

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

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Alamyacin Aerosol - VM 02000/4053
Res : 90162
- 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
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 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.

Acute Tox. 3: Acute toxicity, Category 3, H301+H311+H331

Aerosol 1: Pressurised container: May burst if heated., H229

Aerosol 1: Flammable aerosols, Category 1, H222

Eye Irrit. 2: Eye irritation, Category 2, H319

Repr. 2: Reproductive toxicity, Category 2, H361

Skin Irrit. 2: Skin irritation, Category 2, H315

STOT SE 1: Specific target organ toxicity — single exposure, Category 1, H370

2.2 Label elements:

This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly

CLP Regulation (EC) n° 1272/2008:

Danger



Hazard statements:

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

Aerosol 1: H229 - Pressurised container: May burst if heated

Aerosol 1: H222 - Extremely flammable aerosol

Eye Irrit. 2: H319 - Causes serious eye irritation

Repr. 2: H361 - Suspected of damaging fertility or the unborn child

Skin Irrit. 2: H315 - Causes skin irritation

STOT SE 1: H370 - Causes damage to organs

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand

P102: Keep out of reach of children

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P211: Do not spray on an open flame or other ignition source

P251: Do not pierce or burn, even after use

P280: Wear protective gloves/protective clothing/eye protection/face protection

P410+P412: Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F

P501: Dispose of contents and / or their container according to the separated collection system used in your municipality

Substances that contribute to the classification

Methanol (CAS: 67-56-1); Propan-2-ol (CAS: 67-63-0); Oxytetracycline (CAS: 79-57-2); 2-aminoethanol (CAS: 141-43-5)

2.3 Other hazards:

Non-applicable

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:





Non-applicable

3.2 Mixture:

Chemical description: Aerosol

Components:

In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | Concentration |
|--|---|--|
| CAS: 67-56-1 EC: 200-659-6 Index: 603-001-00-X REACH:01-2119433307-44-XXX X | Methanol ¹ Regulation 1272/2008 Acute Tox. 3: H301+H311+H331; Flam. Liq. 2: H225; STOT SE 1: H370 - Danger | Proprietary  |
| CAS: 67-63-0 EC: 200-661-7 Index: 603-117-00-0 REACH:01-2119457558-25-XXX X | Propan-2-ol ¹ Regulation 1272/2008 Eye Irrit. 2: H319; Flam. Liq. 2: H225; STOT SE 3: H336 - Danger | Proprietary  |
| CAS: 79-57-2 EC: 201-212-8 Index: Non-applicable REACH:Non-applicable | Oxytetracycline ¹ Regulation 1272/2008 Acute Tox. 4: H302+H312+H332; Eye Irrit. 2: H319; Repr. 2: H361 - Warning | Proprietary  |
| CAS: 141-43-5 EC: 205-483-3 Index: 603-030-00-8 REACH:01-2119486455-28-XXX X | 2-aminoethanol ¹ Regulation 1272/2008 Acute Tox. 4: H302+H312+H332; Skin Corr. 1B: H314 - Danger | Proprietary  |

¹ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830

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:

Request medical assistance immediately, 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 lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. 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:

Request medical assistance immediately, showing the SDS of this product. Induce vomiting (ONLY IN CONSCIOUS PEOPLE!) and then ingest large quantities of liquid to dilute the toxin. Keep the person affected at rest.

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:

If possible use polyvalent powder fire extinguishers (ABC powder), alternatively use foam or carbon dioxide extinguishers (CO2). IT IS RECOMMENDED NOT to use tap water as an extinguishing agent.

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SECTION 5: FIREFIGHTING MEASURES (continued)

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. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inertization agent. Destroy any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

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.

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

Avoid the evaporation of the product as it contains flammable substances, which could form flammable vapour/air mixtures in the presence of sources of ignition. Control sources of ignition (mobile phones, sparks,...) and transfer at slow speeds to avoid the creation of electrostatic charges. Avoid projections and pulverizations. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

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.- Technical measures for storage

Maximum Temp.: 25 °C

B.- General conditions for storage

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):

Alamyacin Aerosol is a cutaneous spray indicated for the treatment of foot rot in sheep and topical infections caused by oxytetracycline-sensitive organisms in cattle, sheep and pigs.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

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

| Identification | Environmental limits | | |
|--|----------------------|---------|-----------------------|
| | IOELV (8h) | 200 ppm | 260 mg/m ³ |
| Methanol CAS: 67-56-1 EC: 200-659-6 | IOELV (STEL) | | |
| | Year | 2017 | |
| | IOELV (8h) | 1 ppm | 2.5 mg/m ³ |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | IOELV (STEL) | 3 ppm | 7.6 mg/m ³ |
| | Year | 2017 | |

