Section 1 - Identification of The Material and Supplier

Headway Animal Health Pty Ltd **Phone: (61-2)998960856**
A9/20 Picrite Close
Pemulwuy NSW 2145 AUSTRALIA

Product Name: **Dermasporin 100mg/ml Oral Solution for Cats**
APVMA Codes: 90969
Product Use: Treatment for allergic dermatitis in cats
Other Names: Cyclosporin

Creation Date: 3rd January 2024
Revision Date: 2nd January 2028
Poisons Information Centre: **Phone 13 1126 from anywhere in Australia**

Section 2 - Hazards Identification

Classification of the substance or mixture: FLAMMABLE LIQUIDS - Category 3
CARCINOGENICITY - Category 1
REPRODUCTIVE TOXICITY - Category 2
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE (immune system, kidneys) - Category 1

GHS Label Element: **Acute toxicity, Oral, Category 4 (H302)**
Hazard Pictogram:

Signal Word: **DANGER**
Hazard Statement: **H226 - Flammable liquid and vapour.**
H350 - May cause cancer.
H361 - Suspected of damaging fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure. (immune system, kidneys)

Precautionary statements:
Prevention: **P201 - Obtain special instructions before use.**
P280 - Wear protective gloves, protective clothing, eye protection, face protection, or hearing protection.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 - Do not breathe vapour.
P270 - Do not eat, drink or smoke when using this product.

Response: **P308 + P313 - IF exposed or concerned: Get medical advice or attention.**
Storage: **Not Applicable**
Disposal: **P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.**
Supplemental label Elements: **Not Applicable**

Other Hazars which do not result in classification: **None Known**

Section 3 - Composition/Information on Ingredients

Substance/mixture: Mixture

Ingredient name	% (w/w)	CAS number
Cyclosporin A	≥10 - <25	59865-13-3
ethanol	<10	64-17-5
propane-1,2-diol	≤10	57-55-6
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	≤0.3	10191-41-0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

The total concentration of ingredients in this product, reported or not in this section, is 100%.

Occupational exposure limits, if available, are listed in Section 8.

Section 4 - First Aid Measures

Description of necessary first aid measures

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately.

Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Ingestion: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed Potential acute health Effects.

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms.

Eye contact : No specific data.
Inhalation : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations
Skin contact : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations
Ingestion : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

Advice to doctor: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Specific treatments: No specific Treatment

Protection for First-aiders: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Section 5 - Fire Fighting Measures

Extinguishing Media: Use dry Chemical, Sprayed water(Fog) or foam, CO_2
Do not use water jet.

Hazchem code: 2Y

Specific hazards arising from the chemical: Flammable liquid and vapour. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

Hazards thermal decomposition products: Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides

Special protective actions for fire-fighters: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective actions for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and material for containment and cleaning up

Small Spill: Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large Spill: Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non- combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13).
Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well- ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8 - Exposure Controls and Personal Protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Ethanol	**Safe Work Australia (Australia, 12/2019).** TWA: 1880 mg/m³ 8 hours. TWA: 1000 ppm 8 hours. **EH40/2005 WELs (United Kingdom (UK), 1/2020).** TWA: 1000 ppm 8 hours. TWA: 1920 mg/m³ 8 hours.

	DFG MAC-values list (Germany, 10/2021). TWA: 200 ppm 8 hours. PEAK: 800 ppm, 4 times per shift, 15 minutes. TWA: 380 mg/m³ 8 hours. PEAK: 1520 mg/m³, 4 times per shift, 15 minutes.
propane-1,2-diol	**Safe Work Australia (Australia, 12/2019).** TWA: 10 mg/m³ 8 hours. Form: Particulate TWA: 150 ppm 8 hours. Form: Vapor and particulates TWA: 474 mg/m³ 8 hours. Form: Vapor and particulates **EH40/2005 WELs (United Kingdom (UK), 1/2020).** TWA: 10 mg/m³ 8 hours. Form: Particulate TWA: 474 mg/m³ 8 hours. Form: total vapour and particulates TWA: 150 ppm 8 hours. Form: total vapour and particulates

Biological exposure indices **No exposure indices known.**

Appropriate engineering controls: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures: Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective

properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.

Other skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9 - Physical and Chemical Properties:

Appearance

Physical state: Liquid. [Liquid Filled Gelatin Capsules]
Colour: Yellow or brown.
Odour: Mild.
Odour threshold: Not available.
pH: Not available.
Melting point/freezing point: Not available.
Boiling point, initial boiling point, and boiling range: Not available.
Flash point: Closed cup: 24 to 27°C (75.2 to 80.6°F)
Evaporation rate: Not available.
Flammability: Not available.
Lower and upper explosion limit/flammability limit: Not available.
Vapour pressure:

Ingredient name	Vapour Pressure at 20˚C			Vapour pressure at 50˚C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
ethanol	42.95	5.7				
propane-1,2-diol	0.15	0.02	EU A.4			
3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol	0	0				

Relative vapour density: Not available.
Relative density: Not available.
Solubility(ies) : Not available.

Solubility in water: Not available.
Partition coefficient n- octanol/water: Not applicable.

Auto-ignition temperature:

Ingredient name	°C	°F	Method
propane-1,2-diol	371	699.8	
Corn oil	392.85	739.1	
ethanol	455	851	DIN 51794

Decomposition temperature: Not available.
Viscosity: Not available.
Flow time (ISO 2431) : Not available.
Particle characteristics
Median particle size : Not applicable.

Section 10 - Stability and Reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical stability: The product is stable.

Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid: Avoid all possible sources of ignition (spark or flame). Do not pressurise, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.

Incompatible materials: Reactive or incompatible with the following materials:

Oxidising materials

Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 - Toxicological Information

Information on toxicological effects

Acute Toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Cyclosporin A	LD50 Oral	Rat	1480 mg/kg	-
ethanol	LC50 Inhalation Vapour	Rat	124700 mg/m³	4 hours
	LD50 Dermal	Rabbit	>5000 mg/kg	-
	LD50 Oral	Rat	7 g/kg	-
propane-1,2-diol	LD50 Dermal	Rabbit	20800 mg/kg	-
	LD50 Oral	Rat	20 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	100 uL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	400 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 20 mg	-
propane-1,2-diol	Eyes - Mild irritant	Rabbit	-	100 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Human	-	168 hours 500 mg	-
	Skin - Mild irritant	Woman	-	96 hours 30 %	-
	Skin - Moderate irritant	Child	-	96 hours 30 % C	-
	Skin - Moderate irritant	Human	-	72 hours 104 mg l	-

Sensitisation
Not available.

Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive toxicity
Not available.

Teratogenicity
Not available.

Specific target organ toxicity (single exposure)
Not available.

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Cyclosporin A	Category 1	-	immune system, kidneys

Aspiration hazard
Not available.

Information on likely routes of exposure: Not available.

Potential acute health effects

Eye contact: No known significant effects or critical hazards.

Inhalation: No known significant effects or critical hazards.

Skin contact: No known significant effects or critical hazards.

Ingestion: No known significant effects or critical hazards.

Symptoms related to physical, chemical and toxicological characteristics.

Eye contact: No specific data.

Inhalation: Adverse symptoms may include the following:
reduced foetal weight.
increase in foetal deaths.
skeletal malformations.

Skin contact: Adverse symptoms may include the following:
reduced foetal weight.
increase in foetal deaths.
skeletal malformations.

Ingestion: Adverse symptoms may include the following:
reduced foetal weight.
increase in foetal deaths.
skeletal malformations.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects: Not available.

Potential delayed effects: Not available.

Long term exposure

Potential immediate effects: Not available.

Potential delayed effects: Not available.

Potential chronic health effects

Not available.

General: Causes damage to organs through prolonged or repeated exposure.

Carcinogenicity: May cause cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity: No known significant effects or critical hazards.

Reproductive toxicity: Suspected of damaging fertility or the unborn child.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Dermasporin Oral Solution	14723.6	N/A	N/A	N/A	N/A
Cyclosporin A	1480	N/A	N/A	N/A	N/A
ethanol	7000	N/A	N/A	124.7	N/A
propane-1,2-diol	20000	20800	N/A	N/A	N/A

Section 12 - Ecological Information

Toxicity

Product/ingredient name	Result	Species	Exposure
Cyclosporin A	EC50 20.2 mg/l	Daphnia	48 hours
	LC50 >100 mg/l	Fish	96 hours
ethanol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 11000000 µg/l Marine water	Fish - Alburnus alburnus	96 hours
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 100 ul/L Fresh water	Daphnia - Daphnia magna - Neonate	21 days
propane-1,2-diol	EC50 19000 mg/l	Aquatic plants	72 hours
	EC50 34400 mg/l	Daphnia	48 hours
	Acute LC50 1020000 µg/l Fresh water	Crustaceans - Ceriodaphnia dubia	48 hours
	Acute LC50 710000 µg/l Fresh water	Fish - Pimephales promelas	96 hours

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
propane-1,2-diol	OECD 301F Ready Biodegradability - Manometric Respirometry Test	38 % - Not readily - 28 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
propane-1,2-diol	-	-	Not readily

Bio accumulative potential

Product/ingredient name	LogPow	BCF	Potential
Cyclosporin A	2.92	-	Low
ethanol	-0.35	-	Low
propane-1,2-diol	-1.07	-	Low

Mobility in soil
Soil/water partition coefficient (KOC): Not available.
Other adverse effects: No known significant effects or critical hazards.

Section 13 - Disposal Considerations

Disposal methods: The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapour from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Section 14 - Transport Information

	ADG	ADR/RID	IMDG	IATA
UN number	UN1293	UN1293	UN1293	UN1293
UN proper shipping name	Tinctures, medicinal	Tinctures, medicinal	Tinctures, medicinal	Tinctures, medicinal
Transport hazard class(es)	3 	3 	3 	3 
Packing group	III	III	III	III
Environmental hazards	No.	No.	No.	No.

Additional information

ADG: Hazchem code 2Y

Special precautions for user: Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk According to IMO instruments: Not available.

Section 15 - Regulatory Information

National regulations

Standard for the Uniform Scheduling of Medicines and Poisons

4

Model Work Health and Safety Regulations - Scheduled Substances

No listed substance

APVMA Approval Number: 90969

Inventory list

Australia: **Not determined.**

Section 16 - Other Information

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

Key to Abbreviations:

ADG	**=**	**Australian Dangerous Goods**
ADR	**=**	**The European Agreement concerning the International Carriage of Dangerous Goods by Road**
ATE	**=**	**Acute Toxicity Estimate BCF = Bioconcentration Factor**
GHS=		**Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association**
IBC	**=**	**Intermediate Bulk Container**
IMDG	**=**	**International Maritime Dangerous Goods**
LogPow	**=**	**logarithm of the octanol/water partition coefficient**
MARPOL=		**International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)**
N/A	**=**	**Not available**
SGG	**=**	**Segregation Group**