

Issued on: 2022/09/09

1. Identification of the preparation and of the company

1.1 Identification of the preparation:

SIMPLERA

Presentation in the form of a single-dose tube of 1 ml.

1.2 Use of the product:

Treatment of otitis externa in dogs.

1.3 Identification of the company:

VETOQUINOL USA Inc.
4250 N. Sylvania. Ave.
Fort Worth TX, 76134
customerservice@vetoquinol.com

1.4 Emergency phone numbers:

. +1 817 529 7500 - Toll free number +1 800 285 0508

2. Hazard identification

Flammable liquid cat. 3

Eye irritant cat. 2

STOT RE Cat 3

Acute aquatic toxicity cat 1

Chronic aquatic toxicity cat.2



Warning

H226: Flammable liquid and vapour

H319: Causes serious eye irritation.

H317: May cause an allergic skin reaction.

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H411: Toxic to aquatic life with long lasting effects.

P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking.

P233: Keep container tightly closed.

P264: Wash thoroughly after handling.

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

P273: Avoid release to the environment.

P302+P352: IF ON SKIN: Wash with plenty of soap and 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.
 P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313: If eye irritation persists: Get medical advice/attention.
 P403+P235: Store in a well-ventilated place. Keep cool.
 P501: Dispose of contents/container to a dangerous or special waste collection.

3. Chemical characteristics

Composant	C (M/V)	N° CAS	N°CE	CLP Classification	N° index/N° REACH
Propylene carbonate	40-70%	108-32-7	203-572-1	Eye irrit 2 H319	607-194-00-1/-
Propylene glycol	10-30%	57-55-6	200-338-0	Non classé	-/01-2119456809-23-xxxx
Ethanol	5-10%	64-187-5	200-578-6	Flam liquid 2 H225 - Eye irrit 2 H319	603-002-00-5/01-2119457610-43-xxxx
Terbinafine HCl	1.66%	78628-80-5	616-640-4	Skin irrit 2 H315- Eye irrit 2 H319- STOT SE3 H335 - Aquatic acute 1 H400 - Aquatic chronic 1 H410 - Facteur M Aquatic acute 10	-/01-2119979835-16
Florfenicol	1.66%	73231-34-2	-	Rep tox 2 H361 - STOT RE 1 H372 - Aquatic Acute 1 H400 - Aquatic chronic 2 H411	-/-
Mometasone furoate	0.22%	83919-23-7	-	Acute tox 3 (skin) H311	-/-
PEG 8000	10-20%	25322-68-3	-	Not classified	-/-
Purified water	1-10%	-	-	Not classified	-/-

4. First aid measures

Inhalation: Remove victim to fresh air. If necessary, give artificial respiration and call a physician.

Skin contact: Wash skin thoroughly with water and soap for at least 15 minutes.

Eye contact: If possible, remove contact lenses. Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes. If irritation persists, call a doctor.

Ingestion: Never give anything by mouth to an unconscious person. If the person is conscious, rinse mouth with water then drink fresh water. Consult a physician and show the safety data sheet or package leaflet.

5. Fire-Fighting measures

Suitable extinguishing media: Carbon Dioxide, dry chemical, chemical foam resistant to alcohol and water spray.

Extinguishing measures to be avoided: None.

Combustion / explosion hazards: Produces toxic smokes in case of fire.

Special protective equipment for fire-fighters: In case of fire, wear self-contained breathing apparatus to protect themselves from toxic products released during combustion and protective suit to avoid contact with skin and eyes.

6. Accidental release measures

Measures for personal safety: Use personal protective equipment (gloves, protective clothing, and appropriate safety glasses).

Environmental precautions: Prevent product from entering drains and the environment.

Clean-up / Absorption Procedures: Absorb completely, then pick up absorbent. Wash spill area. Keep in suitable, closed containers for disposal.

7. Handling and storage

Handling: Avoid contact with eyes and skin.

Storage: Keep at room temperature.

8. Exposure control and personal protection

Wear safety gloves for handling.

Hygiene measures: Wash hands after each use.

9. Physical and chemical properties

Appearance: Liquid.

Color: Transparent, yellowish

Flash point: 58°C

Boiling point: 90°C

pH: 4.0-6.0

10. Stability and reactivity

Stability: Stable in the normal conditions of use.

Conditions and materials to avoid: Strong oxidizing.

Hazardous decomposition materials: Hazardous decomposition products formed under fire: carbon oxides (COx), nitrogen oxides (NOx) or sulfur oxides (SOx).

Hazardous reactions: None under normal conditions of use.

11. Toxicological information

No data available

12. Ecological information

No data available. Do not discharge into drains.

13. Disposal considerations

Comply with environmental regulations. Contact a licensed professional waste disposal service to dispose of this product. Dispose of this material and its container at hazardous or special waste collection.

14. Transport information

	Regulations concerned		
	Road Transport	Maritime Transport	Air Transport
	ADR/RID	IMDG	OACI / IATA
ONU N°	UN 1987	UN 1987	UN 1987
Official designation	ALCOHOLS, N.O.S. (Ethanol)	ALCOHOLS, N.O.S.(Ethanol)	ALCOHOLS, N.O.S. (Ethanol)
Hazard class	3	3	3
Packing group	III	III	III
Hazard label	3	3	3
FS	--	F-E ; S-D	--
Marine pollutant	--	NO	--
Limited quantities	Interior: 5 L max. Max gross weight/package: 30 kg.	Interior: 5 L max. Max gross weight/package: 30 kg.	See Y344 : Interior (glass): 2.5 L max. Interior (metal/plast.): 5 L max. Exterior: 10 L max. Max gross weight/package: 30 kg.G.
Excepted quantities	E1	E1	E1
Packing instructions	P001	P001	Passenger plane: 355 Cargo aircraft: 366
Max quantity per package	Cans: 120 kg Box 4H1 : 60 kg Other: 400 kg	Cans: 120 kg Box 4H1 : 60 kg Other: 400 kg	Passenger plane: 60 L Cargo aircraft: 220 L
Special provisions	274 – 601(1)	223 - 274	A3 – A180

(1) ADR: Special Provision 601: Ready-to-use pharmaceutical products (medicines) manufactured and packaged for retail sale or distribution for personal or household use are not subject to the requirements of ADR.

NOTE: For packages of 60 ml or 1 l bottles, Limited Quantities can be used.

15. Regulatory information

This safety data sheet conforms to the requirements of Regulation (EC) Nr. 1907/2006.

16. Other information

This document supplements the technical information notices but does not replace them. The information it contains are based on our knowledge relating to the product concerned on **2022/09/09**. They are issued in good faith.

The attention of users is also drawn to the potential risks incurred when a product is used for purposes other than those for which it was designed.

Under no circumstances does it exempt the user from familiarisation and implementation of all the texts governing his activity. He alone is responsible for implementing all precautions linked to the use of the product with which he is acquainted.

The purpose of all the regulations mentioned is to assist the end user to fulfil the obligations incumbent upon him during the handling of hazardous products.

This list must not be considered exhaustive. It does not exempt the user from ensuring that other obligations are binding upon him on the basis of texts in addition to those quoted and governing the possession and the use of the product for which he is alone responsible.