



SAFETY DATA SHEET

1. Identification

Product identifier	Atopica Oral Solution
Other means of identification	
Item Code	CA4900
Synonyms	ATOPICA Dog Solution * A-12211 A * ATOPLUS 100 MG/ML SOL * ATOPICA 100 MG/ML SOL * ATOPICA CAT Solution * NEORAL 100 MG/ML SOL
Recommended use	Veterinary Product
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Emergency Telephone:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Email:	elanco_sds@elanco.com
Transportation Emergency Telephone:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards	Flammable liquids	Category 3
Health hazards	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (Immune System, Kidney)
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	
H226	Flammable liquid and vapor.
H350	May cause cancer.
H361	Suspected of damaging the unborn child.
H372	Causes damage to organs (Immune System, Kidney) through prolonged or repeated exposure.
Precautionary statement	
Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P260	Do not breathe mist/vapors.
Response	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
Storage	

P403 + P233

Store in a well-ventilated place. Keep container tightly closed.

Disposal

P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Cyclosporin	Cyclo(((E)-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)-6-octenyl)-L-2-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-N-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl)	59865-13-3	10.07
Ethanol		64-17-5	9.5

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

May cause cancer. May cause reproductive effects. Causes damage to organs (Immune System, Kidney) through prolonged or repeated exposure.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures**Suitable extinguishing media**Water fog. Alcohol resistant foam. Carbon dioxide (CO₂). Dry chemical powder, carbon dioxide, sand or earth may be used for small fires only.**Unsuitable extinguishing media**

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

Flammable liquid and vapor.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use.

Avoid discharge into drains, water courses or onto the ground. Use appropriate containment to avoid environmental contamination.

7. Handling and storage

Precautions for safe handling Keep away from sources of ignition - No smoking. Do not breathe mist or vapor. Wear appropriate personal protective equipment. Do not use in areas without adequate ventilation.

Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in a closed container away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

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

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

Lilly (LEG)

Components	Type	Value
Cyclosporin (CAS 59865-13-3)	TWA (12hrs)	12 ug/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

Respiratory protection If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Thermal hazards Not available.

General hygiene considerations When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.
Form Liquid.
Color Yellow to Brown.

Odor Mild.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point	75.2 - 80.6 °F (24.0 - 27.0 °C)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test Results
Cyclosporin (CAS 59865-13-3)		
<u>Acute</u>		
Inhalation		
	Dog	770 mg/m3, 1 hr (no mortality)
Oral		
LD50	Rat	1489 mg/kg
Ethanol (CAS 64-17-5)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	124.7 mg/l, 4 h
Oral		
LD50	Rat	7060 mg/kg

Skin corrosion/irritation Rabbit: No skin irritation. (Ethyl Alcohol)
No data available for remaining ingredient(s).
Due to inconclusive data the classification is not possible.

Serious eye damage/eye irritation Irritating to eyes. (Ethyl Alcohol)
No data available for remaining ingredient(s).
Due to inconclusive data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s)) (Ethyl Alcohol)
Based on available data, the classification criteria are not met.

Carcinogenicity May cause cancer.
The ethanol carcinogenicity information reported below only applies when it is consumed in alcoholic beverages.

IARC Monographs. Overall Evaluation of Carcinogenicity

Cyclosporin (CAS 59865-13-3) 1 Carcinogenic to humans.
Ethanol (CAS 64-17-5) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Cyclosporin (CAS 59865-13-3) Known To Be Human Carcinogen.
Ethanol (CAS 64-17-5) Known To Be Human Carcinogen

Reproductive toxicity Suspected of damaging the unborn child. May cause developmental effects.

Specific target organ toxicity - single exposure No significant target organ toxicity reported. (active ingredient)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Causes damage to organs (Immune system, Kidney.) through prolonged or repeated exposure.

Aspiration hazard Not applicable.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
Cyclosporin (CAS 59865-13-3)	IC50	Activated sludge	> 100 mg/l, 3 h
Aquatic			
Algae	IC50	Algae	> 100 mg/l, 72 h
Crustacea	EC50	Daphnia	20.2 mg/l, 48 h
Fish	LC50	Fish	> 100 mg/l, 96 h
Ethanol (CAS 64-17-5)			
Aquatic			
Fish	LC50	Rainbow Trout	13 g/l, 96 hr
<i>Acute</i>			
Algae	EC50	Algae	1450 mg/l, 8 d
Crustacea	LC50	Daphnia	9.3 g/l, 48 hr

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Cyclosporin 5.5, at 22 °C
Ethanol -0.31

Mobility in soil No data available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

UN number	UN1293
UN proper shipping name	Tinctures, medicinal
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Special precautions for user	Not available.
Special provisions	B1, IB3, T2, TP1
Packaging exceptions	150
Packaging non bulk	203
Packaging bulk	242

IATA

UN number	UN1293
UN proper shipping name	Tinctures, medicinal
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	III
Environmental hazards	No.
ERG Code	3L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

IMDG

UN number	UN1293
UN proper shipping name	TINCTURES, MEDICINAL
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-E, S-D
Special precautions for user	Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

DOT





15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories Flammable (gases, aerosols, liquids, or solids)
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

US state regulations

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Cyclosporin (CAS 59865-13-3) Listed: January 1, 1992

Ethanol (CAS 64-17-5) Listed: April 29, 2011

Listed: July 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Ethanol (CAS 64-17-5) Listed: October 1, 1987

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 09-06-2017

Revision date 03-04-2019

Version # 02

Disclaimer

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 MERCHANTABILITY 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:

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