SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name	Sporimune (cyclosporine capsules) 10, 25, 50, 100 mg
Chemical name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means ofidentification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	For the control of atopic dermatitis in dogs. Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (US)	Dechra Veterinary Products
Address	7015 College Blvd Suite 525 Overland Park, KS 66211 USA
Telephone	866-933-2472
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (US)	866-933-2472

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture

NFPA 704 diamond

Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Serious Eye Serious Eye Damage/Eye Irritation Category 2A, Carcinogenicity Category 1A, Reproductive Toxicity Category 1B
2.2 Label elements	
Hazard pictogram(s)	
Signal word	**Danger**
Hazard statement(s)	
H319	Causes serious eye irritation.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
Hazard(s) not otherwise classified	
Not Applicable	
Precautionary statement(s) Prevention	
P201	Obtain special instructions before use.
P280	Wear protective gloves and protective clothing.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash all exposed external body areas thoroughly after handling.
Precautionary statement(s) Response	
P308+P313	IF exposed or concerned: Get medical advice/attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
Precautionary statement(s) storage	
P405	Store locked up.
Precautionary statement(s) disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

See section below for composition of Mixtures.

3.2 Mixtures

CAS No.	% [weight]	Name
61788-85-0	<30	castor oil, hydrogenated, ethoxylated
9000-70-8	<20	gelatine
61789-25-1	<20	linoleoyl glycerides, ethoxylated
64-17-5	<10	ethanol
59865-13-3	<10	cyclosporin A
13463-67-7	<1	titanium dioxide
Not Available	10-30	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact	Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin contact	Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	Remove from contaminated area. Lay patient down. Keep warm and rested. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor.
Ingestion	If swallowed do **NOT** induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

See section 11.

4.3 Indication of immediate medical attention and special treatment needed

Cyclosporin nephrotoxicity may be avoided by adequate hydration and mannitol diuresis. Absorption from the gastrointestinal tract is incomplete and variable. The absolute bioavailability of oral forms is 20-50% at steady state. Distributed largely outside blood volume and biotransformed to about 15 metabolites which all contain the intact cyclic peptide structure of the parent compound. Elimination is biphasic with an alpha half-life of about 2 hours and a beta (terminal) half-life of about 14 hours irrespective of the dose. Elimination is primarily biliary with only 6% excreted in the urine.

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use foam, dry chemical powder, BCF (where regulations permit), carbon dioxide. For large fires use water spray or fog.

5.2 Special hazards arising from the substance or mixture

Fire incompatibility	Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

5.3 Special protective actions for fire-fighters:

Firefighting	Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control fire and cool adjacent area. **DO NOT** approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard	Combustible solid which burns but propagates flame with difficulty; Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Combustion products include carbon monoxide, carbon dioxide, hydrogen cyanide, acrolein, nitrogen oxide(s), metal oxides, other pyrolysis products typical of burning organic material. May emit corrosive/poisonous fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

See section 8.

6.2 Environmental precautions

See Section 12.

6.3 Methods and material for containment and cleaning up

Minor spills	Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Vacuum up or sweep up. **NOTE:** Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). Dampen with water to prevent dusting before sweeping. Place in suitable containers for disposal.
Major spills	Moderate hazard. **CAUTION**: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. Recover product wherever possible. **IF DRY:** Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. **IF WET:** Vacuum/shovel up and place in labelled containers for disposal. **ALWAYS:** Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling	Overheating of ethoxylates in air should be avoided, as they may undergo exothermic oxidative degeneration resulting in self-heating and autoignition. Nitrogen blanketing will minimize the potential

	for ethoxylate oxidation. Prolonged storage in the presence of air or oxygen may cause product degradation. Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. **DO NOT** enter confined spaces until atmosphere has been checked. **DO NOT** allow material to contact humans, exposed food or food utensils Avoid contact with incompatible materials. When handling, **DO NOT** eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Observe manufacturer's storage and handling recommendations.
Other information	Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Protect containers against physical damage and check regularly for leaks.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable container	Glass container is suitable for laboratory quantities. Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-1	ethanol	Ethyl alcohol (Ethanol)	1000 ppm / 1900 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)	ethanol	Ethyl alcohol	1000 ppm / 1900 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1	titanium dioxide	Titanium dioxide - Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	titanium dioxide	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	titanium dioxide	Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US NIOSH RELs	titanium dioxide	Titanium dioxide	Not Available	Not Available	Not Available	Ca; See Appendix A

Emergency limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
ethanol	Not Available	Not Available	15000 ppm
titanium dioxide	30 mg/m^3	330 mg/m^3	2,000 mg/m^3

Ingredient	Original IDLH	Revised IDLH
castor oil, hydrogenated, ethoxylated	Not Available	Not Available
gelatine	Not Available	Not Available
linoleoyl glycerides, ethoxylated	Not Available	Not Available
ethanol	3,300 ppm	Not Available
cyclosporin A	Not Available	Not Available
titanium dioxide	5,000 mg/m^3	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
cyclosporin A	E	≤ 0.01 mg/m³

