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

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**Norbrook Laboratories Ltd - Levafas Diamond Oral Suspension -
VM 02000/4080
Res : 94101**

SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Due to the danger of this product for the environment it is recommended to use it within an area containing contamination control barriers in case of spillage, as well as having absorbent material in close proximity.

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Maximum Temp.: 25 °C

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity, light and contact with food. For additional information see subsection 10.5

Other information:

Keep container in outer carton

7.3 Specific end use(s):

Levafas Diamond is a broad spectrum anthelmintic for use in the treatment and control of both gastro-intestinal and pulmonary nematode infections and adult liver fluke infections in cattle and sheep only.

Levafas diamond should be used in cases of parasitic gastroenteritis and lungworm disease caused by mature and developing immature forms of those organisms sensitive to treatment with levamisole hydrochloride

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

There are no occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

- CONTINUED ON NEXT PAGE -

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.


B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

D.- Ocular and facial protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			
	Anti-slip work shoes		EN ISO 20347:2012	

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

- V.O.C. (Supply): 0 % weight
- V.O.C. density at 20 °C: 0 kg/m³ (0 g/L)



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Average carbon number: Non-applicable
Average molecular weight: Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Liquid
Appearance: Undefined
Color: Yellow
Odor: Undefined

Volatility:

Boiling point at atmospheric pressure: 100 °C
Vapour pressure at 20 °C: 2350 Pa
Vapour pressure at 50 °C: 12381 Pa (12 kPa)
Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1042 kg/m³
Relative density at 20 °C: 1.042
Dynamic viscosity at 20 °C: Non-applicable *
Kinematic viscosity at 20 °C: Non-applicable *
Kinematic viscosity at 40 °C: Non-applicable *
Concentration: Non-applicable *
pH: Non-applicable *
Vapour density at 20 °C: Non-applicable *
Partition coefficient n-octanol/water 20 °C: Non-applicable *
Solubility in water at 20 °C: Non-applicable *
Solubility properties: Non-applicable *
Decomposition temperature: Non-applicable *
Melting point/freezing point: Non-applicable *
Explosive properties: Non-applicable *
Oxidising properties: Non-applicable *
Flammability:
Flash Point: Non Flammable (>60 °C)
Autoignition temperature: 1010 °C
Lower flammability limit: Non-applicable *
Upper flammability limit: Non-applicable *

9.2 Other information:

Surface tension at 20 °C: Non-applicable *
Refraction index: Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

- CONTINUED ON NEXT PAGE -



SECTION 10: STABILITY AND REACTIVITY (continued)

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
Not applicable	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	Route	Toxicity	
Levamisole hydrochloride CAS: 16595-80-5 EC: 240-654-6	LD50 oral	180 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	Non-applicable	
Oxyclozanide CAS: 2277-92-1 EC: 218-904-0	LD50 oral	1000 mg/kg	Rat
	LD50 dermal	>2000 mg/kg	
	LC50 inhalation	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Identification	Acute toxicity		Species	Genus
	Route	Toxicity		
Oxyclozanide CAS: 2277-92-1 EC: 218-904-0	LC50	0.1 - 1 mg/L (96 h)		Fish
	EC50	0.1 - 1 mg/L		Crustacean
	EC50	0.1 - 1 mg/L		Algae

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 05*	Organic wastes containing dangerous substances	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP14 Ecotoxic

- CONTINUED ON NEXT PAGE -

SECTION 13: DISPOSAL CONSIDERATIONS (continued)

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2015 and RID 2015:



14.1 UN number:	UN3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxyclozanide)
14.3 Transport hazard class(es):	9
Labels:	9
14.4 Packing group:	III
14.5 Dangerous for the environment:	Yes
14.6 Special precautions for user	
Special regulations:	274, 335, 375, 601
Tunnel restriction code:	E
Physico-Chemical properties:	see section 9
Limited quantities:	5 L
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:	Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 37-14:



14.1 UN number:	UN3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxyclozanide)
14.3 Transport hazard class(es):	9
Labels:	9
14.4 Packing group:	III
14.5 Dangerous for the environment:	Yes
14.6 Special precautions for user	
Special regulations:	274, 909
EmS Codes:	F-A, S-F
Physico-Chemical properties:	see section 9
Limited quantities:	5 L
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:	Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

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SECTION 14: TRANSPORT INFORMATION (continued)



14.1 UN number:	UN3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxyclozanide)
14.3 Transport hazard class(es):	9
Labels:	9
14.4 Packing group:	III
14.5 Dangerous for the environment:	Yes
14.6 Special precautions for user	
Physico-Chemical properties:	see section 9
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:	Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable
Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable
Article 95, REGULATION (EU) No 528/2012: Non-applicable
REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable
Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):
Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation
Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Non-applicable

Texts of the legislative phrases mentioned in section 2:

H411: Toxic to aquatic life with long lasting effects

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) n° 1272/2008:



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SECTION 16: OTHER INFORMATION (continued)

Acute Tox. 3: H301 - Toxic if swallowed
Acute Tox. 4: H302 - Harmful if swallowed
Aquatic Acute 1: H400 - Very toxic to aquatic life
Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects

Classification procedure:

Aquatic Chronic 2: Calculation method

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -