

SAFETY DATA SHEET



1. Identification

Product identifier	Poulvac Laryngo SA2
Other means of identification	
Synonyms	Infectious laryngotracheitis, live virus, vaccine -- vaccine for prevention of infectious laryngotracheitis in poultry
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary vaccine
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 Direct contact with eyes may cause temporary irritation. Allergic reactions are possible.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Gentamicin sulfate	1405-41-0	0.44 µg/dose
Infectious laryngotracheitis virus (SA2 strain)	Not established	*
Nystatin	1400-61-9	0.44 units/dose
Stabiliser	Mixture	*

Composition comments * Non-hazardous Ingredients

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

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. 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.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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 (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. Fine particles (such as dust and mists) may fuel fires/explosions.

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 Use water spray to cool unopened containers.

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.

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

Methods and materials for containment and cleaning up Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Remove sources of ignition. Avoid the generation of dusts during clean-up. Prevent 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	Ensure adequate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store below -5°C (freeze). Protect from light. Store away from direct sunlight. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

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).
Control banding approach	Gentamicin sulfate: Zoetis OEB 2 (control exposure to the range of 100ug/m ³ to < 1000ug/m ³)
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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. In case of insufficient ventilation, wear suitable respiratory equipment.
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	Freeze-dried preparation. Reconstitute with water for use.
Physical state	Solid, Liquid.
Form	Solid. Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Decomposes before melting
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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)	Dispersible
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. Avoid exposure to light, sunlight and elevated temperatures.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

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. Allergic reactions are possible. 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.

Components	Species	Test results
Gentamicin sulfate (CAS 1405-41-0)		
Acute		
Intramuscular		
LD50	Rat	384 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Nystatin (CAS 1400-61-9)		
Acute		
Oral		
LD50	Rat	10000 mg/kg
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. Allergic reactions are possible.	
Skin sensitisation	Not classified. Allergic reactions are possible.	

Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Mutagenicity Gentamicin sulfate	DNA Binding Assay Result: negative Species: E. coli
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.
Developmental effects Gentamicin sulfate	375 mg/kg/day Embryo / Fetal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Intraperitoneal 660 mg/kg/day Prenatal & Postnatal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Subcutaneous 660 mg/kg/day Prenatal & Postnatal Development, Neonatal toxicity Result: LOAEL Species: Rat Organ: Subcutaneous
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Other information	The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of microorganisms.

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 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 allow this material to drain into sewers/water supplies. Do not discharge into drains, water courses or onto the ground. 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 applicable.

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: 50573

This SDS replaces version: Issued November, 2015

Poison Schedule (Product) – Schedule 0

Australia Medicines & Poisons Appendix F

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Appendix H

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 2

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 3

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 4

Nystatin (CAS 1400-61-9)

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting 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**

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.