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

8.2 Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required and a HEPA terminated local exhaust ventilation should be considered at points of dust, fume or vapor generation. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/transferring quantities exceeding 500 mg. When handling quantities up to 500 g in a standard laboratory, a general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kg may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kg should be handled in a designated laboratory or containment laboratory using appropriate barrier/containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.
Personal protection	
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs, use safety glasses with side shields or chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class

	of chemicals in use and an account of injury experience.
Skin protection	See Hand protection below.
Hands/feet protection	The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. Personal hygiene is a key element of effective hand care. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.
Body protection	See Other protection below
Other protection	For quantities up to 500 g a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Ensure there is ready access to an eye wash unit and emergency shower. For Emergencies: Vinyl suit
Respiratory protection	Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Gray or yellow solid capsule	Vapor density: Not Available
Physical state: Solid	Auto ignition temperature (°C): Not Available
Odor: Not Available	Decomposition temperature (°C): Not Available
Odor threshold: Not Available	Viscosity (°C): Not Available
pH (as supplied): Not Available	Explosive properties: Not Available
Melting point / freezing point (°C): Not Available	Oxidizing properties: Not Available
Initial boiling point and boiling range: Not Available	Partition coefficient: Not Available
Flash point (°C): Not Available	Molecular weight: Not Available
Evaporation rate: Not Available	Taste: Not Available
Flammability: Not Available	Surface tension: Not Available
Upper/lower flammability or explosive limits: Not Available	Volatile component (%vol): Not Available
Vapor pressure: Not Available	Gas group: Not Available
Relative density (Water = 1): Not Available	pH as a solution: Not Available
Solubility in water (mg/l): Miscible	VOC g/L: Not Available
	Specific gravity @ 20°C (water = 1): Not Available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Possibility of hazardous reactions	See Section 7
Conditions to avoid	See Section 7
Incompatible materials	See Section 7
Hazardous composition	See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhalation	Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual. Limited evidence or practical experience suggests that the material may produce irritation of the respiratory system
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin contact	Repeated exposure may cause skin cracking, flaking, or drying following normal handling and use. Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals.
Eye contact	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	On the basis of epidemiological data, it has been concluded that prolonged inhalation of the material, in an occupational setting, may produce cancer in humans. There is sufficient evidence to provide a strong presumption that human exposure to the material may result in impaired fertility. Inhalation of the material is capable of inducing a sensitization reaction.

Sporimune (cyclosporine capsules) 10, 25, 50, 100 mg	**Acute toxicity**	**Irritation**
	Not Available	Not Available

castor oil, hydrogenated, ethoxylated	**Acute toxicity**	**Irritation**
	Oral (rat) LD50: >2000 mg/kg[1]	Eye (rabbit): slight irritation Eye: no adverse effect observed (not irritating[1] Skin (rabbit): slight irritation Skin: no adverse effect observed (not irritating[1]
gelatine	**Acute toxicity**	**Irritation**
	Not Available	Not Available
linoleoyl glycerides, ethoxylated	**Acute toxicity**	**Irritation**
	Not Available	Not Available
ethanol	**Acute toxicity**	**Irritation**
	Dermal (rabbit) LD50: 17100 mg/kg[1] Inhalation(Rat) LC50; 64000 ppm4h[2] Oral (Rat) LD50: 7060 mg/kg[2]	Eye (rabbit): 500 mg SEVERE Eye (rabbit):100mg/24hr-moderate Eye: adverse effect observed (irritating)[1] Skin (rabbit):20 mg/24hr-moderate Skin (rabbit):400 mg (open)-mild Skin: no adverse effect observed (not irritating)[1]
cyclosporin A	**Acute toxicity**	**Irritation**
	Oral (Rabbit) LD50: >1000 mg/kg[2]	Not Available
titanium dioxide	**Acute toxicity**	**Irritation**
	Dermal (hamster) LD50: >= 10000 mg/kg[2] Inhalation(rat) LC50: >2.28 mg/l4h[1] Oral (Rat) LD50: ≥2000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1] Skin (human): 0.3 mg /3D (int)-mild * Skin: no adverse effect observed (not irritating)[1]

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Acute Toxicity	✗	Carcinogenicity	✓
Skin Irritation/Corrosion	✗	Reproductivity	✓
Serios Eye Damage/Irritation	✓	STOT – Single Exposure	✗
Respiratory or Skin Sensitization	✗	STOT – Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

✗ - Data either not available or does not fill the criteria for classification, ✓ - Data available to make classification.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Sporimune (cyclosporine capsules) 10, 25, 50, 100 mg	**Endpoint**	**Test Duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
castor oil, hydrogenated, ethoxylated	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	EC50(ECx)	72h	Algae or other aquatic plants	>1mg/l	2
	EC50	72h	Algae or other aquatic plants	>1mg/l	2
	EC50	48h	Crustacea	>1mg/l	2
	LC50	96h	Fish	>1mg/l	2
gelatine	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
linoleoyl glycerides, ethoxylated	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
ethanol	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	EC50(ECx)	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC50	72h	Algae or other aquatic plants	275mg/l	2
	EC50	48h	Crustacea	>79mg/L	4
	LC50	96h	Fish	>100mg/l	2
	EC50	96h	Algae or other aquatic plants	<0.001mg/L	2
cyclosporin A	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	NOEC(ECx)	0.5h	Fish	6.013mg/L	4
titanium dioxide	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	BCF	1008h	Fish	<1.1-9.6	7
	EC50	72h	Algae or other aquatic plants	3.75-7.58mg/l	4
	EC50	48h	Crustacea	1.9mg/l	2
	NOEC(ECx)	504h	Crustacea	0.02mg/l	4
	LC50	96h	Fish	1.85-3.06mg/l	4
	EC50	96h	Algae or other aquatic plants	179.05mg/l	2

