

# SAFETY DATA SHEETS

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

078026356

N/A

## MATERIAL SAFETY DATA SHEET

Section I – Product Information			
Product Name or Identity:	IMMUNOREGULIN® IMMUNOSTIMULANT		
Manufacturer's Name:	Neogen Corporation	Emergency Phone No.	859 254 1221
	944 Nandino Blvd.	Fax No.:	859 255 5532
	Lexington, KY 40511	e-mail:	<a href="mailto:inform@neogen.com">inform@neogen.com</a>
Date Prepared or Revised: 11/15/05			

Section II – Hazardous Ingredients / Identity Information			
Hazardous Components (Specific Chemical Identity: Common Names)	OSHA PEL (Permissible Exposure Limits)	ACGIH TLV (Threshold Limit Value)	Toxicity Data LD <sub>50</sub>
Non-hazardous component: Washed inactivated bacterial cell suspension of <i>Propionibacterium acnes</i> in saline solution.	N/A	N/A	N/A.
Hazardous component: Ethyl alcohol      12.5% v/v      CAS 64-17-5	1000 ppm	1000 ppm	Oral-Young rat 10.6 g/kg Oral-Old rat 7.06 g/kg

Section III – Physical Characteristics	
Boiling Point: N/A	Specific Gravity (H <sub>2</sub> O = 1): N/A
Vapor Pressure (mm Hg.): N/A	Melting Point: N/A
Vapor Density (AIR = 1): N/A	Evaporation Rate (Butyl Acetate = 1): N/A
Solubility in Water: Forms a suspension with water	
Appearance and Odor: Clear liquid with visible sediment. No characteristic odor.	

Section IV – Fire and Explosion Hazard Data	
Flash Point ( <i>Method Used</i> ): Not Flammable	Flammable Limits: LEL (Lower Explosive Limit) - N/A UEL (Upper Explosive Limit) - N/A
Extinguishing Media: N/A	
Special Fire Fighting Procedures:	
Unusual Fire and Explosion Hazards: N/A	

Section V – Reactivity Data			
Stability	Unstable		Conditions to Avoid: N/A
	Stable	X	
Incompatibility ( <i>Materials to Avoid</i> ):			
Hazardous Decomposition or Byproducts:			
Hazardous Polymerization	May Occur		Conditions to Avoid: N/A
	Will Not Occur	X	

<b>Section VI – Health Hazard Data</b>			
Route(s) of Entry:	Inhalation-Minor route	Skin-Minor route Eyes-Not considered eye irritant	Ingestion-Minor route
Health Hazards (Acute and Chronic)	Final product poses no known health risk		
Carcinogenicity: NTP-No reason to suspect that these antigens have carcinogenic potential. (National Toxicology Program)	IARC Monograph-Not listed (International Agency for Research in Cancer)	OSHA Regulated-Yes Ethyl alcohol content	
Signs and Symptoms of Exposure: No signs or symptoms of disease are known to be related with this product.			
Medical Conditions Generally Aggravated by Exposure: No applicable information found.			
Emergency / First Aid Procedures	Ingestion: No information available regarding adverse effects via ingestion. Ingestion not considered a likely route of exposure.		
	Inhalation: Not considered a route of potential exposure. Saline media is not volatile.		
	Eye Contact: Not considered an eye irritant. Flush eyes for several minutes with water after prolonged contact. If irritation develops, consult a physician.		
	Skin Contact: Not considered a skin irritant. Wash with soap and water after prolonged contact. If irritation develops, consult a physician.		

<b>Section VII – Precautions for Safe Handling and Use</b>
Accidental Release Measures: Recover spilled product by applying absorbent (towels, rags, sawdust, etc) to the spill. Shovel and sweep up the spilled product and absorbent waste and transfer to a suitable container.
Waste Disposal Method: Product may be deposited in trash and disposed of in a sanitary landfill in accordance with local, state and Federal regulations.
Handling and Storing: Do not store product over 100°F (37°C). Protect product from freezing.
Other Precautions: Avoid injection with product.

<b>Section VIII – Control Measures</b>		
Respiratory Protection (Specify Type): None required		
Ventilation	Local Exhaust: Ordinary exhaust adequate	Special:
	Mechanical (General):	Other:
Protective Gloves:	Eye Protection: Safety glasses or goggles	
Other Protective Clothing or Equipment: Normal work practices and equipment which minimizes prolonged skin or eye contact.		
Work / Hygienic Practices: Normal hygienic practices to minimize exposure.		

