

Norbrook Laboratories Ltd – Flunixin S injection - ANADA 200-476 60644

SECTION 1: IDENTIFICATION

1.1 GHS Product identifier: Norbrook Laboratories Ltd – Flunixin S injection - ANADA 200-476

60644

Other means of identification:

Not applicable (N/A)

1.2 Recommended use of the chemical and restrictions on use:

Relevant uses: Active substance

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: 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 § 1910.1200.

Carc. 2: Carcinogenicity, Category 2, H351

STOT RE 1: Specific target organ toxicity, repeated exposure, Category 1, H372

2.2 Label elements:

29 CFR 1910.1200:

Danger



Hazard statements:

Carc. 2: H351 - Suspected of causing cancer.

STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure.

Precautionary statements:

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P264: Wash thoroughly after use.

P270: Do no eat, drink or smoke when using this product.

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

P314: Get medical advice/attention if you feel unwell.

P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

Substances that contribute to the classification

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate (CAS: 42461-84-7); 2,2´-iminodiethanol (CAS: 111-42-2)

Additional labeling:



WARNING

This product can expose you to chemicals including 2,2 '-iminodiethanol, which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

2.3 Hazards not otherwise classified (HNOC):

Not applicable (N/A)



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances:

Non-applicable

3.2 Mixtures:

Chemical description: Organic compounds

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 §1910.1200. Therefore, in accordance with Appendix D to § 1910.1200, the product contains:

| | Identification | Chemical name/Classification | Concentration |
|------|----------------|---|---------------|
| CAS: | 42461-84-7 | 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | Proprietary |
| | | Acute Tox. 3: H301+H331; Eye Irrit. 2A: H319; STOT RE 1: H372; STOT SE 3: H335 - Danger | • |
| CAS: | 108-95-2 | phenol | Proprietary |
| | | Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H311+H331; Flam. Liq. 4: H227; Muta. 2: H341; Skin Corr. 1B: H314; STOT RE 2: H373 - Acute Tox. 3: H301+H311+H311+H311+H311+H311+H311+H311+ | • |
| CAS: | 111-42-2 | 2,2´-iminodiethanol | Proprietary |
| | | Acute Tox. 4: H302; Carc. 2: H351; Eye Dam. 1: H318; Skin Irrit. 2: H315; STOT RE 2: H373 - Danger | |

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

Other information:

| Identification | Specific concentration limit |
|-------------------------|---|
| phenol CAS: 108-95-2 | % (w/w) >=3: Skin Corr. 1B - H314 1<= % (w/w) <3: Skin Irrit. 2 - H315 |
| | % (w/w) >=1: Eye Irrit. 2 - H319 |

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:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection

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/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:

Date of compilation: 4/23/2018 Revised: 12/4/2023 Version: 4 (Replaced 3) **Page 2/11**



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 5: FIRE-FIGHTING MEASURES (continued)

Product is non-flammable under normal conditions of storage, manipulation and use, but the product contains flammable substances. 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.

Unsuitable extinguishing media:

IT IS RECOMMENDED NOT to use full jet 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:

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 reportables 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.

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

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

Page 3/11

Norbrook[®]

Safety data sheet according to 29 CFR 1910.1200

Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 7: HANDLING AND STORAGE (continued)

Maximum Temp.: 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:

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

| Identification | Identification Occupational exposure limits | | its |
|----------------|---|-------|----------------------|
| phenol | 8-hour TWA PEL | 5 ppm | 19 mg/m ³ |
| CAS: 108-95-2 | Ceiling Values - TWA PEL | | |

US. ACGIH Threshold Limit Values (2022):

| Identification | Occupational exposure limits | | its |
|----------------------|------------------------------|-------|---------------------|
| 2,2 '-iminodiethanol | TLV-TWA | | 2 mg/m ³ |
| CAS: 111-42-2 | TLV-STEL | | |
| phenol | TLV-TWA | 5 ppm | |
| CAS: 108-95-2 | TLV-STEL | | |

