SAFETY DATA SHEET



1. Identification

Product identifier LARYNGO-VAC

Other means of identification

Synonyms LaryngoVac * Fowl Laryngotracheitis Vaccine * Infectious Laryngotracheitis Vaccine * Poulvac ILT

Veterinary vaccine Recommended use **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

1-800-366-5288

Services

Emergency telephone

CHEMTREC (24 hours): 1-800-424-9300

numbers

International CHEMTREC (24 hours): +1-703-527-3887

Zoetis Belgium S.A. Company Name (EU)

> Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone

number

International CHEMTREC (24 hours): +1-703-527-3887

VMIPSrecords@zoetis.com **Contact E-Mail**

2. Hazard(s) identification

Physical hazards Not classified. Health hazards Not classified. Not classified. **Environmental hazards OSHA** defined hazards Not classified.

Label elements

Hazard symbol None. None. Signal word

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Store away from incompatible materials. Storage

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Direct contact with eyes may cause temporary irritation. Allergic reactions are possible.

3. Composition/information on ingredients

Mixtures

| Chemical name | Common name and synonyms | CAS number | % |
|--|--------------------------|--------------|----|
| Fowl Laryngotracheitis Virus, Live Salsbury Strain | | Not assigned | * |
| Gentamicin | | 1403-66-3 | ## |

Material name: LARYNGO-VAC SDS US

| Chemical name | Common name and synonyms | CAS number | % |
|---------------|--------------------------|------------|---|
| Stabilizer | | Mixture | * |
| Sucrose | | 57-50-1 | * |
| Water | | 7732-18-5 | * |

Composition comments

Trace

* Non-hazardous Ingredients

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. 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 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. 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.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

General information

For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

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 firefighters 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.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

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.

Environmental precautions

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

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7. Handling and storage

Precautions for safe handling

Ensure adequate ventilation. Minimize dust generation and accumulation. 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 away from direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. 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/personal protection

Occupational exposure limits

| Components | Туре | Value | Form |
|---------------------------------------|----------------|----------|----------------------|
| Sucrose (CAS 57-50-1) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |
| US. ACGIH Threshold Limit Valu | es | | |
| Components | Туре | Value | |
| Sucrose (CAS 57-50-1) | TWA | 10 mg/m3 | |
| US. NIOSH: Pocket Guide to Che | emical Hazards | | |
| Components | Туре | Value | Form |
| Sucrose (CAS 57-50-1) | TWA | 5 mg/m3 | Respirable. |
| | | 10 mg/m3 | Total |

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Gentamicin: 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. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

If contact is likely, safety glasses with side shields are recommended. Eye/face protection

Skin protection

Hand protection

Wear impervious gloves if skin contact is possible.

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. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Not applicable.

Thermal hazards

General hygiene considerations

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 Lyophilized powder

Physical state Solid. Solid. **Form**

Color Pale yellow - Reddish White.

Odorless. Odor **Odor threshold** Not available.

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Material name: LARYNGO-VAC 922 Version #: 03 Revision date: 05-19-2017 Issue date: 02-12-2014 Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

rianimability mint - ic

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) Soluble

Solubility (other) n-octanol, Methanol, Acetone, Diethylether

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive. **Oxidizing properties** Not oxidizing.

10. Stability and reactivity

ReactivityThe 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. Sunlight. High temperatures. Minimize dust generation and

accumulation.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

InhalationNo adverse effects due to inhalation are expected.Skin contactProlonged skin contact may cause temporary irritation.Eye contactDirect contact with eyes may cause temporary irritation.GentamicinSpecies: Rabbit

Species: Rabbit Severity: Non-irritating

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

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.

Information on toxicological effects

Material name: LARYNGO-VAC SDS US

Expected to be a low hazard for usual industrial or commercial handling by trained personnel. **Acute toxicity**

Gentamicin (CAS 1403-66-3)

Acute

Components

Intramuscular

LD50 Mouse 167 mg/kg Rat

463 mg/kg

Test Results

Oral

Rat LD50 6600 mg/kg

Subcutaneous

LD50 Rat 710 mg/kg

Sucrose (CAS 57-50-1)

Acute

Oral

LD50 Rat 29.7 g/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Species

Serious eve damage/eve irritation

Direct contact with eyes may cause temporary irritation.

Eye Contact

Gentamicin Species: Rabbit Severity: Non-irritating

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

This product is not expected to cause skin sensitization. Skin sensitization

No data available to indicate product or any components present at greater than 0.1% are Germ cell mutagenicity

mutagenic or genotoxic.

Mutagenicity

Sucrose Bacterial Mutagenicity (Ames)

Result: Negative Species: Salmonella

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects

Gentamicin 75 mg/kg/day Embryo / Fetal Development, Developmental

toxicity

Result: LOAEL Species: Rat

Organ: Intramuscular

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Not an aspiration hazard. **Aspiration hazard**

Further information The antigens included in this product are non-infectious. All have been prepared from attenuated

preparations of microorganisms.

Material name: LARYNGO-VAC SDS US

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

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

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 instructionsAvoid release to the environment. Do not contaminate ponds, waterways or ditches with chemical

or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal management 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

None known.

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

Not applicable.

the IBC Code

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No

chemical

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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

Not regulated. (SDWA)

US state regulations 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.

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 |

^{*}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).

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

02-12-2014 Issue date 05-19-2017 **Revision date**

Version # 03

United States & Puerto Rico

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while Disclaimer

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

SDS US

No