

SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name:	CYTOPOINT® 10 mg/mL CYTOPOINT® 20 mg/mL CYTOPOINT® 30 mg/mL CYTOPOINT® 40 mg/mL
ACVM Registration No.:	A011348 A011443 A011444 A011445
Classification:	Restricted Veterinary Medicine (RVM)
Recommended Use:	A caninised monoclonal antibody (mAb) specifically targeting canine interleukin-31 (IL-31) for the treatment of clinical manifestations of atopic dermatitis in dogs.
Company Details:	Zoetis New Zealand Limited
Address:	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 963 847 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	01 July 2019

Section 2: Hazards Identification

Hazard Classification:	Not applicable
Priority Identifier(s):	KEEP OUT OF REACH OF CHILDREN
Secondary Identifier(s):	Not applicable

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Lokivetmab	1533403-95-0	Variable
Buffer solution	Proprietary	Variable
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:	<p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Self-Injection: Immediate medical advice should be sought on the management of all instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</p> <p>Ingestion: If swallowed, contact the National Poisons Centre or seek medical attention if you feel unwell. Rinse mouth. If ingestion of a large amount does occur</p> <p>Eye Contact: Flush the eye(s) with running water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Seek medical advice if irritation develops and persists.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. Seek medical advice if skin irritation or rash occurs.</p> <p>Inhalation: If breathing is difficult, move the patient to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice if symptoms develop or persist.</p>
Poisoning Symptoms:	Direct contact with eyes may cause temporary irritation. Allergic reactions are possible. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterised by rhinitis, sneezing, scratchy throat, oral mucosal oedema, laryngeal mucosal oedema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitised patients.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Notes for Medical Personnel:	Treat symptomatically.

Section 5: Fire-Fighting Measures

Type of hazard:	This product is non-flammable, non-combustible and non-explosive.
Fire Hazard Properties:	During fire, gases hazardous to health may be formed.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use water fog, foam, dry chemical powder or carbon dioxide to extinguish fires involving this product.
Hazchem Code:	Not allocated.
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	No special technical protective measures required. No special handling advice required.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store between 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	No additional requirements.
Packaging:	Store in the original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:	A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m ³ for dusts or mists when limits have not otherwise been established.
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	None set.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	Clear liquid.
Odour:	No data available.
Specific Gravity / Density:	No data available.
Boiling Point:	No data available.
Melting Point:	No data available.
pH:	No data available.
Solubility in Water:	No data available.
Flashpoint:	Not applicable. This product is not flammable
Oxidising Properties:	Not applicable. This product is not an oxidiser
Corrosive Properties:	Not applicable. This product is not corrosive
Vapour Pressure:	No data available.

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable and non-reactive under normal conditions of storage, transport and use.
Conditions to Avoid:	Avoid contact with incompatible materials; heat, flames and sparks. Protect from sunlight and freezing.
Material to Avoid:	Avoid strong oxidising agents, acids and alkalis.
Hazardous Decomposition Products:	No hazardous decomposition products are known. May include products of carbon, nitrogen.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

Not applicable. This product is not classified as toxic.

Acute Effects

Principle routes of exposure are expected to be by skin contact, accidental self-injection, ingestion and/or inhalation of syringe-expressed aerosols. As with any chemical product contact with unprotected bare skin; inhalation of vapour, mist or dust in the workplace atmosphere; or ingestion in any form should be avoided by observing good occupational work practices. The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of micro-organisms.

Self-Injection:	Local injection site reactions may occur from accidental self-injection.
Ingestion:	Expected to be a low ingestion hazard.
Eye contact:	Direct contact with eyes may cause temporary irritation.
Skin Contact:	No adverse effects due to skin contact are expected.
Inhalation:	No adverse effects due to inhalation are expected.

Chronic / Long Term Effects

Skin Irritation:	Prolonged skin contact may cause temporary irritation.
Eye Irritation:	Direct contact with eyes may cause temporary irritation.
Respiratory Sensitisation:	Not a respiratory sensitizer. As with any protein, the possibility of allergic reactions exists.
Skin Sensitisation:	This product is not expected to cause skin sensitization. As with any protein, the possibility of allergic reactions exists.
Mutagenicity:	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity:	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity:	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity:	Not classified.
Aspiration hazard:	Not an aspiration hazard

Section 12: Ecotoxicity Information

HSNO Classifications

Not applicable. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Ecotoxicity Effects / Environmental Fate

Persistence and degradability:	No data is available on the degradability of this product.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Other adverse effects:	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal Considerations

Product Disposal:	Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.
Container Disposal:	Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.:	Not applicable. This product is not a dangerous good.
Class:	Not applicable. This product is not a dangerous good.
Packing Group:	Not applicable. This product is not a dangerous good.
Proper Shipping Name:	Not applicable. This product is not a dangerous good.

Section 15: Regulatory Information

HSNO Approval No.:	Approval not required under the HSNO Act 1996.
HSNO Controls:	Not applicable.
ACVM Registration No.:	10 mg/mL: A011348 20 mg/mL: A011443 30 mg/mL: A011444 40 mg/mL: A011445
ACVM Controls:	See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine 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 Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT: **Zoetis New Zealand Limited:** 0800 963 847 (Business Hours)
 National Poisons Centre: 0800 POISON (0800 764 766)
 Emergency Services: Dial 111

This 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 SDS 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.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

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

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