CALIFORNIA- TABLE AC-1 PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS:

| Identification | Occupational exposure limits | | |
|---------------------|------------------------------|----------|----------------------|
| 2,2´-iminodiethanol | PEL | 0.46 ppm | 2 mg/m ³ |
| CAS: 111-42-2 | STEL | | |
| phenol | PEL | 5 ppm | 19 mg/m ³ |
| CAS: 108-95-2 | STEL | | |

Biological limit values:

Biological Exposure Indices (BEIs®) - ACGIH

| Identification | BEIs® | Determinant | Sampling Time |
|-------------------------|----------|-----------------|---------------|
| phenol CAS: 108-95-2 | 250 mg/L | Phenol in urine | End of shift |

8.2 Appropriate engineering controls:

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

Always provide effective general and, when necessary, local exhaust ventilation to maintain the ambient workplace atmosphere below the exposure limits.. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For additional 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



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

| 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.- Eye and face protection

| 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 3864-1:2011, 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): 21.22 % weight

V.O.C. at 68 °F: 820.15 kg/m³ (820.15 g/L)

Components: Not applicable (N/A)

California Air Resources Board (CARB) - VOC Regulatory:

V.O.C.(weight-percent): 21.22 % weight

V.O.C. at 68 °F: 820.15 kg/m³ (820.15 g/L)

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

V.O.C.(weight-percent): 21.22 % weight

V.O.C. at 68 °F: 820.15 kg/m³ (820.15 g/L) Ozone Transport Commission (OTC) Rules - VOC Regulatory:

V.O.C.(weight-percent): 21.22 % weight

V.O.C. at 68 °F: 820.15 kg/m³ (820.15 g/L)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Date of compilation: 4/23/2018 Revised: 12/4/2023 Version: 4 (Replaced 3) **Page 5/11**



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

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:

233 °F Boiling point at atmospheric pressure: 2200 Pa Vapour pressure at 68 °F:

Vapour pressure at 122 °F: 11593.78 Pa (11.59 kPa) Evaporation rate at 68 °F: Not applicable (N/A) *

Product description:

Density at 68 °F: 1035.1 kg/m³

Relative density at 68 °F: 1.035

Dynamic viscosity at 68 °F: Not applicable (N/A) * Kinematic viscosity at 68 °F: Not applicable (N/A) * 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) *

790 °F Autoignition temperature:

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) * Not applicable (N/A) * Heat of combustion: Aerosols-total percentage (by mass) of flammable Not applicable (N/A) *

components:

Other safety characteristics:

Not applicable (N/A) * Surface tension at 68 °F: *Not relevant due to the nature of the product, not providing information property of its hazards.

Page 6/11



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Refraction index: Not applicable (N/A) *

*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 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 | Precaution | Precaution | 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:

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. However, it does 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. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does 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. However, it contains 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. However, it does contain substances classified as hazardous for this effect. For more information see section 3.
- $\hbox{ D- } CMR \ effects \ (carcinogenicity, \ mutagenicity \ and \ toxicity \ to \ reproduction):$



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Carcinogenicity: Exposure to this product can cause cancer. For more specific information on the possible health effects see section 2.
 - IARC: 2,2 '-iminodiethanol (2B); phenol (3)
- Mutagenicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with mutagenic effects. 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 hazardous 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 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. However, it contains substances classified as hazardous for inhalation. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Serious health effects in the case of prolonged consumption, including death, serious functional disorders or morphological changes of toxicological importance.
 - 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:

| Identification | Acute toxicity | | Genus |
|--|-----------------|---------------|--------|
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | LD50 oral | 157 mg/kg | Rat |
| CAS: 42461-84-7 | LD50 dermal | >5000 mg/kg | |
| | LC50 inhalation | 3 mg/L (ATEi) | |
| phenol | LD50 oral | 100 mg/kg | Rat |
| CAS: 108-95-2 | LD50 dermal | 630 mg/kg | Rabbit |
| | LC50 inhalation | 3 mg/L (ATEi) | |
| 2,2´-iminodiethanol | LD50 oral | 710 mg/kg | Rat |
| CAS: 111-42-2 | LD50 dermal | 12200 mg/kg | Rabbit |
| | LC50 inhalation | >5 mg/L | |

