MATERIAL SAFETY DATA SHEET

Section 1 - Identification of Chemical Product and Company

COMPANY DETAILS:

Novartis Animal Health Australasia Pty Limited
A.C.N. 076 745 198
54 Waterloo Road
North Ryde NSW 2113
Phone: (02) 9805 3555
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Product Name:	ATOPICA® Soft Capsules for Dogs (10mg/25mg/50mg/100mg)
Other Names:	NEORAL® / SANDIMMUN® (human pharmaceutical product)
Active Ingredients:	Cyclosporin
Ciba-Geigy Code :	CGA 116231 A
Product Use:	A soft gel capsule for the treatment of atopic dermatitis in dogs.
Revision Date:	November 2008

Section 2 Hazards Identification

Hazard classification:	None Allocated
Risk Phrases:	R22 Harmful if swallowed R40 Possible risks of irreversible effects.
Safety Phrases:	S22 Avoid contact with skin. S24 Do not breathe dust.
SUSDP Classification:	4
UN Number:	None Allocated

Section 3 Composition / Information on Ingredients

Ingredients	CAS No.	Content (%w/v)	STEL (mg/m^3)
Cyclosporin	[59865-13-3]	10/25/50/100	0.02 [a]
Polyoxyl 40 hydrogenated castor oil	-	30-40	not set
Gelatin (coating)	[9000-70-8]	20-30	not set
other ingredients determined not to be hazardous	Confidential	to 100	not set

[a] Internal guideline exposure limit has been set for cyclosporine by Novartis Pharmaceuticals

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

Section 4 First Aid Measures

Label regulated First Aid Statement:	If poisoning occurs contact a Doctor or **Poisons Information Centre (Phone 131126)**.
Scheduled poisons :	Product is an S_4 scheduled poison. Poisons Information Centres in each State capital city can provide additional assistance for scheduled poisons (**Phone 131126**).
Inhalation:	Due to the nature of this product inhalation is unlikely to occur. No first aid measures are normally required.
Skin Contact:	If product gets on skin, immediately remove contaminated clothing and wash skin thoroughly with soap and water to remove material. If you begin to feel unwell, seek medical attention.
Eye contact:	In the case of contact with eyes rinse eyes to remove material. No further

measures should normally be required.

Swallowed: If poisoning occurs, contact a Doctor or Poisons Information Centre (Phone: 131126).

Advice to doctor: Treat symptomatically. Gastric lavage, activated charcoal. Poisoning symptoms may include; hypertension, gastrointestinal complaints, nausea, vomiting, tremor, paraesthesia, kidney injury may occur, headache.

Section 5 Fire Fighting Measures

Extinguishing Media: This product does not burn. Use extinguishing media suited to the materials that are burning.

Fire and explosion hazards: There is no risk of an explosion from the product or active constituent under normal circumstances if it is involved in a fire.

Fire Fighting: Fight fire in the early stages if safe to do so. When fighting fires involving significant quantities of this product, wear safety boots, non-flammable overalls, gloves, hat and goggles.

Section 6 Accidental Release Measures

Accidental Release: Minor spills do not normally need any special cleanup measures. In the event of a major spill, prevent spillage from entering drains or water courses. Wear full protective clothing including face mask, face shield and gauntlets. All skin areas should be covered. Thoroughly launder protective clothing before storage or re-use.
Take up by mechanical means and dispose. After spills, wash area preventing runoff from entering drains, sewers or wells. If a significant quantity of material enters drains, sewers or wells advise emergency services. Buildings, apparatus, and all items of equipment must be decontaminated and subsequently inspected to ensure that no further risk remains. All wastes, equipment and protective garments must either be decontaminated or properly contained for disposal before leaving the area. Dispose of only in accord with all regulations.

Section 7 Handling and Storage

Safe Handling: Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke while working.

Storage: Keep out of reach of children. Store below 25°C (Air Conditioning) in original container tightly closed. When a blister is opened, a characteristic smell is noticeable, which is normal. Store in a cool and shaded area protected from light and humidity. Keep from extreme heat, humidity and open flames. Do not store with concentrated acids or strong oxidising agents.

