

SAFETY DATA SHEET

according to Regulation (EU) 2015/830

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ImmunoRegulin® (P. acnes Immunostimulant)

Revision 0
Revision date 2019-03-21

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

1.1. Product identifier

Product name	ImmunoRegulin® (P. acnes Immunostimulant)
Product code	08890, 08891, 08892

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

Product Use	[SU22] Professional uses: Public domain (administration, education, entertainment, services, craftsmen); [PC29] Pharmaceuticals;
Description	Injectable for use in horses and dogs.

1.3. Details of the supplier of the safety data sheet

Company	Neogen Corporation
Address	620 Leshar Place Lansing MI 48912 USA
Web	www.neogen.com
Telephone	517-372-9200/800-234-5333
Email	regulatorysupport@neogen.com

1.4. Emergency telephone number

Emergency telephone number	1-800-234-5333
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Further information


Manufactured By:	Neogen Corporation CME Center of Microbiological Excellence Building 1614 E. Kalamazoo Lansing, MI 48913 U.S.A.
Hotline(s):	Medical: United States (1-800-498-5743), International (1-651-523-0318). Spill/CHEMTREC: United States (1-800-424-9300), International (1-703-527-3887).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Flam. Liq. 3: H226;
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2.2. Label elements

Hazard pictograms	
Signal Word	Warning

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2.2. Label elements

Hazard Statement	Flam. Liq. 3: H226 - Flammable liquid and vapour.
Precautionary Statement: Prevention	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 - Keep container tightly closed. P240 - Ground/bond container and receiving equipment. P241 - Use explosion-proof electrical/ventilating/lighting// equipment. P242 - Use only non-sparking tools. P243 - Take precautionary measures against static discharge. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P370+P378 - In case of fire: Use media appropriate to the surrounding conditions to extinguish.
Precautionary Statement: Storage	P403+P235 - Store in a well-ventilated place. Keep cool.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to an approved waste disposal facility in accordance with local and national regulations.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Ethanol	603-002-00-5	64-17-5	200-578-6		10 - 20%	Flam. Liq. 2: H225;
Propionibacterium acnes (inactivated)					0.5 - 1%	

Further information

	The exact percentage (concentration) of composition has been withheld as a trade secret.
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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move the exposed person to fresh air. Seek medical attention if irritation or symptoms persist.
Eye contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	DO NOT INDUCE VOMITING unless advised to do so by a doctor. Seek medical attention if irritation or symptoms persist.

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

Inhalation	May cause irritation to respiratory system.
Eye contact	Causes serious eye irritation.
Skin contact	Causes skin irritation.
Ingestion	Ingestion may cause nausea and vomiting.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Flammable liquid. Burning produces irritating, toxic and obnoxious fumes.
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5.3. Advice for firefighters

	In case of fire and/or explosion do not breathe fumes. Wear suitable respiratory equipment when necessary.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Ensure adequate ventilation of the working area. Wear suitable protective equipment. Avoid contact with eyes and skin.
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6.2. Environmental precautions

	Prevent further spillage if safe. Do not flush into surface water. Do not let product contaminate subsoil.
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6.3. Methods and material for containment and cleaning up

	Absorb with inert, absorbent material. Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.
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6.4. Reference to other sections

	See section 2, 8, and 13 for further information.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.
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7.2. Conditions for safe storage, including any incompatibilities

	Flammable liquid. Avoid contact with: Heat, sparks and open flames. Keep in a cool, dry, well ventilated area. Keep containers tightly closed. Store in correctly labelled containers.
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7.3. Specific end use(s)

	See section 1.2 for further information.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

Ethanol	WEL 8-hr limit ppm: 1000	WEL 8-hr limit mg/m3: 1920
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total inhalable dust: -	WEL 15 min limit mg/m3 total inhalable dust: -
	WEL 8-hr limit mg/m3 total respirable dust: -	WEL 15 min limit mg/m3 total respirable dust: -

8.2. Exposure controls



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8.2. Exposure controls

8.2.1. Appropriate engineering controls	Ensure adequate ventilation of the working area.
8.2.2. Individual protection measures	Wear chemical protective clothing.
Eye / face protection	Wear eye/face protection.
Skin protection - Handprotection	Wear suitable gloves.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Clear
Odour	Odourless/Slight
Evaporation rate	No data available
Flammability (solid, gas)	Not applicable.
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available
Odour threshold	No data available
Initial boiling point	No data available
Flash point	< 49 °C
pH	No data available
Melting point	No data available
Freezing Point	No data available
Solubility	Soluble in water

