

## **SAFETY DATA SHEETS**

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

078446920

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

078446904



**MATERIAL SAFETY DATA SHEET**

<b>IDENTITY</b>		<b>Product # 307, 312</b>	
<b>Vira Shield 6 + VL5 - Bacterin - Killed Virus</b>			
<b>Section I</b>			
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 February 28, 2005	Revised Date: February 15, 2009	
Larchwood, IA 51241-9778	Signature of Preparer (optional)		
<b>Section II - Hazardous Ingredients/Identity Information</b>			
Hazardous Components (Specific Chemical Identity; Common Name(s))	OSHA PEL	ACGIH TLV	Other limits Recommended % (optional)
Thimerosal (merthiolate)	0.01 mg of Hg/ m <sup>3</sup>		≤ 0.03
Thimerosal is an organomercury compound.			
Formaldehyde	0.75 ppm	0.3 ppm	≤ 0.5
<b>Section III - Physical/Chemical Characteristics</b>			
Boiling Point	NA	Specific Gravity (H <sub>2</sub> O = 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			
<b>Section IV - Fire and Explosion Hazard Data</b>			
Flash Point (Method Used) NA	Flammable Limits NA	LEL NA	UEL 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 + VL5 - Bacterin - Killed Virus**

<b>Section V - Reactivity Data</b>			
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	
<b>Section VI - Health Hazard Data</b>			
Route(s) of Entry:	Inhalation?	Skin?	Ingestion?
	Yes	Yes	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? Yes IARC Monographs? Yes OSHA Regulated? Yes			
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.			
<b>Section VII - Precautions for Safe Handling and Use</b>			
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			
<b>Section VIII - Control Measures</b>			
Respiratory Protection (Specify Type)			
An approved cartridge respirator for large spills			
Ventilation	Local Exhaust	NO	Special NA
	Mechanical (General)	Yes	Other NA
Protective Gloves		Eye Protection	
Vinyl or nitrile		Goggles	
Other Protective Clothing or Equipment			
NA			
Work/Hygienic Practices			
Take precautions to prevent accidental injections.			

**Vira Shield 6 + VL5 - Bacterin - Killed Virus**

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.

Component: Formaldehyde

Formaldehyde is subject to SARA (Secs. 312 and 313), CERCLA, and 29 CFR 1910.1048 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

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Povidone-Iodine Cutaneous Solution

**Trade Name:** Povidone Iodine Solution

**Synonyms:** Povidone-Iodine

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as disinfectant, antiseptic

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Povidone-Iodine	25655-41-8	Not Listed	Acute Tox 4 (H312, H332)Acute 1 (H400)	0.85-1.2
Citric acid	77-92-9	201-069-1	Eye Irrit. 2A (H319)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium Phosphate	7632-05-5	231-558-5	Not Listed	*
Nonoxynol-9	26027-38-3	Not Listed	Not Listed	*
Polyethylene glycol 400	25322-68-3	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen and products of iodine.

**Fire / Explosion Hazards:** Not applicable

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### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

### Polyethylene glycol 400

Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	1000 mg/m <sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Povidone-Iodine

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

### Exposure Controls

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
<b>Hands:</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
<b>Respiratory protection:</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Brown
<b>Odor:</b>	None	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Polyethylene glycol 400</b>			
No data available			
<b>Nonoxynol-9</b>			
No data available			
<b>Sodium Phosphate</b>			
No data available			
<b>Water for injection</b>			
No data available			
<b>Citric acid</b>			
No data available			
<b>Povidone-Iodine</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		



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### Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

## 10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:** May cause eye irritation (based on components) .

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Citric acid

Rat Oral LD50 3000 mg/kg

#### Povidone-Iodine

Rat Oral LD50 > 8000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### Polyethylene glycol 400

Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

#### Citric acid

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Mild

#### Povidone-Iodine

Skin Irritation	Rabbit	Mild
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**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Povidone-Iodine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Sodium Phosphate

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### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 3
for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	231-558-5

#### Nonoxynol-9

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Polyethylene glycol 400

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 2
for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

#### Citric acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

#### Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

**Data Sources:** Publicly available toxicity information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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**Revision date:** 22-Feb-2018  
Product Stewardship Hazard Communication  
**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**