Section 8 Exposure Controls / Personal Protection

Exposure Limits: An internal guideline exposure limit of 0.02 mg/m^3 has been set for Cyclosporin by Novartis Pharmaceuticals. The STEL is an exposure value that should not be exceeded by more that 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL.

Eye Protection: Avoid contact with eyes. Wash hands after use.

Skin protection: Avoid contact with skin. Wash hands after use.

Respirator: No respirator is required under normal conditions of use.

General advice: After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.

Section 9 - Physical and Chemical Properties

Physical State: Solid, oblong capsule

Colour: Blue-grey

Flash point Does not burn

Flammability: Non-flammable

Section 10 - Stability and Reactivity

Chemical Stability: This product is unlikely to spontaneously decompose. Isoperibolic decomposition (>8 hr) temperature is 220°C (Air open cup). Dynamic decomposition temperature is 260°C (Air open cup).

Incompatible Materials: Concentrated acids or strong oxidising agents.

Section 11 - Toxicological Information

Acute Toxicity : Harmful if swallowed. Possible risk of irreversible effects.

Oral: Product is harmful if swallowed (increased risk of tumour development due to the immunosuppressive activity of cyclosporin).
Rat oral LD_{50} > 5,000 mg/kg.

Dermal: Product may be harmful by skin absorption. Avoid contact with skin. Cyclosporin is not a skin irritant.

Inhalation: Data suggest that this product being a capsule, should present no significant inhalation problems.

Local Effects: Irritation - (Based on studies with Rabbits using Cyclosporin)

Skin: Non-irritant

Chronic Toxicity: Cyclosporin (under the trade name 'NEORAL' or 'SANDIMMUN NEORAL') is an immunosuppressant in humans Cyclosporin is classified as a known carcinogen (IARC Group 1) and a possible risk of irreversible effects in humans including increased risk of malignant tumour development due to the immunosuppressive activity of the active constituent (cyclosporin) exists. In humans, chronic effects may include leucocytopenia. Kidney injury may result following chronic exposure. Note that cyclosporin's observed chronic effects on human kidney are not mirrored in the target animals (dogs).

Section 12 - Ecological Information

Environmental effects for the active ingredient ***Cyclosporin***

Species	LC_{50} mg/L
Rainbow Trout (96 hrs)	>100
Daphnia (48hrs)	>100
Green algae (72 hrs)	>100
Micro-organisms (sewerage sludge-3hrs)	>100

Biodegradability: Cyclosporin is biodegradable
Octanol/water partition coefficient – Log Po/w 5.5 (app. 22°C)
Melting/softening point: 148-151°C
pH: 6.5-7
Solubility in water (20°C): 0.2 g/L

Solubility in solvents (20°C): acetone > 50 g/L

Section 13 - Disposal Considerations

After intended use: The container can be recycled if it is clean, dry, free of visible residues and has the *drumMUSTER* logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate or any undiluted chemical according to State legislative requirements. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any *drumMuster* collection or similar container management program site. The cap should not be replaced but may be taken separately.
DO NOT burn empty containers or product.

Section 14 - Transport Information

UN Number: None allocated
UN proper shipping name: None allocated
Class & Subsidiary Risk : None allocated
Packaging Group: None allocated
HAZCHEM Code: None allocated

Section 15 - Regulatory Information

Australia: Product first registered 23rd April 2001 with the Australian Pesticides Veterinary Medicines Authority

Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

Acronyms

ADG Code:	Australian Code for the Transport of Dangerous Goods by Road and Rail
AICS:	Australian Inventory of Chemical Substances
CAS Number:	Chemical Abstracts Service Registry Number
Hazchem Number:	Emergency action code of numbers and letters that provide information to emergency services especially fire-fighters
IARC	International Agency for Research on Cancer
NOHSC	National Occupational Health and Safety Commission
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
STEL	Short-term Exposure Limit
SUSDP	Standard for the Uniform Scheduling of Drugs & Poisons
TWA	Time Weighted Average
UN Number	United Nations Number

Note:

This product is a registered veterinary chemical and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Federal health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

Novartis Animal Health Australasia Pty Ltd

MATERIAL SAFETY DATA SHEET

This Material Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.