SAFETY DATA SHEET

1. Identification

Product identifier **Atopica 10 Mg Cap**

Other means of identification

Item Code CA4915

Synonyms A-12214 A * CGA116231 CAP (010) * ATOPLUS 10 MG CAP * ATOPICA 10 MG (CYCLOSP.CAPS.USP) MOD * ATOPICA VET. 10 MG CAP * NEORAL 10 MG CAP

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)

Email: lilly_msds@lilly.com

Emergency Telephone Numbers: Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973

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

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P202	Do not handle until all safety precautions have been read and understood.
P201	Obtain special instructions before use.
P260	Do not breathe mist or vapor.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

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-octenoyl)-L-2-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-Lvalyl-N-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-Nmethyl-L-leucyl-N-methyl-L-valyl)	59865-13-3	9.5
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 Special Exposure Hazard: Capsules contain a flammable liquid. Flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Special Exposure Hazard: Capsules contain a flammable mixture. 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 If capsules remain intact, scoop or scrape up material into containers for disposal. If capsules are broken, absorb with earth, sand, or other non-combustible materials and transfer to containers for later disposal. Following product recovery, flush area with water.

Never return spills to original containers for re-use.

Environmental precautions 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
Special Exposure Hazard: Capsules contain a flammable mixture.
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
Gelatin capsule containing liquid.

Color
White, Grey-blue

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) (Estimate based on similiar products)
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

Components	Species	Test Results
Cyclosporin (CAS 59865-13-3)		
Acute		
Inhalation		
	Dog	770 mg/m3, 1 hr (no mortality)
Oral		
LD50	Rat	1489 mg/kg
Ethanol (CAS 64-17-5)		
Acute		
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.

IARC Monographs. Overall Evaluation of Carcinogenicity

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

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
Acute			
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

General information De minimis exceptions may apply for consumer product packaging. Otherwise, limited quantity exceptions may apply.

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



IATA; IMDG



15. Regulatory information

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

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)

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.

Safe Drinking Water Act (SDWA) 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	12-21-2015
Revision date	12-12-2017
Version #	08

Lilly Lab Code	Health: 1 Fire: 2 Reactivity: 0 Special 1: C
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