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8.Vendor Data

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	**Persistence: Water/Soil**	**Persistence: Air**
ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
cyclosporin A	HIGH	HIGH
titanium dioxide	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	**Bioaccumulation**
ethanol	LOW (LogKOW = -0.31)

cyclosporin A	LOW (LogKOW = 0.9952)
titanium dioxide	LOW (BCF = 10)
12.4 Mobility in soil	
Ingredient	**Mobility**
ethanol	HIGH (KOC = 1)
cyclosporin A	LOW (KOC = 10000000000)
titanium dioxide	LOW (KOC = 23.74)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/ packaging disposal	**DO NOT** allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. Observe all label safeguards until containers are cleaned and destroyed. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority.

SECTION 14: TRANSPORT INFORMATION

Labels required

Marine pollutant	NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR) : NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee) : NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.8 Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	**Group**
	Not available for any ingredient

14.9 Transport in bulk in accordance with ICG Code

Product name	**Group**
	Not available for any ingredient

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for thesubstance or mixture

Product regulated by FDA as a veterinary product.

castor oil, hydrogenated, ethoxylated is found on the following regulatory lists

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

gelatine is found on the following regulatory lists

US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

linoleoyl glycerides, ethoxylated is found on the following regulatory lists

US TSCA - Chemical Substance Inventory

ethanol is found on the following regulatory lists

US - Massachusetts - Right To Know Listed Chemicals, US DOE Temporary Emergency Exposure Limits (TEELs), US NIOSH Recommended Exposure Limits (RELs), US OSHA Permissible Exposure Limits (PELs) Table Z-1, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

cyclosporin A is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List, International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs, IARC - Agents Classified by the IARC Monographs - Group 1: US National Toxicology Program (NTP) 15th Report Part A Known to be Human Carcinogens, US - California Proposition 65 – Carcinogens, US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List, US NTP 15th Report Part A Known to be Human Carcinogens

titanium dioxide is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List, IARC - Agents Classified by the IARC Monographs, IARC - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans, International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS), US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5, US - California Proposition 65 – Carcinogens, US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List, US - Massachusetts - Right To Know Listed Chemicals, US DOE Temporary Emergency Exposure Limits (TEELs), US List of Active Substances Exempt from the TSCA Inventory Notifications (Active-Inactive) Rule, US NIOSH Carcinogen List, US NIOSH Recommended Exposure Limits (RELs), US OSHA PELs Table Z-1, US OSHA PELs Table Z-3, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories	
Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No

Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	Yes
Acute toxicity (any route of exposure)	No
Reproductive toxicity	Yes
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)
None reported

State Regulations

US. California Proposition 65

WARNING: This product can expose you to chemicals including **cyclosporin A, titanium dioxide**, which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

National Inventory Status	
Australia - AIIC / Australia Non-Industrial Use	No (cyclosporin A)
Canada - DSL	No (linoleoyl glycerides, ethoxylated)
Canada - NDSL	No (castor oil, hydrogenated, ethoxylated; gelatine; ethanol; cyclosporin A)
China - IECSC	No (linoleoyl glycerides, ethoxylated)
Europe - EINEC / ELINCS /NLP	No (linoleoyl glycerides, ethoxylated; cyclosporin A)
Japan - ENCS	No (gelatine; linoleoyl glycerides, ethoxylated; cyclosporin A)
Korea - KECI	No (cyclosporin A)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (cyclosporin A)
USA - TSCA	No (cyclosporin A)
Taiwan - TCSI	Yes
Mexico - INSQ	No (castor oil, hydrogenated, ethoxylated; linoleoyl glycerides, ethoxylated)
Vietnam - NCI	No (linoleoyl glycerides, ethoxylated)
Russia - FBEPH	No (linoleoyl glycerides, ethoxylated; cyclosporin A)

Yes = All CAS declared ingredients are on the inventory
No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will requireregistration

SECTION 16: OTHER INFORMATION

Initial date: September 2022 – Classification

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
IDLH: Immediately Dangerous to Life or Health Concentrations
AIIC: Australian Inventory of Industrial Chemicals
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
ENCS: Existing and New Chemical Substances Inventory
PICCS: Philippine Inventory of Chemicals and Chemical Substances
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances
NZIoC: New Zealand Inventory of Chemicals

STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
ES: Exposure Standard
OSF: Odor Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odor Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
NLP: No-Longer Polymers
KECI: Korea Existing Chemicals Inventory
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory

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