SAFETY DATA SHEETS

This SDS packet was issued with item:

078429179

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078429187

NOVARTIS

MATERIAL SAFETY DATA SHEET

IDENTITY
Vira Shield 6 + Somnus Bacterin – Killed Virus **Product # 385, 386**

Section I

Manufacturer's Name Novartis Animal Health, US, Inc.	Emergency Telephone Number 800-454-3424
Address (Number, Street, City, State, and Zip Code)	Telephone Number for Information 800-843-3386
1447 140th Street	Date Prepared July 30, 2004 Revised Date: February 15, 2009
Larchwood, IA 51241-9778	Signature of Preparer (optional)

Section II - Hazardous Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other limits Recommended	% (optional)
Thimerosal (merthiolate)			0.01 mg of Hg/ m^3	$\leq$ 0.03

Thimerosal is an organomercury compound.

Section III - Physical/Chemical Characteristics

Boiling Point	NA	Specific Gravity (H_2O = 1)	NA
Vapor Pressure (mm Hg.)	NA	Melting Point	NA
Vapor Density (AIR = 1)	NA	Evaporation Rate (Butyl Acetate = 1)	NA

Solubility in Water
Yes

Appearance and Odor
Opaque liquid

Section IV - Fire and Explosion Hazard Data

Flash Point (Method Used)	Flammable Limits	LEL	UEL
NA	NA	NA	NA

Extinguishing Media
Dry chemical or carbon dioxide

Special Fire Fighting Procedures Wear protective clothing and a self contained breathing apparatus as appropriate for the surrounding fire.

Unusual Fire and Explosion Hazards None

Vira Shield 6 + Somnus Bacterin – Killed Virus

Section V - Reactivity Data			
Stability	Unstable		Conditions to Avoid Thimerosal will decompose with heat.
	Stable	X	
Incompatibility (Materials to Avoid) None			
Hazardous Decomposition or Byproducts Mercury, carbon monoxide, or carbon dioxide			
Hazardous Polymerization	May Occur		Conditions to Avoid None
	Will Not Occur	X	

Section VI - Health Hazard Data		
Route(s) of Entry:	Inhalation? Yes	Skin? Yes Ingestion? Yes
Health Hazards (Acute and Chronic) The product may be irritating in the case of skin or eye contact. Thimerosal is a toxic compound.		
Carcinogenicity:	NPT? No	IARC Monographs? No OSHA Regulated? No
Emergency and First Aid Procedures In case of skin or eye contact, flush with plenty of water. If the product is ingested, wash the mouth out with water and call a physician. In case of accidental injection, wash the puncture site and see a physician immediately.		

Section VII - Precautions for Safe Handling and Use
Steps to Be Taken in Case Material Is Released or Spilled
Clean up the spill with absorbent material, and afterwards, wash the site thoroughly with water.
Waste Disposal Method
Dispose in accordance with all applicable federal, state and local environmental regulations.
Precautions to Be Taken in Handling and Storing
Refrigerate the product (2° to 7° C) {35° to 45° F}. Keep the container closed when stored, and shake well before using.
Other Precautions N/A

Section VIII - Control Measures		
Respiratory Protection (Specify Type) An approved cartridge respirator for large spills		
Ventilation	Local Exhaust No	Special NA
	Mechanical (General) Yes	Other NA
Protective Gloves Vinyl or nitrile	Eye Protection Goggles	
Other Protective Clothing or Equipment NA		
Work/Hygienic Practices Take precautions to prevent accidental injections.		

Section IX - Regulatory Information

Component: Thimerosal

Mercury and mercury compounds are subject to CWA, SDWA, CAA, RCRA, CERCLA, SARA (Secs. 312 and 313), DOT and 29 CFR 1910.1200 regulations.

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This Material Safety Data Sheet and the information it contains is offered to you in good faith as accurate. We have reviewed any information contained in this data sheet which we received from sources outside our company. We believe that information to be correct but cannot guarantee its accuracy or completeness. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. No statement made in this data sheet shall be construed as a permission or recommendation for the use of any product in a manner that might infringe existing patents. Accordingly, no guarantee expressed or implied is made by Novartis Animal Vaccines, Inc. as to the results to be obtained based upon your use of the information, nor does Novartis Animal Vaccines, Inc. assume any liability arising out of your use of the information.

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SAFETY DATA SHEET

1. Identification

Product identifier **Vira Shield 6 + Somnus**

Other means of identification

Item Code ZD6155, AV6155

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	Inhalable fraction.
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 mm²/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)		
Acute		
Inhalation		
LC50	Rat	10500 mg/m³, 4 hours
Oral		
LD50	Rat	640 mg/kg

Components	Species	Test Results
Thimerosal (CAS 54-64-8)		
Acute		
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)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	29 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	24.1 mg/l, 96 hours
Chronic			
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

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