DNEL (Workers):

| Identification | | Short exposure | | Long exposure | |
|--|------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | | Systemic | Local | Systemic | Local |
| Methanol CAS: 67-56-1 EC: 200-659-6 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | 40 mg/kg | Non-applicable | 40 mg/kg | Non-applicable |
| | Inhalation | 260 mg/m ³ | 260 mg/m ³ | 260 mg/m ³ | 260 mg/m ³ |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | 888 mg/kg | Non-applicable |
| | Inhalation | Non-applicable | Non-applicable | 500 mg/m ³ | Non-applicable |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | 1 mg/kg | Non-applicable |
| | Inhalation | Non-applicable | Non-applicable | Non-applicable | 3,3 mg/m ³ |

DNEL (General population):

| Identification | | Short exposure | | Long exposure | |
|--|------------|----------------------|----------------------|----------------------|----------------------|
| | | Systemic | Local | Systemic | Local |
| Methanol CAS: 67-56-1 EC: 200-659-6 | Oral | 8 mg/kg | Non-applicable | 8 mg/kg | Non-applicable |
| | Dermal | 8 mg/kg | Non-applicable | 8 mg/kg | Non-applicable |
| | Inhalation | 50 mg/m ³ | 50 mg/m ³ | 50 mg/m ³ | 50 mg/m ³ |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | Oral | Non-applicable | Non-applicable | 26 mg/kg | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | 319 mg/kg | Non-applicable |
| | Inhalation | Non-applicable | Non-applicable | 89 mg/m ³ | Non-applicable |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | Oral | Non-applicable | Non-applicable | 3,75 mg/kg | Non-applicable |
| | Dermal | Non-applicable | Non-applicable | 0,24 mg/kg | Non-applicable |
| | Inhalation | Non-applicable | Non-applicable | Non-applicable | 2 mg/m ³ |

PNEC:

| Identification | | PNEC | | |
|--|--------------|----------------|-------------------------|----------------|
| | | 100 mg/L | Fresh water | 154 mg/L |
| Methanol CAS: 67-56-1 EC: 200-659-6 | Soil | 23,5 mg/kg | Marine water | 15,4 mg/L |
| | Intermittent | 1540 mg/L | Sediment (Fresh water) | 570,4 mg/kg |
| | Oral | Non-applicable | Sediment (Marine water) | Non-applicable |
| | STP | 2251 mg/L | Fresh water | 140,9 mg/L |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | Soil | 28 mg/kg | Marine water | 140,9 mg/L |
| | Intermittent | 140,9 mg/L | Sediment (Fresh water) | 552 mg/kg |
| | Oral | 160 g/kg | Sediment (Marine water) | 552 mg/kg |
| | STP | 100 mg/L | Fresh water | 0,085 mg/L |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | Soil | 0,035 mg/kg | Marine water | 0,0085 mg/L |
| | Intermittent | 0,025 mg/L | Sediment (Fresh water) | 0,425 mg/kg |
| | Oral | Non-applicable | Sediment (Marine water) | 0,0425 mg/kg |

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)



8.2 Exposure controls:

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



In accordance with the order of importance to control professional exposure (Directive 98/24/EC) it is recommended to use localized extraction in the work area as a collective protection measure to avoid exceeding the professional exposure limits. In case of using individual protection equipment they should have the 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 additional 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



| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---|--|---|--|---|
|  Mandatory respiratory tract protection | Filter mask for gases, vapours and particles |  | EN 149:2001+A1:2009 EN 405:2001+A1:2009 | Replace when an increase in resistance to breathing is observed and/or a smell or taste of the contaminant is detected. |

C.- Specific protection for the hands





| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|---|--|---|--|
|  Mandatory hand protection | NON-disposable chemical protective gloves |  | EN 374-1:2003 EN 374-3:2003/AC:2006 EN 420:2003+A1:2009 | 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. |

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

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|-----------|---|---|---|
|  Mandatory face protection | Face mask |  | EN 166:2001 EN 167:2001 EN 168:2001 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 |
|---|---|---|---|---|
|  Mandatory complete body protection | Disposable clothing for protection against chemical risks, with antistatic and fireproof properties |  | EN 1149-1,2,3 EN 13034:2005+A1:2009 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2001 EN ISO 6530:2005 EN ISO 13688:2013 EN 464:1994 | For professional use only. Clean periodically according to the manufacturer's instructions. |
|  Mandatory foot protection | Safety footwear for protection against chemical risk, with antistatic and heat resistant properties |  | EN 13287:2008 EN ISO 20345:2011 EN 13832-1:2006 | Replace boots at any sign of deterioration. |

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

Volatile organic compounds:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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

| | |
|---------------------------|----------------|
| V.O.C. (Supply): | 68,21 % weight |
| V.O.C. density at 20 °C: | Non-applicable |
| Average carbon number: | 2 |
| Average molecular weight: | 46,38 g/mol |

