

SAFETY DATA SHEET

Optimmune[®]

Section 1: Identification of the Substance and Supplier

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| 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

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| 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. |
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Section 3: Composition/Information on Ingredients

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

Section 4: First Aid Measures

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| Necessary first aid measures | <p>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.</p> <p>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.</p> <p>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.</p> |
| 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

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| 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

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| 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

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| 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

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| 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

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| 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 ₂ O) | Not determined |
| Percent Volatiles | Not applicable |
| Evaporation Rate | Not applicable |

Section 10: Stability and Reactivity

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| 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

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| 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.

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

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