This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Neogen Corporation shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute **NO WARRANTY**.

## SECTION 1: Identification of the substance/mixture and of the company

### 1.1 Product identifier

- Product: ***Propionibacterium Acnes* Immunostimulant**
- Product Name(s): **EqStim<sup>®</sup>, ImmunoRegulin<sup>®</sup>**
- Product Part Number(s): **08890, 08891, 08891-CAN, 08892**
- Brand(s): NeogenVet<sup>®</sup>

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

- Use of the substance/preparation: Injectable suspension of inactivated *P. acnes* for use in horses or dogs. Follow label/insert directions carefully.
- Uses advised against: Restricted to use by or under the supervision of a licensed veterinarian. For veterinary use only. Do not use in conjunction with glucocorticoids or other immune suppressors. Do not use within 7 days of steroid therapy. Do not use when pregnancy is known or suspected or if cardiac condition exists. Do not treat food-producing animals within 21 days of slaughter.

### 1.3 Details of the supplier of the safety data sheet

- Name of Manufacturer: Neogen Corporation
- Address of Manufacturer: 1614 E. Kalamazoo St.  
Lansing, MI 48912  
USA
- Telephone: 859/254-1221 • 800/525-2022
- Email: [Inform@neogen.com](mailto:Inform@neogen.com)

### 1.4 Emergency telephone number

- Emergency Telephone: Chemtrec: 1 (800) 424-9300  
Outside USA and Canada: +1 (703) 527-3887

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## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

- Classification (29 CFR 1910.1200)
- Not classified as hazardous for supply
- Classification (WHMIS 2015 HPR)
- Not classified as hazardous for supply

### 2.2 Label elements

- Signal Word: None
- Symbols: None
- Hazard phrases  
None
- Precautionary Phrases  
Sterile when unopened.  
Do not freeze.  
Not for human use.

### 2.3 Other hazards

- Keep out of reach of children.
- May be combustible near sources of excessive heat or flame.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

### 3.2 Mixtures

This product is a mixture of the substances listed below with the addition of non-hazardous materials

Chemical	Concentration	CAS No.	H-Statements	Symbols
<i>Propionibacterium acnes</i> (inactivated)	0.5 – 1.0%	n/a	None	None
Ethanol	12.5%	64-17-5	H225	GHS02
Saline solution	86.5 – 87.0%	7647-14-5	None	None

Ingredients not precisely identified are proprietary or non-hazardous. Values are not product specifications.

- For full text of Hazard statements: see Section 16.

## SECTION 4 First aid measures

### 4.1 Description of first aid measures

- General  
In case of doubt, or when symptoms persist, seek medical attention.  
In general, this product is not hazardous to humans or animals, but like any other chemical, it should be treated with care, respect, and common sense.
- Contact with skin  
Remove contaminated clothing.  
Wash affected area with plenty of soap and water.  
If skin irritation or rash occurs: Get medical advice/attention.  
Contaminated clothing should be laundered before reuse.
- Contact with eyes  
If substance has gotten into eyes, rinse with plenty of water for at least 15 minutes.  
Irrigate eyes thoroughly while lifting eyelids.  
Seek medical advice if necessary.
- Ingestion  
Rinse mouth with water (do not swallow).  
May cause dizziness, nausea, confusion, headache, or visual disturbance if ingested in significant quantities.  
Never make an unconscious person vomit or drink fluids.  
If medical advice is needed, have product container or label at hand.
- Inhalation  
If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  
Call a poison center or doctor/physician if you feel unwell.

### 4.2 Most important symptoms and effects, both acute and delayed

- The most important known symptoms are described in the labeling (see Section 2.2) and/or in Section 11.

### 4.3 Indication of any immediate medical attention and special treatment needed

- Transitory local reactions at the injection site such as heat and minor swelling may occur. In the event of anaphylactoid reactions, epinephrine is antidotal.

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## SECTION 5: Fire-fighting measures

### 5.1 Extinguishing media

- In case of fire: use water spray, foam, carbon dioxide or dry agent for extinction.

### 5.2 Special hazards arising from the substance or mixture

- Smoke from fires is toxic. Take precautions to protect personnel from exposure.
- May be combustible near sources of excessive heat or flame.
- See Section 10.

### 5.3 Advice for firefighters

- Keep container(s) exposed to fire cool, by spraying with water.
- Wear chemical protection suit and positive-pressure breathing apparatus, if necessary.
- Wear protective clothing as per Section 8.

