

## SAFETY DATA SHEETS

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

078567425

**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).**

078548658 078548666 078658701



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Vira Shield 6 + VL5 HB Somnus

**Other means of identification**

Item Code ZD6160, AV6160

**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)

**Email:** lilly\_msds@lilly.com

**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** Aspiration hazard Category 1

**OSHA defined hazards** Not classified.

**Label elements**



**Signal word** Danger

**Hazard statement**

H304 May be fatal if swallowed and enters airways.

**Precautionary statement**

**Prevention** Not available.

**Response**

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.  
P331 Do NOT induce vomiting.

**Storage**

P405 Store locked up.

**Disposal**

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** Accidental injection may cause local swelling, irritation or necrosis at the injection site. Get medical attention immediately. See also section 4.

**Supplemental information** None.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Mineral Oil Adjuvant SO 3-003		Mixture	20
Formaldehyde		50-00-0	<= 0.074
Thimerosal		54-64-8	<= 0.01

**Composition comments** \* Mineral Oil Adjuvant contains up to 92% Light Mineral Oil (CAS 8042-47-5)  
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.

**Ingestion** Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention.

**Most important symptoms/effects, acute and delayed** Aspiration may cause pulmonary edema and pneumonitis. Accidental injection may cause local swelling, irritation or necrosis at the injection site.

**Indication of immediate medical attention and special treatment needed** In case of accidental self-injection of oil emulsion vaccines, get medical attention immediately.

SEEK IMMEDIATE MEDICAL TREATMENT at nearest Hospital Emergency Room even if only a very small amount is injected, as failure to treat may result in the mineral oil adjuvant causing sterile abscess and/or loss of affected finger or thumb. If pain persists for more than 12 hours after medical examination, seek additional medical advice.

To the Doctor: This product contains mineral oil. Accidental injection with this oil-based product, even in small quantities, can cause intense swelling which may, for example, result in ischaemic necrosis and the loss of a digit. Expert PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

**General information** 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

**Suitable extinguishing media** Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media** Not available.

**Specific hazards arising from the chemical** Not applicable.

**Special protective equipment and precautions for firefighters** Wear suitable protective equipment.

**General fire hazards** No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Not available.

**Methods and materials for containment and cleaning up** Prevent entry into waterways, sewer, basements or confined areas.

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.

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

#### 7. Handling and storage

**Precautions for safe handling** Use a needle guard to help prevent self-injection. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities** Store in original tightly closed container.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. ACGIH Threshold Limit Values Components

Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Light Mineral Oil (CAS 8042-47-5)	TWA	5 mg/m3
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

#### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 ppm
	TWA	0.75 ppm

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Light Mineral Oil (CAS 8042-47-5)	PEL	5 mg/m3	Mist.

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

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0.1 ppm	
	TWA	0.016 ppm	
Light Mineral Oil (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

### Biological limit values

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

### Exposure guidelines

#### US - California OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

#### US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

#### 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

Use a needle guard to help prevent self-injection. 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	Not available.
Odor	Not available.
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

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 < 20.5 mm<sup>2</sup>/s at 40 C

### 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 May be fatal if swallowed and enters airways.

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	10500 mg/m <sup>3</sup> , 4 hours
<b>Oral</b>		
LD50	Rat	640 mg/kg

Components	Species	Test Results
Thimerosal (CAS 54-64-8)		
<u>Acute</u>		
Oral		
LD50	Rat	75 mg/kg
Skin corrosion/irritation	Rabbit: Corrosive. (Formaldehyde) No skin irritation. (0.1% Thimerosal) Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Rabbit: Corrosive. (Formaldehyde) Slight irritation. (0.1% Thimerosal) Based on available data, the classification criteria are not met.	
Respiratory or skin sensitization		
ACGIH sensitization		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization	Respiratory sensitization
Respiratory sensitization	Exposure to formaldehyde may cause respiratory sensitization in some individuals or aggravate pre-existing asthmatic conditions. Based on available data, the classification criteria are not met.	
Skin sensitization	May cause an allergic skin reaction. (Formaldehyde) 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): Mixed results (Formaldehyde) Result in genetic toxicity assays (in vitro and in vivo): Negative (Thimerosal) Based on available data, the classification criteria are not met.	
Carcinogenicity	May cause cancer. (Formaldehyde) Based on available data, the classification criteria are not met.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Formaldehyde (CAS 50-00-0)	Cancer	
US. National Toxicology Program (NTP) Report on Carcinogens		
Formaldehyde (CAS 50-00-0)	Known To Be Human Carcinogen.	
Reproductive toxicity	No effects identified in animal studies. (Formaldehyde) May damage fertility or the unborn child. (Thimerosal) Based on available data, the classification criteria are not met.	
Specific target organ toxicity - single exposure	May cause respiratory irritation. (Formaldehyde) Based on available data, the classification criteria are not met.	
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (Formaldehyde) May cause damage to organs through prolonged or repeated exposure. (Thimerosal) Based on available data, the classification criteria are not met.	
Aspiration hazard	May be fatal if swallowed and enters airways. (Mineral oil)	
Further information	Accidental injection may cause local swelling, irritation or necrosis at the injection site.	

## 12. Ecological information

### Ecotoxicity

Components	Species	Test Results
Formaldehyde (CAS 50-00-0)		
<b>Aquatic</b>		
<b>Acute</b>		
Crustacea	EC50	Water flea (Daphnia magna) 29 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas) 24.1 mg/l, 96 hours
<b>Chronic</b>		
Fish	NOEC	Medaka, high-eyes (Oryzias latipes) > 48 mg/l, 28 days

Components	Species		Test Results
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.		
Partition coefficient n-octanol / water (log Kow)			
Formaldehyde		0.35	
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 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)

Formaldehyde (CAS 50-00-0) Listed.

#### SARA 304 Emergency release notification

Formaldehyde (CAS 50-00-0) 100 LBS

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Formaldehyde (CAS 50-00-0)  
 Cancer  
 Skin sensitization  
 Respiratory sensitization  
 Eye irritation  
 Skin irritation  
 respiratory tract irritation  
 Acute toxicity  
 Flammability

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

**Hazard categories**  
 Immediate Hazard - Yes  
 Delayed Hazard - No  
 Fire Hazard - No  
 Pressure Hazard - No  
 Reactivity Hazard - No

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

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

Formaldehyde (CAS 50-00-0)

Thimerosal (CAS 54-64-8)

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

Formaldehyde (CAS 50-00-0)

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** WARNING: This product contains a chemical known to the State of California to cause cancer.

**US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Formaldehyde (CAS 50-00-0) Listed: January 1, 1988

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

Thimerosal (CAS 54-64-8) Listed: July 1, 1990

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

Formaldehyde (CAS 50-00-0)

**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** 10-05-2017

**Version #** 01

**Disclaimer** As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health

0011+1-877-352-6261

0011+1-800-428-4441