# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078950712

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078951874



# SAFETY DATA SHEET

Claro® Otic Solution

# **Section 1. Identification**

**GHS** product identifier

**Product code** 

Other means of identification

: Claro® Otic Solution

122000013292

: 90201819; Florfenicol + Mometasone furoate + Terbinafine hydrochloride solution; Neptra Otic Sol; 84328952; 84328960; 84328979; 84711225; 86378043; 86378884; 86378922; 86455455; 86455498; 86594501; 86845814; 86887207; 86887258; 86887266; 86887339; 86920301; 86928175; 86940027; 86951509; 86951517; 86951584; 86954117; 86968142; 86978768; 86980347; 86987104; 86987120; 86991535; 86991543; 86991594; 87016064; 87032353; 87032426; 87032469; 87032477; 87050858; 87050882; 87050904; 87050939; 87050955; 87050971; 87051005; 87053997; 87054039; 87068536; 87113124; 87131106; 87222713; 87238954; 87408817; 87408825; 87409732; 87409759; 87409767; 87409775; 87438198; 87456277; 87456285; 90198718; 90198719; 90198861; 90198862; 90199237; 90200377; 90201080; 90201095; 90201096; 90201669; 90201818; 90202671; 90202991; 90203167; 90203168; 90204118; 90205053; 90205907; 90205908; 90206095; 90206850; 90207613; 90209438; Claro Otic Solution

### Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Veterinary pharmaceutical.

Uses advised against : None known.

Company Name : Elanco US Inc.

2500 Innovation Way Greenfield IN, US 46140

**Telephone number** : 1-877 Elanco1 (1-877-352-6261)

**Emergency telephone** 

number

: Elanco Product Technical Support / Human or Animal Exposure Reporting:

1-888-545-5973

Email
Transportation Emergency

telephone number

: CHEMTREC: 1-800-424-9300

: elanco sds@elancoah.com

(Outside U.S. CHEMTREC International: 00 1-703-527-3887)

# Section 2. Hazards identification

**OSHA/HCS status** 

: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture

: FLAMMABLE LIQUIDS - Category 3 EYE IRRITATION - Category 2A

TOXIC TO REPRODUCTION - Category 1B

**GHS** label elements

Hazard pictograms







Signal word : Danger

**Hazard statements** : H226 - Flammable liquid and vapor.

H319 - Causes serious eye irritation.

H360 - May damage fertility or the unborn child.

**Precautionary statements** 

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation1/13

# Section 2. Hazards identification

**Prevention** 

Response

P201 - Obtain special instructions before use.

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

P280 - Wear protective gloves, protective clothing and eye or face protection.

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

P241 - Use explosion-proof electrical, ventilating or lighting equipment.

P242 - Use non-sparking tools.

P243 - Take action to prevent static discharges.

P233 - Keep container tightly closed. P264 - Wash thoroughly after handling.

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

P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated

clothing. Rinse skin with water.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.

**Storage** : P405 - Store locked up.

P403 + P235 - Store in a well-ventilated place. Keep cool.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

Supplemental label elements

**Hazards not otherwise** 

classified

: Avoid contact with skin and clothing. Wash thoroughly after handling.

: Prolonged or repeated contact may dry skin and cause irritation.

# Section 3. Composition/information on ingredients

Substance/mixture : Mixture

| Ingredient name   | %         | CAS number |
|---|-----------|------------|
| propylene carbonate   | ≥25 - ≤50 | 108-32-7   |
| ethanol   | ≤10       | 64-17-5    |
| Florfenicol   | ≤3        | 73231-34-2 |
| Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[(2-furanylcarbonyl)oxy] -11-hydroxy-16-methyl-, (11β,16α)- | ≤0.3      | 83919-23-7 |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

# Section 4. First aid measures

#### **Description of necessary first aid measures**

**Eye contact** 

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Inhalation

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

 Product name :
 Claro® Otic Solution
 US : ENGLISH

 Version : 0.01
 Date of revision : 12 May 2023
 Date of previous issue : No previous validation
 2/13

# Section 4. First aid measures

#### **Skin contact**

Wash skin thoroughly with soap and water or use recognized skin cleanser. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

#### Ingestion

: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

#### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

**Inhalation** : No known significant effects or critical hazards.

**Skin contact**: Defatting to the skin. May cause skin dryness and irritation.

**Ingestion** : No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

**Eye contact** : Adverse symptoms may include the following:

pain or irritation watering redness

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

irritation dryness cracking

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

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

Notes to physician

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

**Specific treatments** 

: No specific treatment.