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: | Aerosol |
| Appearance: | Amorphous |
| Colour: | Blue |
| Odour: | Not available |
| Odour threshold: | Non-applicable * |

Volatility:

| | |
|--|----------------------|
| Boiling point at atmospheric pressure: | 80 °C (Propellant) |
| Vapour pressure at 20 °C: | Non-applicable * |
| Vapour pressure at 50 °C: | <300000 Pa (300 kPa) |
| Evaporation rate at 20 °C: | Non-applicable * |

Product description:

| | |
|--|------------------|
| Density at 20 °C: | Non-applicable * |
| Relative density at 20 °C: | Non-applicable * |
| 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 * |
| Recipient pressure: | Non-applicable * |
| Explosive properties: | Non-applicable * |
| Oxidising properties: | Non-applicable * |

Flammability:

| | |
|----------------------------|---------------------|
| Flash Point: | 19 °C (Propellant) |
| Flammability (solid, gas): | Non-applicable * |
| Autoignition temperature: | 399 °C (Propellant) |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |

Explosive:

| | |
|------------------------|------------------|
| Lower explosive limit: | 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)

Upper explosive 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 | Risk of combustion | Avoid direct impact | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Combustive 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 : Can be fatal if consumed. For more information see section 2.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

- Acute toxicity : Inhalation after prolonged exposure may be lethal.
- Corrosivity/Irritability: 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.

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

- Contact with the skin: Can be fatal if the product is absorbed through the skin. For more information on the secondary effects of contact with the skin see section 2.
- Contact with the eyes: Produces eye damage after contact.

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

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- 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: Suspected of damaging 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 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:

Its ingestion, inhalation or absorption through the skin results in the risk of serious irreversible effects caused by a single exposure, not including effects which are carcinogenic, mutagenic or toxic for reproduction.

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 |
|--|-----------------|----------------------|--------|
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | LD50 oral | 500 mg/kg | Rat |
| | LD50 dermal | 1025 mg/kg | Rabbit |
| | LC50 inhalation | 11 mg/L (4 h) | Rat |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | LD50 oral | 5280 mg/kg | Rat |
| | LD50 dermal | 12800 mg/kg | Rat |
| | LC50 inhalation | 72,6 mg/L (4 h) | Rat |
| Methanol CAS: 67-56-1 EC: 200-659-6 | LD50 oral | 100 mg/kg | Rat |
| | LD50 dermal | 300 mg/kg | Rabbit |
| | LC50 inhalation | 3 mg/L (4 h) | Rat |
| Oxytetracycline CAS: 79-57-2 EC: 201-212-8 | LD50 oral | 302 mg/kg | Rat |
| | LD50 dermal | 1100 mg/kg (ATEi) | |
| | LC50 inhalation | 11 mg/L (4 h) (ATEi) | |

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 |
|--|----------------|-------------------|-------------------------|------------|
| Methanol CAS: 67-56-1 EC: 200-659-6 | LC50 | 15400 mg/L (96 h) | Lepomis macrochirus | Fish |
| | EC50 | 12000 mg/L (96 h) | Nitrocras spinipes | Crustacean |
| | EC50 | 530 mg/L (168 h) | Microcystis aeruginosa | Algae |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | LC50 | 9640 mg/L (96 h) | Pimephales promelas | Fish |
| | EC50 | 13299 mg/L (48 h) | Daphnia magna | Crustacean |
| | EC50 | 1000 mg/L (72 h) | Scenedesmus subspicatus | Algae |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | LC50 | 349 mg/L (96 h) | Cyprinus carpio | Fish |
| | EC50 | 65 mg/L (48 h) | Daphnia magna | Crustacean |
| | EC50 | 22 mg/L (72 h) | Scenedesmus subspicatus | Algae |

12.2 Persistence and degradability:

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SECTION 12: ECOLOGICAL INFORMATION (continued)

| Identification | Degradability | | Biodegradability | |
|--|---------------|----------------|------------------|----------|
| | Parameter | Value | Parameter | Value |
| Methanol CAS: 67-56-1 EC: 200-659-6 | BOD5 | Non-applicable | Concentration | 100 mg/L |
| | COD | 1.42 g O2/g | Period | 14 days |
| | BOD5/COD | Non-applicable | % Biodegradable | 92 % |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | BOD5 | 1.19 g O2/g | Concentration | 100 mg/L |
| | COD | 2.23 g O2/g | Period | 14 days |
| | BOD5/COD | 0.53 | % Biodegradable | 86 % |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | BOD5 | Non-applicable | Concentration | 20 mg/L |
| | COD | Non-applicable | Period | 21 days |
| | BOD5/COD | Non-applicable | % Biodegradable | 90 % |

