


SECTION 1: IDENTIFICATION

- 1.1 GHS Product identifier:** Norbrook Laboratories Ltd - Loxicom 1.5mg/ml Oral Suspension
Res : 64517
- Other means of identification:**
Not applicable (N/A)
- 1.2 Recommended use of the chemical and restrictions on use:**
Relevant uses: Veterinary Pharmaceutical Product
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:**
Norbrook Laboratories Ltd
Carnbane Industrial Estate
BT35 6QQ Newry - Northern Ireland
Phone: +44 (0)28 3026 4435 - Fax: +44 (0)28 3026 5060
<http://www.norbrook.com>

Norbrook, Inc.
9733 Loiret Blvd
Lenexa, KS 66219

Emergency Telephone Number 913-599-5777
- 1.4 Emergency phone number:** 913-599-5777

SECTION 2: HAZARD(S) IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
29 CFR 1910.1200:
Classification of this product has been carried out in accordance with paragraph (d) of 29 CFR 1910.1200.
Repr. 1A: Reproductive toxicity, Category 1A, H360
- 2.2 Label elements:**
29 CFR 1910.1200:
Danger
- 
- Hazard statements:**
Repr. 1A: H360 - May damage fertility or the unborn child.
- Precautionary statements:**
P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P280: Wear protective gloves/protective clothing/eye protection/protective footwear.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P405: Store locked up.
P501: Dispose of the contents/containers according to the local, state and federal regulations.
- Substances that contribute to the classification**
Meloxicam (CAS: 71125-38-7)
- Additional labeling:**
Federal Hazardous Substances Act (FHSA) >> Chronic toxicity (Reproductive Toxicants)
May damage fertility or the unborn child. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep out of reach of children. Store locked up.
FIRST AID TREATMENT
IF exposed or concerned: Get medical advice/attention.
Contains : Meloxicam (CAS 71125-38-7).

SECTION 2: HAZARD(S) IDENTIFICATION (continued)

2.3 Hazards not otherwise classified (HNO):

Not applicable (N/A)

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances:

Non-applicable

3.2 Mixtures:

Chemical description: Aqueous emulsion

Components:

Remaining components are non-hazardous and/or present at amounts below reportable limits. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of 29 CFR 1910.1200. Therefore, in accordance with Appendix D to 29 CFR 1910.1200, the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 71125-38-7	Meloxicam Acute Tox. 3: H301; Repr. 1A: H360 - Danger	<1 %

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

SECTION 4: FIRST-AID MEASURES

4.1 Description of necessary 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 changes to 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/effects, acute and delayed:

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

4.3 Indication of immediate medical attention and special treatment needed, if necessary:

Not applicable (N/A)

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Suitable (and unsuitable) extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

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SECTION 5: FIRE-FIGHTING MEASURES (continued)

5.2 Specific hazards arising from the chemical:

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 Special protective equipment and precautions for fire-fighters:

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,...)

Additional provisions:

As in any fire, prevent human exposure to fire, smoke, fumes or products of combustion. Only properly trained personnel should be involved in firefighting. Evacuate nonessential personnel from the fire area. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation. 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:

For non-emergency personnel:

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.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

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 materials for containment and cleaning up:

For accidental releases in excess of reportable quantities (RQ) (Table 302.4), refer to 40 CFR 302 for detailed instructions concerning reporting requirements and notify the National Response Center (800) 424-8802.

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.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

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 on general occupational hygiene

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in fixed places that comply with the necessary security conditions (emergency showers and eyewash stations in close proximity), using personal protection equipment, especially on the hands and face (See section 8). Limit manual transfers to containers of small amounts. 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.- Specific storage requirements

Maximum Temp.: 86 °F

B.- General conditions for storage

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SECTION 7: HANDLING AND STORAGE (continued)

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

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace:

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000):

Identification	Occupational exposure limits		
Glycerol CAS: 56-81-5	8-hour TWA PEL		5 mg/m ³
	Ceiling Values - TWA PEL		

US. ACGIH Threshold Limit Values (2022):

Identification	Occupational exposure limits		
Sodium benzoate CAS: 532-32-1	TLV-TWA		2.5 mg/m ³
	TLV-STEL		
Glycerol CAS: 56-81-5	TLV-TWA		10 mg/m ³
	TLV-STEL		

8.2 Appropriate engineering controls:


A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protection Equipment. 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, the information on clothing performance must be combined with professional judgment, and a clear understanding of the clothing application, to provide the best protection to the worker. All chemical protective clothing use must be based on a hazard assessment to determine the risks for exposure to chemicals and other hazards. Conduct hazard assessments in accordance with 29 CFR 1910.132.