### 5.4 Hazardous Combustion Products

- May include carbon oxides.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Spills should be cleaned up immediately to avoid slip and fall accidents and injuries.
- Wear protective clothing as per Section 8.
- Evacuate personnel not directly involved in spill clean-up.
- Shut off source of leak/release, if safe to do so.
- Shut down and/or remove equipment in spill area, if safe to do so.
- Wash thoroughly after dealing with spillage.

### 6.2 Environmental Precautions

- Do not allow to enter public sewers and watercourses.
- Avoid releasing to the environment.

## SECTION 6: Accidental release measures (continued)

### 6.3 Methods and material for containment and cleaning up

- Absorb spillage in inert material and shovel up.
- Dike large spills as necessary.
- Place in sealable containers and label them.
- Ventilate the area and wash spill site after material pick-up is complete.
- Dispose of contaminated materials and wastes in accordance with local/national/international regulations.

### 6.4 Reference to other sections

- See Section 7 for storage. For disposal, see Section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Do not breathe mist/vapors/fumes/spray.
- Avoid contact with eyes.
- Do not eat, drink, smoke, or apply cosmetics when using this product.
- Eyewash bottles should be available.
- Wash hands thoroughly after using this substance.

### 7.2 Conditions for safe storage, including any incompatibilities

- Store at a temperature between 2-25°C (35-77°F) until opened, then 2-7°C (35-45°F) once opened.
- Shake well before use.
- Do not freeze.
- May be combustible near sources of excessive heat or flame.
- Sterile when unopened.
- Keep out of reach of children.

### 7.3 Specific end use(s)

- Injectable suspension of inactivated *P. acnes* for use in horses or dogs.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Components with workplace control parameters

Component	CAS No.	Value	Control Parameters	Basis
Ethanol	7784-30-7	TWA	1,000 ppm, 1,900 mg/m <sup>3</sup>	USA-OSHA Table Z-1 Limits for Air Contaminants - 1910.1000
		TWA	1,000 ppm, 1,900 mg/m <sup>3</sup>	USA-NIOSH Recommended Exposure Limits
		STEL	1,000 ppm	USA-ACGIH Threshold Limit Values (TLV)

### 8.2 Exposure controls

- Eyewash bottles should be available.
- No respiratory protection is needed if ventilation/extraction is adequate, otherwise wear approved respiratory protection.
- Wear protective gloves to prevent prolonged or repeated skin contact.
- Wear safety glasses approved to standard for ANSI Z87, according to the concentration and amount of dangerous substance at the specific workplace.
- Wear suitable protective clothing in accordance with good industrial hygiene and safety practices in the event of prolonged exposure to bulk quantities.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance: Clear liquid
- Odor: Odorless to slight alcohol-like odor
- pH: No information available
- Melting Point/Range: Not applicable
- Boiling Point/Range: No information available
- Flashpoint: No information available
- Evaporation Rate: No information available

## SECTION 9: Physical and chemical properties (continued)

- Flammability: No information available
- Vapor Pressure: No information available
- Vapor Density: No information available
- Specific Gravity: No information available
- Solubility in water: No information available
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: Product is not self-igniting
- Viscosity: No information available
- Explosive Properties: Product does not present an explosion hazard
- Oxidizing Properties: Product is not classified as an oxidizer

### 9.2 Other information

- Product may be combustible near sources of excessive heat or flame.

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

- No information available

### 10.2 Chemical stability

- Considered stable under normal conditions

### 10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose.

### 10.4 Conditions to avoid

- Do not freeze.
- May be combustible near sources of excessive heat or flame.

### 10.5 Incompatible materials

- None known

### 10.6 Hazardous Decomposition Products

- May include carbon oxides.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

- No experimental test data available for mixture
- ATE<sub>mix</sub> = 3,846 mg/kg (oral)
- Contact with skin  
May cause redness and irritation in sensitive individuals.  
Based on available data, the classification criteria are not met.
- Contact with eyes  
May cause redness and irritation in sensitive individuals.  
Based on available data, the classification criteria are not met.
- Ingestion  
Product is not toxic, but may cause nausea, dizziness, confusion, headache, or visual disturbances in sensitive individuals if significant quantities are ingested.  
Based on available data, the classification criteria are not met.
- Inhalation  
Not a likely route of exposure. May cause irritation in sensitive individuals if inhaled.  
Based on available data, the classification criteria are not met.
- Carcinogenicity  
Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens.  
Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112.  
Not listed in OSHA standard 1910.1003 Carcinogens.
- Mutagenicity  
No information available
- Teratogenicity  
No information available

