SAFETY DATA SHEETS

This SDS packet was issued with item:

078073732

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078946874

SAFETY DATA SHEET

Optimmune®

Section 1: Identification of the Substance and Supplier

Product name	**Optimmune**
Recommended use	Veterinary immunomodulator for dogs.
Company details	**Schering-Plough Animal Health Limited** **33 Whakatiki Street, Upper Hutt 5018, New Zealand** **Phone: 0800 800 543 Fax: 0800 808 100** **Website: www.msd-animal-health.co.nz** **Hours: 8 am – 5 pm, Mon – Fri**
Emergency telephone	**0800 764 766 (0800 POISON) 24 hours human health** **0800 243 622 (0800 CHEMCALL) 24 hours**
Date of preparation	April 2019

Section 2: Hazards Identification

Hazard classifications	This product is considered non-hazardous as it does not trigger any of the minimum degrees of hazard under the HSNO Act 1996.

Section 3: Composition/Information on Ingredients

Chemical name	CAS number	Concentration
Cyclosporin A	59865-13-3	0.2%

Section 4: First Aid Measures

Necessary first aid measures	**SKIN CONTACT** In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a doctor. **EYE CONTACT** In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor. **INGESTION** Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Centre. If symptoms persist, consult a doctor.
Required instructions	For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.
Notes for medical personnel	This product contains cyclosporine, an immunosuppressive agent, which is known to cause cancer and kidney damage in humans.

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Section 5: Fire Fighting Measures

Type of hazard	Not classified as flammable
Fire hazard properties	Not applicable
Regulatory requirements	Not applicable
Extinguishing media and methods	Carbon dioxide (CO_2), extinguishing powder or water spray.
Hazchem code	Not applicable
Recommended protective clothing	Wear self-contained breathing apparatus (SCBA) plus protective gloves.

Section 6: Accidental Release Measures

Personal Precautions	Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental Precautions	Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Avoid release to the environment.
Emergency procedures	Wear chemical resistant gloves and overalls, facemask or goggles. Prevent further spillage. Adsorb spilled product and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance.
Regulatory requirements	None specified.
Handling practices	Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.
Certified handlers	Not required
Conditions for safe storage	Store in original container in a cool, dry, ventilated place away from direct heat or direct sunlight. Keep container sealed when not in use. Keep out of reach of children.
Store site requirements	Store below 25°C.
Packaging	Not applicable

Section 8: Exposure Control/Personal Protection

Occupational exposure limits	No WES is set for this substance at this time.
Application in the workplace	Ensure adequate ventilation. Keep container sealed when not in use.
Exposure standards outside the workplace	No TEL or EEL is set for this substance at this time.

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Personal protection	No requirements.
Engineering controls	The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

Section 9: Physical and Chemical Properties

Appearance	Translucent colourless to light yellow ointment with no grittiness
Boiling Point	Not applicable
Melting/Softening point	Not determined
Vapour Pressure	Not applicable
Specific Gravity	Not applicable
Solubility (H_2O)	Not determined
Percent Volatiles	Not applicable
Evaporation Rate	Not applicable

Section 10: Stability and Reactivity

Stability of the substance	Stable under normal conditions.
Conditions to avoid	Extremes of temperature. Exposure to light.
Material to avoid	Avoid food products
Hazardous decomposition products	No dangerous decomposition is expected if used according to manufacturer's specifications.

Section 11: Toxicological Information

Acute effects for individual ingredients only

ORAL	Cyclosporine: LD50 1480 mg/kg (rat). Toxic signs observed during the determination of the oral LD50 in rats included hyperventilation, drowsiness, muscle spasm, piloerection, weight loss and diarrhoea.
TEL	No TEL is set for this substance at this time.

Chronic/long term effects for individual ingredients only

Three-month oral toxicity studies in rats and rhesus monkeys and a one year oral toxicity study in dogs were conducted with cyclosporine. Rats dosed at 45 mg/kg/day and greater exhibited serious nephron - and hepatotoxicity. Immunosuppressive activity was observed in rats at 14 mg/kg/day; however, this was attributed to the pharmacological activity of the material and was not considered a toxic effect. There were no signs of toxicity observed in monkeys or dogs at doses up to 300 mg/kg/day except for a high incidence of infectious lesions in dogs which was attributed to the immunosuppressive activity of cyclosporine.

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REPRODUCTIVE / DEVELOPMENTAL TOXICITY
Two-generation reproduction and peri and postnatal development studies were conducted in rats and developmental toxicity studies were conducted in rats and rabbits with cyclosporine. No reproductive or developmental toxicity was observed at dose levels that were not maternally toxic. No effect levels were 15 mg/kg/day for reproductive effects, 17 mg/kg/day for developmental effects in rats and 30 mg/kg/day for developmental effects in rabbits.

MUTAGENICITY / GENOTOXICITY
Cyclosporine was negative in a bacterial mutagenicity study (Ames), in mouse and Chinese hamster micronucleus assays, in a chromosome aberration assay in Chinese hamster bone marrow cells, and in a dominant lethal test in male mice. Cyclosporine and its metabolites were negative in V79 Chinese hamster fibroblasts in the HGPRT test system.

CARCINOGENICITY
There was no evidence of carcinogenicity in rats or mice given cyclosporine at doses up to 8 or 16 mg/kg/day, respectively. There was no evidence of carcinogenicity when petrolatum was given to mice dermally or subcutaneously or in rats intraperitoneally or orally.

Section 12: Environmental Information

Effects for individual ingredients only

EEL	No EEL is set for this substance at this time.

Section 13: Disposal Considerations

Disposal information

Disposal
Dispose of unused contents in a suitable landfill. Where possible, dispose of unused product through AgRecovery Chemicals. Avoid contamination of any water source or the environment with product or empty container.

Container Disposal
Dispose of empty container by puncturing and burying in a suitable landfill. Where possible, recycle through AgRecovery. Do NOT burn.

Needle Disposal
Discarded needles should immediately be placed in a designated and appropriately labelled ‘sharps’ container

Reference

Current version of NZS 8409 Management of Agrichemicals

Section 14: Transport Information

Relevant information

Not classified as a dangerous good for transport

Section 15: Regulatory Information

Regulatory status

ACVM Registration No: A7869
For conditions of registration see www.foodsafety.govt.nz

Approval not required under the HSNO Act 1996.

RESTRICTED VETERINARY MEDICINE

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Section 16: Other Information

Additional information Optimmune is a registered trademark.

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