Acute Toxicity Estimate (ATE mix):

| | Ingredient(s) of unknown toxicity | | |
|--|------------------------------------|-----|--|
| Oral | 2713.92 mg/kg (Calculation method) | 0 % | |
| Dermal 126000 mg/kg (Calculation method) | | 0 % | |
| Inhalation 54.55 mg/L (4 h) (Calculation method) | | 0 % | |

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:



Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 12: ECOLOGICAL INFORMATION (continued)

| Identification | | Concentration | Species | Genus |
|--|------|-----------------|-------------------------|------------|
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3- (perfluoromethyl)anilino]nicotinate | LC50 | 9.2 mg/L (96 h) | Salmo gairdneri | Fish |
| CAS: 42461-84-7 | EC50 | 25 mg/L (48 h) | Daphnia magna | Crustacean |
| | EC50 | 78 mg/L (72 h) | N/A | Algae |
| phenol | LC50 | 14 mg/L (96 h) | Leuciscus idus | Fish |
| CAS: 108-95-2 | EC50 | 12 mg/L (24 h) | Daphnia magna | Crustacean |
| | EC50 | 370 mg/L (96 h) | Chlorella vulgaris | Algae |
| 2,2´-iminodiethanol | LC50 | 800 mg/L (24 h) | Carassius auratus | Fish |
| CAS: 111-42-2 | EC50 | 180 mg/L (24 h) | Daphnia magna | Crustacean |
| | EC50 | 75 mg/L (72 h) | Scenedesmus subspicatus | Algae |

Chronic toxicity:

| Identification | | Concentration | Species | Genus |
|---------------------|------|---------------|------------------|------------|
| phenol | NOEC | 0.077 mg/L | Cirrhina mrigala | Fish |
| CAS: 108-95-2 | NOEC | 0.16 mg/L | Daphnia magna | Crustacean |
| 2,2´-iminodiethanol | NOEC | 1 mg/L | N/A | Fish |
| CAS: 111-42-2 | NOEC | 0.78 mg/L | Daphnia magna | Crustacean |

12.2 Persistence and degradability:

Substance-specific information:

| Identification | Degradability | | Biodegradability | |
|----------------------|---------------|-------------|------------------|----------|
| phenol | BOD5 | 1.68 g O2/g | Concentration | 100 mg/L |
| CAS: 108-95-2 | COD | 2.33 g O2/g | Period | 14 days |
| | BOD5/COD | 0.72 | % Biodegradable | 85 % |
| 2,2 ´-iminodiethanol | BOD5 | 0.03 g O2/g | Concentration | 100 mg/L |
| CAS: 111-42-2 | COD | 1.52 g O2/g | Period | 21 days |
| | BOD5/COD | 0.02 | % Biodegradable | 54 % |

12.3 Bioaccumulative potential:

Substance-specific information:

| Identification | Bioacc | Bioaccumulation potential | | |
|---------------------|-----------|---------------------------|--|--|
| phenol | BCF | 17 | | |
| CAS: 108-95-2 | Pow Log | 1.48 | | |
| | Potential | Low | | |
| 2,2´-iminodiethanol | BCF | 1 | | |
| CAS: 111-42-2 | Pow Log | -1.43 | | |
| | Potential | Low | | |

12.4 Mobility in soil:

| Identification | Absorption/desorption | | Volatility | |
|----------------------|-----------------------|--------------------------|------------|----------------------|
| phenol | Koc | 50 | Henry | 2.2E-2 Pa·m³/mol |
| CAS: 108-95-2 | Conclusion | Very High | Dry soil | Yes |
| | Surface tension | 1.847E-2 N/m (447.82 °F) | Moist soil | Yes |
| 2,2 ´-iminodiethanol | Koc | Not applicable (N/A) | Henry | Not applicable (N/A) |
| CAS: 111-42-2 | Conclusion | Not applicable (N/A) | Dry soil | Not applicable (N/A) |
| | Surface tension | 3.4E-2 N/m (299.21 °F) | Moist soil | Not applicable (N/A) |