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	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 /industrial users, we recommend using chemical protection gloves. Use gloves in accordance with manufacturer's use limitations and OSHA standard 1910.138 (29CFR)

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has to be checked prior to the application.

D.- Eye and face protection

Pictogram	PPE	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. Use this PPE in accordance with manufacturer's use limitations and OSHA standard 1910.133 (29CFR)

E.- Bodily protection



Pictogram	PPE	Remarks
	Work clothing	Replace before any evidence of deterioration.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Remarks
	Anti-slip work shoes	Replace before any evidence of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

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

40 CFR Part 59 (VOC):

V.O.C.(weight-percent):	0 % weight
V.O.C. at 68 °F:	0 kg/m ³ (0 g/L)

California Air Resources Board (CARB) - VOC Regulatory:

V.O.C.(weight-percent):	0 % weight
V.O.C. at 68 °F:	0 kg/m ³ (0 g/L)

South Coast Air Quality Management District (AQMD) - VOC Regulatory:

V.O.C.(weight-percent):	0 % weight
V.O.C. at 68 °F:	0 kg/m ³ (0 g/L)

Ozone Transport Commission (OTC) Rules - VOC Regulatory:

V.O.C.(weight-percent):	0 % weight
V.O.C. at 68 °F:	0 kg/m ³ (0 g/L)

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 68 °F:	Liquid
Appearance:	Not available
Color:	Not available
Odor:	Not available
Odour threshold:	Not applicable (N/A) *

Volatility:

Boiling point at atmospheric pressure:	212 °F
Vapour pressure at 68 °F:	2350 Pa
Vapour pressure at 122 °F:	12381.01 Pa (12.38 kPa)
Evaporation rate at 68 °F:	Not applicable (N/A) *

Product description:

Density at 68 °F:	1066 kg/m ³
Relative density at 68 °F:	1.066
Dynamic viscosity at 68 °F:	Not applicable (N/A) *
Kinematic viscosity at 68 °F:	Not applicable (N/A) *

*Not applicable (N/A) 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)

Kinematic viscosity at 104 °F:	Not applicable (N/A) *
Concentration:	Not applicable (N/A) *
pH:	Not applicable (N/A) *
Vapour density at 68 °F:	Not applicable (N/A) *
Partition coefficient n-octanol/water 68 °F:	Not applicable (N/A) *
Solubility in water at 68 °F:	Not applicable (N/A) *
Solubility properties:	Not applicable (N/A) *
Decomposition temperature:	Not applicable (N/A) *
Melting point/freezing point:	Not applicable (N/A) *
Flammability:	
Flash Point:	Non Flammable (>199.4 °F)
Flammability (solid, gas):	Not applicable (N/A) *
Autoignition temperature:	797 °F
Lower flammability limit:	Not applicable (N/A) *
Upper flammability limit:	Not applicable (N/A) *
Particle characteristics:	
Median equivalent diameter:	Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Not applicable (N/A) *
Oxidising properties:	Not applicable (N/A) *
Corrosive to metals:	Not applicable (N/A) *
Heat of combustion:	Not applicable (N/A) *
Aerosols-total percentage (by mass) of flammable components:	Not applicable (N/A) *

Other safety characteristics:

Surface tension at 68 °F:	Not applicable (N/A) *
Refraction index:	Not applicable (N/A) *

*Not applicable (N/A) 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 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated 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	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

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SECTION 10: STABILITY AND REACTIVITY (continued)

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 hazardous 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 hazardous 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 hazardous 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 hazardous 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 hazardous 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 hazardous for the effects mentioned. For more information see section 3.
IARC: Polyvinylpyrrolidone (3)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: May damage fertility or the unborn child

E- Sensitizing effects:

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

Other information:

Not applicable (N/A)

Specific toxicology information on the substances:

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
Meloxicam	LD50 oral	83.5 mg/kg	Rat
CAS: 71125-38-7	LD50 dermal	>5000 mg/kg	
	LC50 inhalation		

Acute Toxicity Estimate (ATE mix):

ATE mix		Ingredient(s) of unknown toxicity
Oral	55666.67 mg/kg (Calculation method)	0 %
Dermal	13333.33 mg/kg (Calculation method)	Non-applicable
Inhalation	>20 mg/L (4 h) (Calculation method)	Non-applicable

SECTION 12: ECOLOGICAL INFORMATION

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

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

12.1 Ecotoxicity (aquatic and terrestrial, where available):

Acute toxicity:

Identification	Concentration		Species	Genus
Meloxicam	LC50	50 mg/L (96 h)	N/A	Fish
CAS: 71125-38-7	EC50	50 mg/L (48 h)	N/A	Crustacean
	EC50	13 mg/L (72 h)	N/A	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 Disposal methods:

Wastes generated by normal household activities (e.g., routine house and yard maintenance) are excluded from the definition of hazardous waste (Title 40 of the Code of Federal Regulations Part 261.4)

Waste management (disposal and evaluation):

Follow RCRA framework and EPA regulation for to ensure that hazardous waste is managed safely and properly. Waste should not be disposed of to drains. Remind, It is the responsibility of the waste generator to evaluate whether his wastes are hazardous by characteristics or listing. See section 6 for further information about Accidental release measures.

Regulations related to waste management:

Legislation related to waste management:

40 CFR Solid Wastes - Part 239 through 282.

State regulatory requirements for generators may be more stringent than those in the federal program. Be sure to check the state's policies.

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport.

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SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations specific for the product in question:

- CALIFORNIA LABOR CODE - The Hazardous Substances List: Not applicable (N/A)
- California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) - Birth defects or other reproductive harm: Not applicable (N/A)
- California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) - Cancer: Not applicable (N/A)
- CANADA-Domestic Substances List (DSL): Not applicable (N/A)
- CANADA-Non-Domestic Substances List (NDSL): Not applicable (N/A)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantities: Not applicable (N/A)
- Hazardous Air Pollutants (Clean Air Act): Not applicable (N/A)
- Massachusetts RTK - Substance List: Not applicable (N/A)
- Minnesota - Hazardous substances ERTK: Not applicable (N/A)
- New Jersey Worker and Community Right-to-Know Act: Not applicable (N/A)
- New York RTK - Substance list: Not applicable (N/A)
- NTP (National Toxicology Program): Not applicable (N/A)
- OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096): Not applicable (N/A)
- Pennsylvania Worker and Community Right-to-Know Law: Not applicable (N/A)
- Rhode Island - Hazardous substances RTK: Not applicable (N/A)
- The Toxic Substances Control Act (TSCA) : Not applicable (N/A)
- Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): Not applicable (N/A)

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information provided in this safety data sheet as a foundation for conducting workplace-specific risk assessments. These assessments will help establish the appropriate risk prevention measures for handling, using, storing, and disposing of this product.

Other legislation:

Take into consideration other applicable federal, state, and local laws and local regulations.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Appendix d to 29 CFR 1910.1200 - Safety data sheets

Texts of the legislative phrases mentioned in section 2:

H360: May damage fertility or the unborn child.

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

29 CFR 1910.1200:

Acute Tox. 3: H301 - Toxic if swallowed.

Repr. 1A: H360 - May damage fertility or the unborn child.

Advice related to training:

According to 29 CFR 1910. 1200, training on chemical hazards is necessary for employees using this product. This training will facilitate their understanding and interpretation of the safety data sheet, as well as the product label.

Principal bibliographical sources:

Occupational Safety & Health Administration (OSHA).

Abbreviations and acronyms:

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

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

IARC: International Agency for Research on Cancer

Date of compilation: 11/6/2018

Revised: 8/20/2024

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Safety data sheet
according to 29 CFR 1910.1200

Norbrook Laboratories Ltd - Loxicom 1.5mg/ml Oral Suspension
Res : 64517

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END OF SAFETY DATA SHEET