**Protection of first-aiders** 

: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

### See toxicological information (Section 11)

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation3/13

# Section 5. Fire-fighting measures

#### **Extinguishing media**

Suitable extinguishing

media

Unsuitable extinguishing

media

: Use dry chemical, CO<sub>2</sub>, water spray (fog) or foam.

: Do not use water jet.

#### Specific hazards arising from the chemical

: Flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

### **Hazardous thermal** decomposition products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides

halogenated compounds

### **Special protective actions** for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

### **Special protective** equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

# Section 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

### For emergency responders

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".

#### **Environmental precautions**

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

#### Methods and materials for containment and cleaning up

Small spill

Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

### Large spill

Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Product name: Claro® Otic Solution **US: ENGLISH** Version: 0.01 4/13

Date of revision: 12 May 2023

# Section 7. Handling and storage

#### **Precautions for safe handling**

#### **Protective measures**

Put on appropriate personal protective equipment (see Section 8). Avoid exposure obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and can be hazardous. Do not reuse container.

### **Advice on general** occupational hygiene

: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### Conditions for safe storage, including any incompatibilities

: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

# Section 8. Exposure controls/personal protection

#### **Control parameters**

#### **Occupational exposure limits**

| Ingredient name  | Exposure limits                        |
|--|--|
| propylene carbonate  | None.                                  |
| ethanol  | ACGIH TLV (United States, 1/2022).     |
|  | STEL: 1000 ppm 15 minutes.             |
|  | OSHA PEL 1989 (United States, 3/1989). |
|  | TWA: 1000 ppm 8 hours.                 |
|  | TWA: 1900 mg/m <sup>3</sup> 8 hours.   |
|  | NIOSH REL (United States, 10/2020).    |
|  | TWA: 1000 ppm 10 hours.                |
|  | TWA: 1900 mg/m³ 10 hours.              |
|  | OSHA PEL (United States, 5/2018).      |
|  | TWA: 1000 ppm 8 hours.                 |
|  | TWA: 1900 mg/m³ 8 hours.               |
| Florfenicol  | None.                                  |
| Pregna-1,4-diene-3,20-dione, 9,21-dichloro-<br>17-[(2-furanylcarbonyl)oxy]-11-hydroxy-<br>16-methyl-, (11β,16α)- | None.                                  |

### **Biological exposure indices**

No exposure indices known.

#### **Appropriate engineering** controls

: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Product name: Claro® Otic Solution **US: ENGLISH** Version: 0.01 5/13

# Section 8. Exposure controls/personal protection

# **Environmental exposure** controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### **Individual protection measures**

### Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

#### **Eye/face protection**

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

# **Skin protection**

**Hand protection** 

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

#### **Body protection**

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear antistatic protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.

#### Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

### **Respiratory protection**

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

# Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

#### **Appearance**

Physical state : Liquid.

Color : Not available.

Odor : Characteristic.

Odor threshold : Not available.

PH : Not available.

Melting point/freezing point : Not available.

Boiling point, initial boiling point, and boiling range : Not available.

Flash point

: Closed cup: 45°C (113°F)

Evaporation rate: Not available.Flammability: Not available.Lower and upper explosion: Not available.

limit/flammability limit

Vapor pressure :

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation6/13

# Section 9. Physical and chemical properties and safety characteristics

|  | Vapoi     | r Pressui  | re at 20°C | 20°C Vapor pressure at 50° |     | re at 50°C |
|--|-----------|------------|------------|----------------------------|-----|------------|
| Ingredient name  | mm Hg     | kPa        | Method     | mm<br>Hg                   | kPa | Method     |
| ethanol  | 42.95     | 5.7        |            |                            |     |            |
| water  | 23.8      | 3.2        |            |                            |     |            |
| propane-1,2-diol   | 0.15      | 0.02       | EU A.4     |                            |     |            |
| Poly(oxy-1,2-ethanediyl),<br>α-hydro-ω-hydroxy-<br>Ethane-1,2-diol,<br>ethoxylated | 0.0000003 | 0.00000004 |            |                            |     |            |

Relative vapor density

: Not available.

