

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

1.1 Product identifier

- Product: ***Propionibacterium Acnes* Immunostimulant**
- Product Name(s): **EqStim[®], ImmunoRegulin[®]**
- Product Part Number(s): **08890, 08891, 08891-CAN, 08892**
- Brand(s): NeogenVet[®]

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

1.4 Emergency telephone number

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

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.

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.

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.

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 ³	USA-OSHA Table Z-1 Limits for Air Contaminants - 1910.1000
		TWA	1,000 ppm, 1,900 mg/m ³	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.

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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- No experimental test data available for mixture
- ATE_{mix} = 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

LC₅₀ – *Leuciscus idus* (Golden orfe) – 8.14 mg/L-48h

Toxicity to daphnia and other aquatic invertebrates

EC₅₀ – *Daphnia magna* (Water flea) – 9268 mg/L-48h

EC₅₀ – *Daphnia magna* (Water flea) – 10800 mg/L-24h

Sodium chloride

Toxicity to fish

LC₅₀ – *Lepomis macrochirus* (Bluegill) – 5840 mg/L-96h

Toxicity to daphnia and other aquatic invertebrates

NOEC = 1500 mg/L-7d

EC₅₀ – *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.

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.

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

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.