

SECTION 1: IDENTIFICATION




- 1.1 GHS Product identifier:** Norbrook Laboratories Ltd - Firox Chewable Tablets US
- 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
- 1.4 Emergency phone number:** +44 (0)28 3026 4435

SECTION 2: HAZARD(S) IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
29 CFR 1910.1200:
 While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
- 2.2 Label elements:**
 This mixture is regulated under Veterinary Medicines Regulations and will be labelled accordingly
29 CFR 1910.1200:
 None
 This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).
- 2.3 Other hazards which do not result in classification:**
 Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substances:**
 Non-applicable
- 3.2 Mixtures:**
Chemical description: Tablets
Components:
 Remaining components are non-hazardous and/or present at amounts below reportable limits. Exact percentage values for components are proprietary in accordance with 29 CFR 1910.1200(i). Therefore, in accordance with Appendix D to § 1910.1200, the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 189954-96-9	Firocoxib Repr. 1B: H360 - Danger	Proprietary 
CAS: Non-applicable	Dried Pork Liver Skin Sens. 1B: H317 - Warning	Proprietary 
CAS: 25086-89-9	Kollidon VA64 Acute Tox. 4: H302 - Warning	Proprietary 

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

SECTION 4: FIRST-AID MEASURES

- 4.1 Description of necessary measures:**

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SECTION 4: FIRST-AID MEASURES (continued)

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:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

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:

Non-applicable

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Suitable (and unsuitable) 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 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:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

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:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

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 standards 29 CFR 1910 Occupational Safety and Health Standards. 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

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

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.: 51-86°F

B.- General conditions for storage

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


Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

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

Pictogram	PPE	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29CFR)

C.- Specific protection for the hands


Pictogram	PPE	Remarks
 Mandatory hand protection	NON-disposable chemical protective gloves	The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin. 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 therefore to be checked prior to the application



D.- Ocular and facial protection

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Remarks
 Mandatory face protection	Face shield	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
 Mandatory complete body protection	Disposable clothing for protection against chemical risks	For professional use only. Clean periodically according to the manufacturer's instructions.
 Mandatory foot protection	Safety footwear for protection against chemical risk	Replace boots at any sign of deterioration. Use foot protection in accordance with manufacturer's use limitations and OSHA standard 1910.136 (29CFR)

F.- 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

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: Solid
 Appearance: Not available
 Color: Not available
 Odor: Not available
 Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: Non-applicable *
 Vapour pressure at 68 °F: Non-applicable *
 Vapour pressure at 122 °F: Non-applicable *
 Evaporation rate at 68 °F: Non-applicable *

Product description:

Density at 68 °F: Non-applicable *
 Relative density at 68 °F: Non-applicable *
 Dynamic viscosity at 68 °F: Non-applicable *
 Kinematic viscosity at 68 °F: Non-applicable *
 Kinematic viscosity at 104 °F: Non-applicable *
 Concentration: Non-applicable *

*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)

pH:	Non-applicable *
Vapour density at 68 °F:	Non-applicable *
Partition coefficient n-octanol/water 68 °F:	Non-applicable *
Solubility in water at 68 °F:	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-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Explosive:

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

9.2 Other information:

Surface tension at 68 °F:	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
Avoid strong acids	Not applicable	Not applicable	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

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

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.
IARC: Silicon dioxide (1 % < RCS < 10 %) (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, however it does 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, however, it contains substances classified as dangerous with sensitising effects. 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:

Identification	Acute toxicity		Genus
Firocoxib CAS: 189954-96-9	LD50 oral	>5000 mg/kg	
	LD50 dermal	>5000 mg/kg	
	LC50 inhalation	>5 mg/L (4 h)	
Kollidon VA64 CAS: 25086-89-9	LD50 oral	10000 mg/kg	Rat
	LD50 dermal	>5000 mg/kg	
	LC50 inhalation	>5 mg/L (4 h)	

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Dried Pork Liver	>5000 mg/kg	>5000 mg/kg	
CAS: Non-applicable		Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Ecotoxicity (aquatic and terrestrial, where available):

Not available

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:

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations. 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 recommended disposal down the drain. See epigraph 6.2.

Regulations related to waste management:

Legislation related to waste management:

40 CFR Part 261- IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport.

SECTION 15: REGULATORY INFORMATION

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

SECTION 15: REGULATORY INFORMATION (continued)

SARA Title III - Toxic Chemical Release Inventory Reporting (Section 313): Non-applicable
California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986): Non-applicable
The Toxic Substances Control Act (TSCA) : Kollidon VA64
Massachusetts RTK - Substance List: Non-applicable
New Jersey Worker and Community Right-to-Know Act: Non-applicable
New York RTK - Substance list: Non-applicable
Pennsylvania Worker and Community Right-to-Know Law: Non-applicable
CANADA-Domestic Substances List (DSL): Kollidon VA64
CANADA-Non-Domestic Substances List (NDSL): Non-applicable
NTP (National Toxicology Program): Non-applicable
Minnesota - Hazardous substances ERTK: Non-applicable
Rhode Island - Hazardous substances RTK: Non-applicable
Hazardous substances release notification under CERCLA sections 102-103 (40 CFR Part 302): 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 Toxic Substances Control Act (TSCA)
SARA Title III - Community Right-to-Know Reporting Requirements (Sections 311-312)
SARA Title III - Toxic Chemical Release Inventory Reporting (Section 313)
Emergency Planning and Community Right-to-Know Act (EPCRA) Reportable Quantities

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Appendix d to §1910.1200 – Safety data sheets

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. 4: H302 - Harmful if swallowed
Repr. 1B: H360 - May damage fertility or the unborn child
Skin Sens. 1B: H317 - May cause an allergic skin reaction

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:

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

The information contained in this safety data sheet is based on sources, technical knowledge and current USA legislation, 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