**Relative density** 

**Density** 

: 1 g/cm³ [20°C (68°F)]

Solubility in water Partition coefficient: nNot available.

Solubility(ies)

: Not available.

octanol/water

: Not applicable.

**Auto-ignition temperature** 

| Ingredient name  | °C  | °F    | Method    |
|------------------|-----|-------|-----------|
| propane-1,2-diol | 371 | 699.8 |           |
| ethanol          | 455 | 851   | DIN 51794 |

**Decomposition temperature** 

: Not available.

**Viscosity** 

: Not available.

Flow time (ISO 2431)

: Not available.

**Particle characteristics** 

Median particle size : Not applicable.

# Section 10. Stability and reactivity

Reactivity

: No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** 

: The product is stable.

**Possibility of hazardous** reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

**Conditions to avoid** 

: Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.

**Incompatible materials** 

: Reactive or incompatible with the following materials: oxidizing materials

**Hazardous decomposition** products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Product name: Claro® Otic Solution **US: ENGLISH** Version: 0.01 Date of revision: 12 May 2023 7/13 Date of previous issue : No previous validation

# **Section 11. Toxicological information**

### Information on toxicological effects

### **Acute toxicity**

| Product/ingredient name | Result                | Species | Dose                     | Exposure |
|-------------------------|-----------------------|---------|--------------------------|----------|
| propylene carbonate     | LD50 Oral             | Rat     | >5000 mg/kg              | -        |
| ethanol                 | LC50 Inhalation Vapor | Rat     | 124700 mg/m <sup>3</sup> | 4 hours  |
|                         | LD50 Dermal           | Rabbit  | >5000 mg/kg              | -        |
|                         | LD50 Oral             | Rat     | 7 g/kg                   | -        |
| Florfenicol             | LD50 Oral             | Rat     | >2000 mg/kg              | -        |

#### **Irritation/Corrosion**

| Product/ingredient name   | Result                   | Species | Score | Exposure                               | Observation |
|---|--------------------------|---------|-------|--|-------------|
| propylene carbonate   | Eyes - Moderate irritant | Rabbit  | -     | 60 mg                                  | -           |
| ethanol   | Eyes - Mild irritant     | Rabbit  | -     | 24 hours 500                           | -           |
|   | Eyes - Moderate irritant | Rabbit  | -     | mg<br>0.066666667<br>minutes 100<br>mg | -           |
|   | Eyes - Moderate irritant | Rabbit  | -     | 100 uL                                 | -           |
|   | Eyes - Severe irritant   | Rabbit  | -     | 500 mg                                 | -           |
|   | Skin - Mild irritant     | Rabbit  | -     | 400 mg                                 | -           |
|   | Skin - Moderate irritant | Rabbit  | -     | 24 hours 20<br>mg                      | -           |
| Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[ (2-furanylcarbonyl)oxy] -11-hydroxy-16-methyl-, (11β, 16α)- | Skin - Mild irritant     | Woman   | -     | 0.01 %                                 | -           |

#### **Sensitization**

Not available.

# **Mutagenicity**

Not available.

### **Carcinogenicity**

Not available.

# Reproductive toxicity

Not available.

### **Teratogenicity**

Not available.

# Specific target organ toxicity (single exposure)

Not available.

# Specific target organ toxicity (repeated exposure)

Not available.

### **Aspiration hazard**

Not available.

Information on the likely routes of exposure

: Not available.

### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

**Inhalation** : No known significant effects or critical hazards.

**Skin contact**: Defatting to the skin. May cause skin dryness and irritation.

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation8/13

# Section 11. Toxicological information

**Ingestion** : No known significant effects or critical hazards.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact**: Adverse symptoms may include the following:

pain or irritation watering redness

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

irritation dryness cracking

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

### Delayed and immediate effects and also chronic effects from short and long term exposure

**Short term exposure** 

**Potential immediate** 

effects

: Not available.