SECTION 10: Stability and reactivity

10.1. Reactivity

	Flammable liquid and vapour.
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10.2. Chemical stability

	Stable under normal conditions.
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10.3. Possibility of hazardous reactions

	No data available.
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10.4. Conditions to avoid

	Keep away from sources of ignition - No smoking.
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10.5. Incompatible materials

	Strong oxidising agents.
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10.6. Hazardous decomposition products

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10.6. Hazardous decomposition products

Carbon oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	No known adverse health effects.
Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/irritation	Causes serious eye irritation.
Respiratory or skin sensitisation	May cause allergic reactions in susceptible people.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112. Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens. Not listed in the OSHA standard 1910.1003 Carcinogens.
Reproductive toxicity	No teratogenic effects reported.
STOT-single exposure	May cause irritation to respiratory system.
Repeated or prolonged exposure	Avoid prolonged or repeated exposure.

11.1.4. Toxicological Information

Ethanol	Oral Rat LD50: 10470 mg/kg Dermal Rabbit LD50: 15800 mg/kg	Oral Mouse LD50: 3450 mg/kg Inhalation Rat LC50/4 h: 30000 mg/kg
ImmunoRegulin® (P. acnes Immunostimulant)	Oral Rat LD50: 3846	

SECTION 12: Ecological information

12.1. Toxicity

Ethanol	Algae EC50/72h: 275 mg/l Fathead minnows LC50/96h: 14200 mg/l	Daphnia LC50/48h: 5012 mg/l
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12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

Partition coefficient

ImmunoRegulin® (P. acnes Immunostimulant)	No data available	Ethanol -0.349 log P
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of in compliance with all local and national regulations.

General information

Dispose of in compliance with all local and national regulations. Do not contaminate water by cleaning of equipment or disposal of wastes.

Disposal of packaging

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Disposal of packaging

Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.

SECTION 14: Transport information

Hazard pictograms



14.1. UN number

UN1170

14.2. UN proper shipping name

ETHANOL SOLUTION

14.3. Transport hazard class(es)

ADR/RID	3
Subsidiary risk	-
IMDG	3
Subsidiary risk	-
IATA	3
Subsidiary risk	-

14.4. Packing group

Packing group III

14.5. Environmental hazards

Environmental hazards	No
Marine pollutant	No

ADR/RID

Hazard ID	30
Tunnel Category	(D/E)

IMDG

EmS Code	F-E S-D
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IATA

Packing Instruction (Cargo)	366
Maximum quantity	220 L
Packing Instruction (Passenger)	355
Maximum quantity	60 L

SECTION 15: Regulatory information

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

Regulations	Hazard Communication Standard: 29 Code of Federal Regulations 1910.1200: Occupational Safety and Health Standards: Z: Toxic and Hazardous Substances: Hazard Communication. All chemicals in this product are TSCA listed or excluded from listing, on the United States
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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

	<p>Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory. TSCA - United States Toxic Substances Control Act Section 8(b) Inventory.</p> <p>US State Regulations: New Jersey Right-to-Know Hazardous Substance List: Ethanol</p> <p>Pennsylvania Right-to-Know Hazardous Substance List: Ethanol.</p> <p>Rhode Island Right-to-Know Hazardous Substance List: Ethanol.</p>
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SECTION 16: Other information

Other information

Text of Hazard Statements in Section 3	Flam. Liq. 2: H225 - Highly flammable liquid and vapour.
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Further information

	<p>DISCLAIMER: The information and recommendations set forth herein ("Information") are presented in good faith and believed to be correct as of the date issued. No representation is made regarding the completeness or accuracy of the Information. Further, because of the many factors that affect the use of this product, the Information is supplied upon the condition that the person(s) receiving it will make their own determination regarding its suitability for their own unique purpose(s), prior to use.</p> <p>Except as expressly stated herein, NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF PERFORMANCE, USAGE OF TRADE, OR RESULTS TO BE OBTAINED BY USE OF THIS PRODUCT are made with respect to this product or use of this product. The product covered is furnished "as is" and only subject to the warranties herein provided, no liability is assumed resulting from the use of this product.</p>
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