

SAFETY DATA SHEET



1. Identification

Product identifier	Librela
Other means of identification	
Synonyms	Beransa (AU) * Canine Anti-NGF mAb
Recommended use	Veterinary analgesic
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone:	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

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

Label elements



Signal word	Danger
Hazard statement	May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
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.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Canine Anti-NGF mAb		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. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. 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 center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	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.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	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. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

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 firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted. This product is a nonflammable aqueous solution.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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. Local authorities should be advised if significant spillages cannot be contained.
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.

Environmental precautions	Avoid discharge into drains, water courses or onto the ground. Use appropriate containment to avoid environmental contamination.
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/personal protection

Occupational exposure limits	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
Appropriate engineering controls	General ventilation normally adequate.
Individual protection measures, such as personal protective equipment	
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.
General hygiene considerations	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.
Color	Clear to opalescent
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	32 °F (0 °C)
Initial boiling point and boiling range	212 °F (100 °C)
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.
Vapor pressure	Not available.
Vapor 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 information	
Density	1.04 g/l
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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 oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely 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 the physical, chemical and toxicological characteristics	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.

Information on toxicological 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/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.
Skin sensitization	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.
IARC Monographs. Overall Evaluation of Carcinogenicity	Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens	Not listed.

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.
Further 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 instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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

DOT
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

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Toxic Substances Control Act (TSCA)	One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
SARA 304 Emergency release notification	Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Reproductive toxicity**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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
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, including date of preparation or last revision**Issue date** 10-05-2020**Version #** 01

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Revision information This document has undergone significant changes and should be reviewed in its entirety.