Potential delayed effects : Not available.

**Long term exposure** 

**Potential immediate** 

effects

: Not available.

Potential delayed effects : Not available.

#### Potential chronic health effects

| Product/ingredient name | Result            | Species | Dose    | Exposure |
|-------------------------|-------------------|---------|---------|----------|
| Florfenicol             | Chronic NOEL Oral | Rat     | 1 mg/kg | -        |

General : Prolonged or repeated contact can defat the skin and lead to irritation, cracking and/or

dermatitis.

Carcinogenicity : No known significant effects or critical hazards.Mutagenicity : No known significant effects or critical hazards.

**Reproductive toxicity**: May damage fertility or the unborn child.

#### **Numerical measures of toxicity**

#### **Acute toxicity estimates**

| Product/ingredient name | Oral (mg/<br>kg) | Dermal<br>(mg/kg) | (gases) | (vapors) | Inhalation<br>(dusts and<br>mists) (mg/<br>I) |
|-------------------------|------------------|-------------------|---------|----------|---|
| Claro® Otic Solution    | 166666.7         | N/A               | N/A     | N/A      | N/A   |
| ethanol                 | 7000             | N/A               | N/A     | 124.7    | N/A   |
| Florfenicol             | 2500             | N/A               | N/A     | N/A      | N/A   |

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation9/13

# Section 12. Ecological information

#### **Toxicity**

| Product/ingredient name | Result                                | Species   | Exposure |
|-------------------------|---------------------------------------|---|----------|
| propylene carbonate     | EC50 >900 mg/l                        | Algae   | 72 hours |
|                         | EC50 >500 mg/l                        | Daphnia - Daphnia magna                                 | 48 hours |
|                         | LC50 5300 mg/l                        | Fish - Leuciscus idus                                   | 96 hours |
|                         | Acute EC50 >1000 mg/l                 | Crustaceans - Daphnia magna                             | 48 hours |
| ethanol                 | Acute EC50 17.921 mg/l Marine water   | Algae - Ulva pertusa                                    | 96 hours |
|                         | Acute EC50 2000 µg/l Fresh water      | Daphnia - Daphnia magna                                 | 48 hours |
|                         | Acute LC50 25500 µg/l Marine water    | Crustaceans - Artemia<br>franciscana - Larvae           | 48 hours |
|                         | Acute LC50 11000000 µg/l Marine water | Fish - Alburnus alburnus                                | 96 hours |
|                         | Chronic NOEC 4.995 mg/l Marine water  | Algae - Ulva pertusa                                    | 96 hours |
|                         | Chronic NOEC 100 ul/L Fresh water     | Daphnia - Daphnia magna -<br>Neonate                    | 21 days  |
| Florfenicol             | Acute EC50 3.83 mg/l                  | Algae   | 72 hours |
|                         | Acute EC50 337 mg/l Fresh water       | Daphnia - Daphnia magna -<br>Neonate                    | 48 hours |
|                         | Acute IC50 6.06 mg/l Marine water     | Algae - Tetraselmis chuii -<br>Exponential growth phase | 96 hours |
|                         | Acute LC50 95.2 ug/ml Marine water    | Crustaceans - Litopenaeus                               | 48 hours |
|                         | Acute LC50 >900 mg/l                  | Fish - Oncorhynchus mykiss                              | 96 hours |
|                         | Acute NOEC >900 mg/l                  | Fish  | 96 hours |
|                         | Chronic NOEC 0.001 mg/l               | Algae - Isochrysis galbana                              | 72 hours |

### Persistence and degradability

Not available.

