

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078366734

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078910002



# MATERIAL SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** LeptoVax™ 4

**Product No.:** RM1000184

**GHS Product Identifier:** Not applicable

**Synonyms:** No data available

Molecular Formula: Mixture, not applicable

Molecular Weight: Mixture, not applicable

CAS Number: Mixture, not applicable

Chemical Family: Vaccine

**Manufacturer:**

Boehringer Ingelheim Vetmedica, Inc.

800 5<sup>th</sup> Street NW

PO Box 518

Fort Dodge, IA 50501

**Telephone: (515) 955-4600**

**Transportation Emergency:** For Chemical

Emergency Spill, Leak, Fire, Exposure, or

Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887

(collect calls accepted)

**Medical Emergency (24HR):** (866) 638-2226

**Non-Emergency Telephone:** (800) 821-7467

**Intended Use:** Vaccine for injection.

## 2 HAZARDS IDENTIFICATION

### Emergency Overview

**Physical State:** Bacterin in a powder cake with sterile diluent.

**Color:** Reddish-white

**Odor:** Odorless



### **WARNING!**

**For use in canines only.**

**Not for human use.**

**Allergic reactions can occur.**

### **Precautionary Statements:**

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Keep at a temperature between 2 - 7°C.

Do not freeze.

Store out of direct sunlight.

Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Wear suitable gloves and eye/face protection.

Spills: Cover with absorbent or contain. Collect and incinerate.

In case of accident/exposure or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

In case of contact with eyes, flush with gently flowing fresh water thoroughly.

Wash skin thoroughly with soap and water after handling.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Keep away from food, drink, and animal feedstuffs.

### **Potential Health Effects**

**Inhalation:** Not expected to be an inhalation hazard with prescribed use.

**Eye Contact:** Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.

**Skin Contact:** Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

**Ingestion:** Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

**Injection:** Swelling at injection site may occur.

**Chronic Health Effects:** Possible hypersensitization (development of abnormal sensitivity).

**Target Organ(s):** Skin

**OSHA Regulatory Status:** Non-hazardous (exempt)

**Environment:** No data available

<b>3</b>	<b>COMPOSITION / INFORMATION ON INGREDIENTS</b>
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Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Leptospira Canicola- Grippytyphosa- Icterohaemorrhagiae- Pomona bacterin	----	----	proprietary	----	---

Components not listed are not hazardous or are below reportable limits.

The full texts for all R-Phrases are displayed in Section 16, if applicable.

#### 4 FIRST AID MEASURES

**General:** Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

**Inhalation:** Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

**Skin Contact:** In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

**Ingestion:** 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.

**Injection:** In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

**Note to Physician:** For animal injection only. Not for human use.

#### 5 FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known

**Special Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.

**Unusual Fire & Explosion Hazards:** None known

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide

#### 6 ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Wear appropriate personal protective equipment (See Section 8).

**Spill Cleanup Methods:** STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

**Environmental Precautions:** Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

## 7 HANDLING AND STORAGE

**Handling:** HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

**Storage:** Store at 2°-7°C (35°-45°F). Do not freeze. Shake well before using.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Limits:** None Established.

**Engineering Controls:** Not generally required when handling vials or containers. Good 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.

**Respiratory Protection:** Not generally required when handling vials or containers. 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

**Europe:** Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

**PERSONAL PROTECTIVE EQUIPMENT:** Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

**Eye Protection:** Wear safety glasses with side shields (or goggles).

**Hand Protection:** Wear suitable gloves.

**Skin Protection:** Wear lab coat, apron or appropriate clothing to prevent skin contact.

**Hygiene Measures:** Eye bath, washing facilities

## 9 PHYSICAL AND CHEMICAL PROPERTIES

**Color:** Reddish-white

**Odor:** Odorless

**Odor Threshold:** No data available

**Physical State:** Bacterin in a powder cake with sterile diluent.

**pH:** 6 - 8

**Melting Point:** No data available

**Freezing Point:** No data available

**Boiling Point:** No data available

**Flash Point:** No data available

**Flammability Limit – Upper (%):** No data available

**Flammability Limit – Lower (%):** No data available

**Evaporation rate:** No data available

**Vapor Pressure:** No data available

**Vapor Density (Air=1):** No data available

**Specific Gravity:** No data available

**Solubility:** Easily soluble in cold water, hot water, methanol, diethyl ether, n-octanol, acetone.

**Partition Coefficient (n-Octanol/water):** No data available

**Autoignition Temperature:** Not applicable

**Decomposition Temperature:** No data available

<b>10</b>	<b>STABILITY AND REACTIVITY</b>
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**Stability:** Stable