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:

Date of compilation: 4/23/2018 Revised: 12/4/2023 Version: 4 (Replaced 3) **Page 9/11**

Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 13: DISPOSAL CONSIDERATIONS (continued)

IT IS THE RESPONSIBILITY OF THE WASTE GENERATOR TO EVALUATE WHETHER HIS WASTES ARE HAZARDOUS BY CHARACTERISTICS OR LISTING.

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.

SECTION 15: REGULATORY INFORMATION

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

- CALIFORNIA LABOR CODE The Hazardous Substances List: phenol (108-95-2); 2.2 '-iminodiethanol (111-42-2)
- 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: 2,2 '-iminodiethanol (111-42-2)
- CANADA-Domestic Substances List (DSL): phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- CANADA-Non-Domestic Substances List (NDSL); Not applicable (N/A)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Reportable Quantities: phenol (108-95-2)
- U188; 2,2 '-iminodiethanol (111-42-2) 100 lb
- Hazardous Air Pollutants (Clean Air Act): phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2) Massachusetts RTK Substance List: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- Minnesota Hazardous substances ERTK: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- New Jersey Worker and Community Right-to-Know Act: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- New York RTK Substance list: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- 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: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- Rhode Island Hazardous substances RTK: phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2) The Toxic Substances Control Act (TSCA): phenol (108-95-2); 2,2 '-iminodiethanol (111-42-2)
- Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372); phenol (108-95-2); 2,2 '-iminodiethanol

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:

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 §1910.1200 - Safety data sheets

Texts of the legislative phrases mentioned in section 2:

H372: Causes damage to organs through prolonged or repeated exposure.

H351: Suspected of causing cancer.

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:

Date of compilation: 4/23/2018 Revised: 12/4/2023 Version: 4 (Replaced 3) Page 10/11

Norbrook[®]

Safety data sheet according to 29 CFR 1910.1200

Norbrook Laboratories Ltd - Flunixin injection - ANADA 200-308 60644

SECTION 16: OTHER INFORMATION (continued)

Acute Tox. 3: H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.

Acute Tox. 3: H301+H331 - Toxic if swallowed or if inhaled.

Acute Tox. 4: H302 - Harmful if swallowed. Carc. 2: H351 - Suspected of causing cancer. Eye Dam. 1: H318 - Causes serious eye damage. Eye Irrit. 2A: H319 - Causes serious eye irritation.

Flam. Liq. 4: H227 - Combustible liquid.

Muta. 2: H341 - Suspected of causing genetic defects.

Skin Corr. 1B: H314 - Causes severe skin burns and eye damage.

Skin Irrit. 2: H315 - Causes skin irritation.

STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure. STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure.

STOT SE 3: H335 - May cause respiratory irritation.

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 IARC: International Agency for Research on Cancer

Date of compilation: 4/23/2018

Revised: 12/4/2023

Manufacturer Disclaimer: The information contained in this safety date sheet ("SDS") is based on sources, technical knowledge and current legislation. Furthermore, is based on data believed to be accurate; thus, the company does not assume any liability for its accuracy. The information provided herein cannot be considered a guarantee of the properties of this product and the same is simply a description of the security requirements. The use, occupational methodology and/or conditions for users of this product are not within our awareness or control. It is ultimately the responsibility of the user(s) to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information of this SDS only refers to this product, which should not be used for purposes other than those specified. Finally, the manner in which this product is used and whether there is any infringement of patents is the sole responsibility of the user(s).

END OF SAFETY DATA SHEET

Date of compilation: 4/23/2018 Revised: 12/4/2023 Version: 4 (Replaced 3) Page 11/11