#### **Bioaccumulative potential**

| Product/ingredient name   | LogPow                        | BCF | Potential         |
|---|-------------------------------|-----|-------------------|
| propylene carbonate ethanol Florfenicol Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[ (2-furanylcarbonyl)oxy] -11-hydroxy-16-methyl-, (11β, 16α)- | -0.41<br>-0.35<br>0.37<br>3.9 | -   | low<br>low<br>low |

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

# Section 13. Disposal considerations

### **Disposal methods**

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Product name: Claro® Otic Solution **US: ENGLISH** Version: 0.01 Date of revision: 12 May 2023 10/13

# **Section 14. Transport information**

|                            | DOT<br>Classification                           | TDG<br>Classification                           | Mexico<br>Classification   | IMDG  | IATA   |
|----------------------------|---|---|--|---|--|
| UN number                  | UN1170  | UN1170  | UN1170   | UN1170  | UN1170   |
| UN proper shipping name    | Ethanol solution<br>(Ethyl alcohol<br>solution) | Ethanol solution<br>(Ethyl alcohol<br>solution) | Ethanol solution<br>(Ethyl alcohol<br>solution)                    | Ethanol solution<br>(Ethyl alcohol<br>solution) | Ethanol solution<br>(Ethyl alcohol<br>solution)                    |
| Transport hazard class(es) | 3   | 3   | 3  | 3   | 3  |
| Packing group              | III   | III   | III  | III   | III  |
| Environmental hazards      | No.   | Yes.  | Yes. The environmentally hazardous substance mark is not required. | Yes.  | Yes. The environmentally hazardous substance mark is not required. |

#### **Additional information**

**DOT Classification** 

: This product may be re-classified as "Combustible Liquid," unless transported by vessel or aircraft. Non-bulk packages (less than or equal to 119 gal) of combustible liquids are not regulated as hazardous materials.

**TDG Classification** 

: Product classified as per the following sections of the Transportation of Dangerous Goods Regulations: 2.18-2.19 (Class 3), 2.7 (Marine pollutant mark).

The marine pollutant mark is not required when transported by road or rail.

**IMDG IATA** 

: The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg.

The environmentally hazardous substance mark may appear if required by other transportation regulations.

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according : Not available.

to IMO instruments

# Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

**Clean Air Act Section 112** 

(b) Hazardous Air **Pollutants (HAPs)**  : Not listed

**Clean Air Act Section 602** 

: Not listed

**Class I Substances** 

: Not listed

**Clean Air Act Section 602** Class II Substances

: Not listed

**DEA List I Chemicals** (Precursor Chemicals)

**DEA List II Chemicals** (Essential Chemicals)

: Not listed

**SARA 302/304** 

**Composition/information on ingredients** 

Product name: Claro® Otic Solution **US: ENGLISH** Version: 0.01 Date of revision: 12 May 2023 Date of previous issue : No previous validation 11/13

# Section 15. Regulatory information

No products were found.

SARA 304 RQ : Not applicable.

**SARA 311/312** 

Classification : FLAMMABLE LIQUIDS - Category 3

EYE IRRITATION - Category 2A

TOXIC TO REPRODUCTION - Category 1B

HNOC - Defatting irritant

#### **Composition/information on ingredients**

| Name  | %                | Classification   |
|---|------------------|--|
| propylene carbonate ethanol   | ≥25 - ≤50<br>≤10 | EYE IRRITATION - Category 2A FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A HNOC - Defatting irritant |
| Florfenicol Pregna-1,4-diene-3,20-dione, 9,21-dichloro-17-[ (2-furanylcarbonyl)oxy] -11-hydroxy-16-methyl-, (11β, 16α)- | ≤3<br>≤0.3       | TOXIC TO REPRODUCTION - Category 2 TOXIC TO REPRODUCTION - Category 1B   |

#### **State regulations**

Massachusetts : The following components are listed: ETHYL ALCOHOL

New York : None of the components are listed.

New Jersey : The following components are listed: PROPYLENE GLYCOL; ETHYL ALCOHOL

Pennsylvania : The following components are listed: 1,2-PROPANEDIOL; ETHANOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

**Inventory list** 

United States : Not determined.

# Section 16. Other information

**History** 

Date of issue/Date of : 5/12/2023

revision

Date of previous issue : No previous validation

Version : 0.01

Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

as modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available SGG = Segregation Group UN = United Nations

: Not available.

Indicates information that has changed from previously issued version.

**Notice to reader** 

References

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation12/13

# Section 16. Other information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact: Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441

Product name :Claro® Otic SolutionUS : ENGLISHVersion : 0.01Date of revision : 12 May 2023Date of previous issue : No previous validation13/13