



SAFETY DATA SHEET

1. Identification

Product identifier	ATOPICA 100 MG/ML ORAL SOLUTION FOR CATS
Other means of identification	
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
Item Code	CA4900
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary Product
Restrictions on use	Not available.
Details of manufacturer or importer	
Company name	Elanco Australasia Pty Ltd. ACN: 076 745 198
Address	112 Wharf Road West Ryde, NSW 2114 Australia
Telephone	1800 995 709 (toll free)
E-mail	elanco_sds@elanco.com
Emergency phone number	Elanco Australasia 1800 995 709 (toll free)
24 hr emergency contact number	CHEMWATCH 1800 039 008 (spills and accidents)
24 hr emergency contact number (Local)	CHEMWATCH +61 2 9186 1132 (spills and accidents)

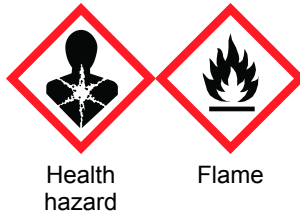
2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Flammable liquids	Category 3
Health hazards	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 2
	Specific target organ toxicity following repeated exposure	Category 1
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Signal word

Danger

Hazard statement(s)

Flammable liquid and vapour. May cause cancer. Causes damage to organs (Immune System, Kidney) through prolonged or repeated exposure. Suspected of damaging the unborn child.

Precautionary statement(s)

Prevention

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

Response

IF exposed or concerned: Get medical advice/attention.

Storage

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

Disposal

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

Other hazards which do not result in classification

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Cyclosporin Cyclo(((E)-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)-6-octenoyl)-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

Description of necessary 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.

Personal protection for first-aid responders

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

Symptoms caused by exposure

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

Medical attention and special treatment

Not available.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

Water fog. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO₂).

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 fire fighters

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.

Hazchem code

2Y

General fire hazards

Flammable liquid and vapour.

Specific methods

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Not available.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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.

Never return spills to original containers for re-use.

7. Handling and storage

Precautions for safe handling Keep away from sources of ignition - No smoking. Do not breathe mist or vapour. 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 and personal protection

Occupational exposure limits

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1880 mg/m ³ 1000 ppm

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1880 mg/m ³ 1000 ppm

US. ACGIH Threshold Limit Values

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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1920 mg/m ³ 1000 ppm

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	960 mg/m ³ 500 ppm

Lilly (LEG)

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

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

Appropriate engineering controls Explosion-proof general and local exhaust ventilation.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection Wear safety glasses with side shields (or goggles). (AS/NZS 1337)

Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. (AS/NZS 2161)
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. (AS/NZS 1715)
Thermal hazards	Not available.
Hygiene measures	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.
Colour	Yellow to Brown.
Odour	Mild.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	24.0 - 27.0 °C (75.2 - 80.6 °F)
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.
Vapour pressure	Not available.
Vapour 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 physical and chemical parameters	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

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	No dangerous reaction known under conditions of normal use.
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 oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Acute toxicity	Based on available data, the classification criteria are not met.		
Components	Species	Test Results	
Cyclosporin (CAS 59865-13-3)			
Acute			
Inhalation			
	Dog	770 mg/m ³ , 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/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 sensitisation			
Respiratory sensitisation	Due to lack of data the classification is not possible.		
Skin sensitisation	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.	
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

Components	Species	Test Results
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 for this product.

Other adverse effects Not available.

13. Disposal considerations

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

14. Transport information

ADG

UN number	1293
UN proper shipping name	TINCTURES, MEDICINAL
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Environmental hazards	Not available.
Hazchem code	•2Y
Special precautions for user	Not available.

RID

UN number	1293
UN proper shipping name	TINCTURES, MEDICINAL
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Environmental hazards	No.
Special precautions for user	Not available.

IATA

UN number	1293
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	1293
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.

ADG



IATA; IMDG; RID



15. Regulatory information

Safety, health and environmental regulations

National regulations APVMA approval number: 66305
Poison Schedule: 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Ethanol (CAS 64-17-5)

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Cyclosporin (CAS 59865-13-3)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

Ethanol (CAS 64-17-5)

10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

Ethanol (CAS 64-17-5)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date	11-November-2016
Revision date	04-March-2019
Disclaimer	<p>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.</p> <p>For additional information contact: Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441</p>
Revision information	Product and Company Identification: Product and Company Identification Hazard(s) identification: Prevention Hazard(s) identification: Supplemental information Exposure controls and personal protection: Hand protection Toxicological information: Acute toxicity Toxicological information: Specific target organ toxicity - single exposure Other information: Disclaimer