

SAFETY DATA SHEET



Section 1 - Identification

Product identifier CYTOPOINT; Cypoint Solution for Injection for Dogs

Other means of identification

Synonyms CYTOPOINT™ * Cypoint 10, 20, 30 or 40 mg solution for injection for dogs * Canine Atopic Dermatitis Immunotherapeutic * Lokivetmab formulated solution for injection * Anti-canine IL31 mAb

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product

Restrictions on use Not for human use

Details of manufacturer or importer

Company Name (AU) Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA

Tel 1800 814 883

Fax (02) 8876 0444

Email productsupport.au@zoetis.com

Emergency Phone 1800 814 883 (all hours)

Police and Fire Brigade Dial 000

If ineffective Dial Poisons Information Centre (13 1126 from anywhere in Australia)

Section 2 - Hazard(s) identification

Classification of the hazardous chemical

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s) None.

Signal word None.

Hazard statement(s) The mixture does not meet the criteria for classification.

Precautionary statement(s)

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Supplemental information In the event of accidental injection, an allergic reaction may occur.

Other hazards which do not result in classification None known.

Section 3 - Composition and information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Excipients	Mixture	*
Lokivetmab	Not assigned	10, 20, 30, or 40***

Composition comments ***mg/ml
* Non-hazardous Ingredients

Section 4 - First aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Get medical advice/attention if you feel unwell.
Skin contact	Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Personal protection for first-aid responders	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.
Medical attention and special treatment	Treat symptomatically.

Section 5 - Firefighting measures

Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Hazchem code	None.
General fire hazards	No unusual fire or explosion hazards noted.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Extinguishing media	
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Section 6 - Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
For emergency responders	Keep unnecessary personnel away. Ventilate the contaminated area. Avoid contact with eyes, skin, and clothing. For personal protection, see section 8 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Avoid release to the environment. Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Section 7 - Handling and storage

Precautions for safe handling	Avoid accidental injection. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store out of direct sunlight in dark, dry conditions. Store at 2-8°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Protect from light. Store away from incompatible materials (see Section 10 of the SDS).

Section 8 - Exposure controls and personal protection

Control parameters	Follow standard monitoring procedures.
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Not applicable.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9 - Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Colour	Clear.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

Viscosity Not available.

Other physical and chemical parameters

Explosive properties Not explosive.

Oxidising properties Not oxidising.

Section 10 - Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Heat, flames and sparks. Excessive heat. Exposure to light. Protect from sunlight. Protect from freezing.

Incompatible materials Strong oxidising agents. Acids. Alkalies.

Hazardous decomposition products No hazardous decomposition products are known. May include products of carbon, nitrogen.

Section 11 - Toxicological information

Information on possible routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact No adverse effects due to skin contact are expected.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion Health injuries are not known or expected under normal use.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitisation

Respiratory sensitisation Not classified. In the event of accidental injection, an allergic reaction may occur.

Skin sensitisation Not classified. In the event of accidental injection, an allergic reaction may occur.

Germ cell 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 Due to partial or complete lack of data the classification is not possible. This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.

Aspiration hazard Not an aspiration hazard.

Other information Caution - Pharmaceutical agent.

Section 12 - Ecological information

Ecotoxicity Avoid release to the environment. 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.

Persistence and degradability No data available for this product.

Bioaccumulative potential No data available.

Mobility in soil No data available for this product.

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

Disposal methods Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14 - Transport information

ADG

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

Section 15 - Regulatory information

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA No.:
CYTOPOINT 40 mg: 83539
CYTOPOINT 30 mg: 83545
CYTOPOINT 20 mg: 83541
CYTOPOINT 10 mg: 83544

High Volume Industrial Chemicals (HVIC)

Excipients (CAS Mixture)

1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10, as amended)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16 - Any other relevant information

Issue date	19-May-2018
Revision date	14-June-2023
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals.

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Revision information	<p>Section 1 - Identification: Restrictions on use</p> <p>Section 4 - First aid measures: Skin contact</p> <p>Section 4 - First aid measures: Personal protection for first-aid responders</p> <p>Section 6 - Accidental release measures: Methods and materials for containment and cleaning up</p> <p>Section 6 - Accidental release measures: For emergency responders</p> <p>Section 6 - Accidental release measures: For non-emergency personnel</p> <p>Section 7 - Handling and storage: Conditions for safe storage, including any incompatibilities</p> <p>Section 9 - Physical and chemical properties: Appearance</p> <p>Section 12 - Ecological information: Persistence and degradability</p> <p>Section 15 - Regulatory information: International regulations</p> <p>Section 16 - Any other relevant information: References</p> <p>Section 16 - Any other relevant information: Key abbreviations or acronyms used</p>
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