12.3 Bioaccumulative potential:

| Identification | Bioaccumulation potential | |
|--|---------------------------|-------|
| | Parameter | Value |
| Methanol CAS: 67-56-1 EC: 200-659-6 | BCF | 3 |
| | Pow Log | -0.77 |
| | Potential | Low |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | BCF | 3 |
| | Pow Log | 0.05 |
| | Potential | Low |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | BCF | 3 |
| | Pow Log | -1.31 |
| | Potential | Low |

12.4 Mobility in soil:

| Identification | Absorption/desorption | | Volatility | |
|--|-----------------------|----------------------|------------|---------------------------------|
| | Parameter | Value | Parameter | Value |
| Methanol CAS: 67-56-1 EC: 200-659-6 | Koc | Non-applicable | Henry | Non-applicable |
| | Conclusion | Non-applicable | Dry soil | Non-applicable |
| | Surface tension | 2,355E-2 N/m (25 °C) | Moist soil | Non-applicable |
| Propan-2-ol CAS: 67-63-0 EC: 200-661-7 | Koc | 1.5 | Henry | 8,207E-1 Pa·m ³ /mol |
| | Conclusion | Very High | Dry soil | Yes |
| | Surface tension | 2,24E-2 N/m (25 °C) | Moist soil | Yes |
| 2-aminoethanol CAS: 141-43-5 EC: 205-483-3 | Koc | 0.27 | Henry | 3,7E-5 Pa·m ³ /mol |
| | Conclusion | Very High | Dry soil | No |
| | Surface tension | 5,025E-2 N/m (25 °C) | Moist soil | No |

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

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 05 04* | Gases in pressure containers (including halons) containing dangerous substances | Dangerous |

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

HP3 Flammable, HP4 Irritant — skin irritation and eye damage, HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP6 Acute Toxicity, HP10 Toxic for reproduction

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:

- CONTINUED ON NEXT PAGE -

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 2017 and RID 2017:



- | | |
|---|----------------------------|
| 14.1 UN number: | UN1950 |
| 14.2 UN proper shipping name: | AEROSOLS, toxic, flammable |
| 14.3 Transport hazard class(es): | 2 |
| Labels: | 2.1, 6.1 |
| 14.4 Packing group: | N/A |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Special regulations: | 190, 327, 344, 625 |
| Tunnel restriction code: | D |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | 120 mL |
| 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 38-16:



- | | |
|---|-----------------------------|
| 14.1 UN number: | UN1950 |
| 14.2 UN proper shipping name: | AEROSOLS, toxic, flammable |
| 14.3 Transport hazard class(es): | 2 |
| Labels: | 2.1, 6.1 |
| 14.4 Packing group: | N/A |
| 14.5 Environmental hazards: | No |
| 14.6 Special precautions for user | |
| Special regulations: | 63, 959, 190, 277, 327, 344 |
| EmS Codes: | F-D, S-U |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | 120 mL |
| 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 2017:



- | | |
|---|----------------------------|
| 14.1 UN number: | UN1950 |
| 14.2 UN proper shipping name: | AEROSOLS, toxic, flammable |
| 14.3 Transport hazard class(es): | 2 |
| Labels: | 2.1, 6.1 |
| 14.4 Packing group: | N/A |
| 14.5 Environmental hazards: | 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 |

SECTION 15: REGULATORY INFORMATION

- CONTINUED ON NEXT PAGE -

SECTION 15: REGULATORY INFORMATION (continued)**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: Propan-2-ol (Product-type 1, 2, 4)

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

Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers

Commission Directive 94/1/EC of 6 January 1994 adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers

Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers

Commission Directive 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

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 (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:

H315: Causes skin irritation

H370: Causes damage to organs

H361: Suspected of damaging fertility or the unborn child

H301+H311+H331: Toxic if swallowed, in contact with skin or if inhaled

H229: Pressurised container: May burst if heated

H222: Extremely flammable aerosol

H319: Causes serious eye irritation

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+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled

Acute Tox. 4: H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled

Eye Irrit. 2: H319 - Causes serious eye irritation

Flam. Liq. 2: H225 - Highly flammable liquid and vapour

Repr. 2: H361 - Suspected of damaging fertility or the unborn child

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

STOT SE 1: H370 - Causes damage to organs

STOT SE 3: H336 - May cause drowsiness or dizziness

Classification procedure:

SECTION 16: OTHER INFORMATION (continued)

Skin Irrit. 2: Calculation method
STOT SE 1: Calculation method
Repr. 2: Calculation method
Acute Tox. 3: Calculation method
Aerosol 1: Calculation method
Aerosol 1: Calculation method
Eye Irrit. 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://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 -