

SAFETY DATA SHEET



1. Identification

Product identifier	CYTOPOINT; Cytopoint Solution for Injection for Dogs
Other means of identification	
Synonyms	CYTOPOINT™ * Cytopoint 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	australia.animalhealth@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)

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.

Other hazards which do not result in classification None known.

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

3. Composition/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

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.
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.
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.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

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.

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. Use personal protection recommended in Section 8 of the SDS. Ventilate the contaminated area. Avoid contact with eyes, skin, and clothing.

Environmental precautions

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

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid release to the environment.

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. Following product recovery, flush area with water.

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.

7. Handling and storage

Precautions for safe handling

Observe good industrial hygiene practices. Wear personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities 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. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

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.

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

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

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.

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.

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 Due to partial or complete lack of data the classification is not possible.

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.

12. Ecological information

Ecotoxicity 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.

Persistence and degradability No data is available on the degradability of 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.

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 (see: Disposal instructions).

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

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.

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 Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

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 Chemical Substances (AICS)	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
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).

16. Other information

Issue date	19-May-2018
Revision date	26-July-2018
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Toxicological information: Respiratory sensitisation Toxicological information: Skin contact Regulatory information: National regulations