**Conditions to Avoid:** Temperatures below 2° C (35° F)

**Incompatible Materials:** Strong oxidizing agents

**Hazardous Decomposition Products:** None known

**Possibility of Hazardous Reactions:** Will not occur.

<b>11</b>	<b>TOXICOLOGICAL INFORMATION</b>
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LeptoVax 4 is considered non-toxic.

**Listed Carcinogens:** None

<b>12</b>	<b>ECOLOGICAL INFORMATION</b>
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**Ecotoxicity:** No data available

**Persistence and degradability:** No data available

**Mobility in soil:** No data available

**Other adverse effects:** No data available

**Germany WGK:** Not applicable

<b>13</b>	<b>DISPOSAL CONSIDERATIONS</b>
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**General Information:** Dispose of in accordance with local, state, federal, national or international regulations.

**Disposal Methods:** No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

**RCRA Information:** Not applicable

<b>14</b>	<b>TRANSPORT INFORMATION</b>
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**DOT:** Not regulated

**TDG:** Not regulated

**ADR/RID:** Not regulated

**IATA:** Not regulated

**IMDG:** Not regulated

<b>15</b>	<b>REGULATORY INFORMATION</b>
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**Canadian Controlled Products Regulations:** This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

**WHMIS Classification:** Non-controlled

**Inventory Status**

This material is **not** listed on the following inventories: TSCA, DSL, AICS, EINECS, IECSC, ENCS, PICCS, KECI, and NZIoC. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

**US Regulations**

**CERCLA Hazardous Substance List (40 CFR 302.4):** None listed.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):** None listed.

**Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):** None listed.

**SARA Title III**

**Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):** None listed.

**Section 311/312 (40 CFR 370):** Not Regulated.

**Section 313 Toxic Release Inventory (40 CFR 372):** None listed.

**State Regulations**

**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):** None listed.

**Massachusetts Right-To-Know List:** None listed.

**Minnesota Hazardous Substances List:** None listed.

**New Jersey Right-To-Know List:** None listed.

**Pennsylvania Right-To-Know List:** None listed.

**Rhode Island Right-To-Know List:** None listed.

**European Regulations**

**Austria MAK List (Annex I):** None listed.

**Denmark (Annex 3.6):** None listed.

**Germany (Dangerous Substances Ordinance 2004, Annex III):** None listed.

**Norway (List of Dangerous Substance):** None listed.

**Sweden (Annex 3):** None listed.

**Switzerland (Toxins List 1):** None listed.

<b>16</b>	<b>OTHER INFORMATION</b>
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**Hazard Ratings**

	Health Hazard	Fire Hazard	Reactivity Hazard
<b>HMIS</b>	1	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
<b>NFPA</b>	1	0	0	N/A

\* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

**ABBREVIATIONS:**

BIV – Boehringer Ingelheim Vetmedica, Inc.

N/A – Not applicable

N/E – Not established

pph – parts per hour

**References:**

1. LeptoVax 4 MSDS and Label. Fort Dodge Animal Health.
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

**Revision Information:** 04/14/2010

**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.

**Issue Date:** 4/20/2012

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# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Leptovax 4

**Other means of identification**

**Item Code** AV6880

**Synonyms** Leptospira Canicola- Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract

**Recommended use** Veterinary Vaccine

**Recommended restrictions** None known.

**Manufacturer/Importer/Supplier/Distributor information**

**Company Name** Elanco Animal Health  
2500 Innovation Way  
Greenfield, IN 46140  
US

**Phone:** 1-877-Elanco1 (1-877-352-6261)

**Emergency Telephone Numbers:** Elanco Product Technical Support / Human or Animal Exposure Reporting:  
1-888-545-5973

**Transportation Emergency Telephone:** CHEMTREC: 1-800-424-9300  
(Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**