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Ethanol

##### Toxicity to fish

LC<sub>50</sub> – *Leuciscus idus* (Golden orfe) – 8.14 mg/L-48h

##### Toxicity to daphnia and other aquatic invertebrates

EC<sub>50</sub> – *Daphnia magna* (Water flea) – 9268 mg/L-48h

EC<sub>50</sub> – *Daphnia magna* (Water flea) – 10800 mg/L-24h

#### Sodium chloride

##### Toxicity to fish

LC<sub>50</sub> – *Lepomis macrochirus* (Bluegill) – 5840 mg/L-96h

##### Toxicity to daphnia and other aquatic invertebrates

NOEC = 1500 mg/L-7d

EC<sub>50</sub> – *Daphnia magna* (Water flea) – 1661 mg/L-48h

### 12.2 Persistence and degradability

- No information available

### 12.3 Bioaccumulation Potential

- No information available

### 12.4 Mobility in soil

- No information available

### 12.5 Other Adverse Effects

- To the best of our knowledge, the properties of this material have not been fully evaluated.
- On available data, substance is not harmful to the environment.

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- Disposal should be in accordance with local, regional, national, and/or international regulations.
- Do not discharge into drains or the environment, dispose to an authorized waste collection point.
- Do not reuse empty containers.

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## SECTION 14: Transport information

### 14.1 UN Number

- 1987

### 14.2 UN Proper Shipping Name

- Alcohols, n.o.s. (Ethanol solution)

### 14.3 Transport hazard class(es)

- 3

### 14.4 Packing group

- II

### 14.5 Environmental hazards

- Not a marine pollutant

### 14.6 Special precautions for user

- None

### 14.7 Domestic Surface Transport (US DOT)

- Proper Shipping Name: Alcohols, n.o.s. (Ethanol solution)
- DOT UN No.: 1987
- DOT Hazard Class: 3
- DOT Packing Group: II

### 14.8 International Road/Rail (ADR/RID)

- Proper Shipping Name: Alcohols, n.o.s. (Ethanol solution)
- ADR UN No.: 1987
- ADR Hazard Class: 3
- ADR Packing Group: II
- Tunnel Code: 2 (D/E)

## SECTION 14: Transport information (continued)

### 14.9 Ocean/Sea (IMO/IMDG)

- Proper Shipping Name: Alcohols, n.o.s. (Ethanol solution)
- IMDG UN No.: 1987
- IMDG Hazard Class: 3
- IMDG Packing Group: II

### 14.10 Air (ICAO/IATA)

- Proper Shipping Name: Alcohols, n.o.s. (Ethanol solution)
- ICAO UN No.: 1987
- ICAO Hazard Class: 3
- ICAO Packing Group: II

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- The labeling requirements of the Virus-Serum-Toxin Act (VSTA) differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200. Following is the hazard information as required on the vaccine label:

RESTRICTED TO USE BY, OR UNDER THE SUPERVISION OF, A VETERINARIAN.  
FOR VETERINARY USE ONLY  
U.S. Vet. Lic. No. 302

### 15.2 United States Regulatory Information

#### SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

#### SARA 313 Components

The material does not contain any chemical components with known CAS numbers that exceed the threshold (de minimis) reporting levels established by SARA Title III, Section 313.

#### SARA 311/312

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	Yes
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

#### Toxic Substance Control Act (TSCA)

This product is exempt from TSCA under Section 3(2)(B)(vi) when used for pharmaceutical application.

#### State Right-to-Know

Massachusetts

Ethanol, CAS No. 64-17-5

New Jersey

Ethanol, CAS No. 64-17-5

Pennsylvania

Ethanol, CAS No. 64-17-5

#### California Prop 65

This product does not contain chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

### 15.3 Canadian Regulatory Information

- This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR). The labelling may differ subject to the requirements under the jurisdiction of the Center for Veterinary Biologics.

- WHMIS Classification: Exempt

- Inventory Status

Domestic Substances List (DSL)	Listed
Non-Domestic Substances List (NDSL)	Not listed

## SECTION 16: Other information

Document Number: SDS-0066, Propionibacterium Acnes Immunostimulant

Date of Preparation: June 7, 2016

Revision: Rev. 0

Replaces: New issue

Text not given with phrase codes where they are used elsewhere in this safety data sheet: H225: Highly flammable liquid and vapor.

This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Neogen Corporation shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute NO WARRANTY.