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(s) 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

<table>
<thead>
<tr>
<th>Mixture Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin sulfate</td>
<td>1405-41-0</td>
<td>0.44 µg/dose</td>
</tr>
<tr>
<td>Infectious laryngotracheitis virus (SA2 strain)</td>
<td>Not established</td>
<td>*</td>
</tr>
<tr>
<td>Nystatin</td>
<td>1400-61-9</td>
<td>0.44 units/dose</td>
</tr>
<tr>
<td>Stabiliser</td>
<td>Mixture</td>
<td>*</td>
</tr>
</tbody>
</table>
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**
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**Suitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

**Unsuitable extinguishing media**
During fire, gases hazardous to health may be formed. Fine particles (such as dust and mists) may fuel fires/explosions.

**Specific hazards arising from the chemical**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special protective equipment and precautions for fire fighters**
Use water spray to cool unopened containers.

**Fire fighting equipment/instructions**
None.

**Hazchem Code**
No unusual fire or explosion hazards noted.

**General fire hazards**
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/m3 to < 1000ug/m3)

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
Wear appropriate chemical resistant gloves.

Hand protection
Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Other

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin sulfate (CAS 1405-41-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intramuscular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>384 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Nystatin (CAS 1400-61-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>10000 mg/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Dose</th>
<th>Route</th>
<th>Developmental toxicity</th>
<th>Result</th>
<th>Species</th>
<th>Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>375 mg/kg/day</td>
<td>Embryo / Fetal Development</td>
<td>Developmental toxicity</td>
<td>LOAEL</td>
<td>Rat</td>
<td>Intraperitoneal</td>
</tr>
<tr>
<td>660 mg/kg/day</td>
<td>Prenatal &amp; Postnatal Development</td>
<td>Developmental toxicity</td>
<td>LOAEL</td>
<td>Rat</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>660 mg/kg/day</td>
<td>Prenatal &amp; Postnatal Development</td>
<td>Neonatal toxicity</td>
<td>LOAEL</td>
<td>Rat</td>
<td>Subcutaneous</td>
</tr>
</tbody>
</table>

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 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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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.