

SAFETY DATA SHEET



1. Identification

Product identifier	Librela
Other means of identification	
Synonyms	Beransa (AU) * Canine Anti-NGF mAb * Beransa 5 mg Solution for Injection for Dogs * Beransa 10 mg Solution for Injection for Dogs * Beransa 15 mg Solution for Injection for Dogs * Beransa 20 mg Solution for Injection for Dogs * Beransa 30 mg Solution for Injection for Dogs
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary analgesic
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)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word	Danger
Hazard statement(s)	May damage fertility or the unborn child.

Precautionary statement(s)

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental information Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur.

Other hazards which do not result in classification None known.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Canine Anti-NGF mAb Bedinvetmab	Not established	*

Composition comments % = w/v
Other components below reportable levels
*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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 In the case of skin contact, immediately wash the skin with plenty of soap and water. 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 Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.

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 IF exposed or concerned: Get medical advice/attention. 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. 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. For personal protection, see section 8 of the SDS.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and 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. May cause reproductive effects.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

5. Fire-fighting measures

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.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Firefighters should wear full protective clothing including self contained breathing apparatus.

Fire fighting equipment/instructions During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazchem code None.

General fire hazards No unusual fire or explosion hazards noted. This product is a nonflammable aqueous solution.

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 Personnel must wear appropriate protective equipment (see Section 8).

For emergency responders	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Use appropriate containment to avoid environmental contamination.
Methods and materials for containment and cleaning up	Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up. 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.

7. Handling and storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. Wear appropriate personal protective equipment. Handle and open container with care. Avoid accidental injection. Avoid contact during pregnancy/while nursing. Avoid contact with eyes, skin, and clothing. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in a cool, dry place out of direct sunlight. Store in tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Protect from heat and light. @ 2 - 8°C (36 - 46°F). Do not freeze.

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	Observe any medical surveillance requirements. 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	Sterile solution
Physical state	Liquid.
Form	Liquid.
Colour	Clear to opalescent.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	0 °C (32 °F)
Initial boiling point and boiling range	100 °C (212 °F)
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)	> 0.1 g/ml
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Density	1.04 g/l
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. Direct sources of heat. Sunlight. High temperatures. Do not allow material to freeze. Keep away from heat, sparks and open flame.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged skin contact may cause temporary irritation.
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. Exposed individuals may experience eye tearing, redness, and 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. May cause reproductive effects.
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	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.
Skin sensitisation	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity	Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	May damage fertility or the unborn child.
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	Due to partial or complete lack of data the classification for hazardous to the aquatic environment, is not possible. 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 available for this product.
Bioaccumulative potential	No data available for this product. Not expected to bioaccumulate.
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 discharge into drains, water courses or onto the ground. Do not dispose of waste into sewer. 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.

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 Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals.
	Poison Schedule (Product) - Schedule 4
	APV No. 89658: Beransa 5 mg Solution for Injection for Dogs APV No. 89657: Beransa 10 mg Solution for Injection for Dogs APV No. 89656: Beransa 15 mg Solution for Injection for Dogs APV No. 89655: Beransa 20 mg Solution for Injection for Dogs APV No. 89695: Beransa 30 mg Solution for Injection for Dogs

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

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 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).

16. Other information

Issue date	05-October-2020
Revision date	05-August-2022
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	Product and Company Identification: Synonyms Physical and chemical properties: Colour Regulatory information: National regulations