**Hazard symbol** None.

**Signal word** None.

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

**Precautionary statement**

**Prevention** Not available.

**Response** Not available.

**Storage** Not available.

**Disposal** Not available.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** None.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Thimerosal		54-64-8	<= 0.01

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

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

**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

<b>Ingestion</b>	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention.
<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>General information</b>	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	Not available.
<b>Specific hazards arising from the chemical</b>	Not applicable.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Not available.
<b>Methods and materials for containment and cleaning up</b>	Prevent entry into waterways, sewer, basements or confined areas.  Large Spills: Stop the flow of material, if this is without risk. 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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in the dark between 35 - 45 °F (2 - 7 °C). Do not freeze.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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### Exposure guidelines

#### US - California OELs: Skin designation

Thimerosal (CAS 54-64-8)	Can be absorbed through the skin.
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#### US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8)	Can be absorbed through the skin.
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**US ACGIH Threshold Limit Values: Skin designation**

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

**US NIOSH Pocket Guide to Chemical Hazards: Skin designation**

Thimerosal (CAS 54-64-8)

Can be absorbed through the skin.

**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Safety glasses.

**Skin protection****Hand protection**

Wear appropriate chemical resistant gloves.

**Other**

Wear suitable protective clothing.

**Respiratory protection**

In case of insufficient ventilation, wear suitable respiratory equipment.

**Thermal hazards**

Not available.

**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****Physical state**

Liquid.

**Form**

Liquid

**Color**

Reddish - White

**Odor**

Odorless

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**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.

**Vapor pressure**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)****Solubility (water)**

Not available.

**Partition coefficient (n-octanol/water)**

Not available.

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.

**Viscosity**

Not available.

**Other information****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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
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Thimerosal (CAS 54-64-8)

#### Acute

##### Oral

LD50

Rat

75 mg/kg

#### Skin corrosion/irritation

No skin irritation. (0.1% Thimerosal)  
Based on available data, the classification criteria are not met.

#### Serious eye damage/eye irritation

Slight irritation. (0.1% Thimerosal)  
Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

##### Respiratory sensitization

Based on available data, the classification criteria are not met.

##### Skin sensitization

Risk of sensitization or allergic reactions among sensitive individuals. (Thimerosal)  
Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity

Result in genetic toxicity assays (in vitro and in vivo): Negative (Thimerosal)  
Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

#### Reproductive toxicity

May damage fertility or the unborn child. (Thimerosal)  
Based on available data, the classification criteria are not met.

#### Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

#### Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure. (Thimerosal)  
Based on available data, the classification criteria are not met.

#### Aspiration hazard

Not available.

## 12. Ecological information

### Ecotoxicity

Components	Species	Test Results
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Thimerosal (CAS 54-64-8)

#### Aquatic

##### Acute

Fish

LC50

Bullhead, catfish (Ictalurus sp.)

7.5 mg/l, 24 hours

#### Persistence and degradability

No data is available on the degradability of this product.

#### Bioaccumulative potential

No data available.

#### Mobility in soil

No data available.

#### Other adverse effects

Not available.

### 13. Disposal considerations

**Disposal instructions** Dispose of contents/container in accordance with local/regional/national/international regulations.

### 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 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 1910.1001-1052)

Not regulated.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

##### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

##### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Thimerosal (CAS 54-64-8)

##### 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



**WARNING:** This product can expose you to Thimerosal, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

##### California Proposition 65 - CRT: Listed date/Developmental toxin

Thimerosal (CAS 54-64-8)

Listed: July 1, 1990

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	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** 04-19-2018

**Version #** 01

**List of abbreviations**

LEG: Lilly Exposure Guideline.  
STEL: Short-Term Exposure Limit.  
TWA: Time Weighted Average

**Disclaimer**

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For additional information contact:  
Elanco Animal Health  
0011+1-877-352-6261  
0011+1-800-428-4441