Affinity Resins in Ethyl Alcohol Solution (Aqueous)

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Date of Issue: 27/10/2023 Version: 1.1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

Product Form : Mixture

Product Name : Affinity Resins in Ethyl Alcohol Solution (Aqueous)

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

1.2.1. Relevant Identified Uses

Use of the Substance/Mixture : Laboratory chemicals

1.2.2. Uses Advised Against

Uses Advised Against : No uses advised against are specified

1.3. Details of the Supplier of the Safety Data Sheet

Company

Repligen Corporation
41 Seyon Street, Building 1, Suite 100
Waltham, MA 02453
USA
+1 781-250-0111

customerserviceUS@repligen.com

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification According to Regulation (EC) No. 1272/2008

Flam. Liq. 3 H226

Full text of hazard classes, H-statements: see section 16

2.2. Label Elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

Hazard Pictograms (CLP) :

GHS02

Signal Word (CLP) : Warning

Hazard Statements (CLP) : H226 - Flammable liquid and vapour.

Precautionary Statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting equipment.
P242 - Use non-sparking tools.
P243 - Take action to prevent static discharges.
P280 - Wear eye protection, protective clothing, protective gloves.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P370+P378 - In case of fire: Use appropriate media other to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other Hazards

Other Hazards Not Contributing to the Classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

This substance/mixture does not meet the PBT/vPvB criteria of REACH regulation, annex XIII

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Ethyl alcohol(64-17-5)	The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
Ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5	17,8 – 18,9	Flam. Liq. 2, H225

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-Aid Measures General : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-Aid Measures After Inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-Aid Measures After Skin Contact : Immediately drench affected area with water for at least 15 minutes. Immediately remove contaminated clothing. Obtain medical attention if irritation develops or persists. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

First-Aid Measures After Eye Contact : Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

First-Aid Measures After Ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Effects : Causes eye irritation.

Symptoms/Effects After Inhalation : Prolonged exposure may cause irritation.

Symptoms/Effects After Skin Contact : Prolonged exposure may cause skin irritation.

Symptoms/Effects After Eye Contact : May cause eye irritation.

Symptoms/Effects After Ingestion : Ingestion may cause adverse effects. May cause headache, dizziness, drowsiness, and loss of coordination.

Chronic Symptoms : Repeated exposure may cause skin dryness or cracking.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media : Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO_2). Water may be ineffective but water should be used to keep fire-exposed container cool.

Unsuitable Extinguishing Media : Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard : Flammable liquid and vapour. Alcohols burn with a pale blue flame that is difficult to see under normal lighting conditions.

Explosion Hazard : May form flammable or explosive vapour-air mixture. Vapours are heavier than air and may travel considerable distance to an ignition source and flash back to source of vapours.

Reactivity : Reacts violently with strong oxidisers. Increased risk of fire or explosion.

Hazardous Combustion Products : Carbon oxides (CO, CO_2).

5.3. Advice for Firefighters

Precautionary Measures Fire : Exercise caution when fighting any chemical fire.

Firefighting Instructions : Use water spray or fog for cooling exposed containers. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information : No additional information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures : If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Avoid breathing (vapour, mist, spray). Do not get in eyes, on skin, or on clothing. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Use special care to avoid static electric charges.

6.1.1. For Non-Emergency Personnel

Protective Equipment : Use appropriate personal protective equipment (PPE).

Emergency Procedures : Evacuate unnecessary personnel. Stop leak if safe to do so.

6.1.2. For Emergency Responders

Protective Equipment : Equip cleanup crew with proper protection.

Emergency Procedures : Upon arrival at the scene, a first responder is expected to recognise the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Eliminate ignition sources first, then ventilate the area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up : Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Do not take up in combustible material such as: saw dust or cellulosic material. Use only non-sparking tools. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed : Handle empty containers with care because residual vapours are flammable. Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling : Avoid contact with skin, eyes and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapours, mist, spray. Take precautionary measures against static discharge. Use only non-sparking tools.

Hygiene Measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures : Comply with applicable regulations. Take action to prevent static discharges. Ground and bond container and receiving equipment. Use explosion-proof electrical, ventilating, and lighting equipment.

Storage Conditions : Store in accordance with applicable national storage class systems. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in a well-ventilated place. Keep container tightly closed. Keep in fireproof place.

Incompatible Materials : Oxidizers. Acids. Halogens. Alkali metals.

7.3. Specific End Use(s)

Laboratory chemicals

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Please see section 16 for the legal basis of limit value information in section 8.1, including the national legislation or provision which gives rise to a given limit.

Ethyl alcohol (64-17-5)		
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	1900 mg/m³
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	1000 ppm
Austria	OEL STEL (Legal Basis:BGBl. II Nr. 254/2018)	3800 mg/m³
Austria	OEL STEL (Legal Basis:BGBl. II Nr. 254/2018)	2000 ppm
Belgium	OEL TWA (Legal Basis:Royal Decree 21/01/2020)	1907 mg/m³
Belgium	OEL TWA (Legal Basis:Royal Decree 21/01/2020)	1000 ppm
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	1000 mg/m³
Croatia	OEL TWA (Legal Basis:OG No. 91/2018)	1900 mg/m³
Croatia	OEL TWA (Legal Basis:OG No. 91/2018)	1000 ppm
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	1000 mg/m³
Denmark	OEL TWA (Legal Basis:BEK No. 698 of 28/05/2020)	1900 mg/m³
Denmark	OEL TWA (Legal Basis:BEK No. 698 of 28/05/2020)	1000 ppm
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	1000 mg/m³
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	500 ppm
Estonia	OEL STEL (Legal Basis:Regulation No. 105)	1900 mg/m³
Estonia	OEL STEL (Legal Basis:Regulation No. 105)	1000 ppm
Finland	OEL TWA (Legal Basis:HTP-ARVOT 2020)	1900 mg/m³
Finland	OEL TWA (Legal Basis:HTP-ARVOT 2020)	1000 ppm
Finland	OEL STEL (Legal Basis:HTP-ARVOT 2020)	2500 mg/m³
Finland	OEL STEL (Legal Basis:HTP-ARVOT 2020)	1300 ppm
France	OEL STEL (Legal Basis:INRS ED 984)	9500 mg/m³
France	OEL STEL (Legal Basis:INRS ED 984)	5000 ppm
France	OEL TWA (Legal Basis:INRS ED 984)	1900 mg/m³
France	OEL TWA (Legal Basis:INRS ED 984)	1000 ppm
Germany	OEL TWA (Legal Basis:TRGS 900)	380 mg/m³ (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Germany	OEL TWA (Legal Basis:TRGS 900)	200 ppm (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Greece	OEL TWA (Legal Basis:PWHSE)	1900 mg/m³
Greece	OEL TWA (Legal Basis:PWHSE)	1000 ppm
Hungary	OEL TWA (Legal Basis:Decree No. 05/2020)	1900 mg/m³
Hungary	OEL STEL (Legal Basis:Decree No. 05/2020)	3800 mg/m³
Ireland	OEL STEL (Legal Basis:2020 COP)	1000 ppm
USA ACGIH	OEL STEL (Legal Basis:IMDFN1)	1000 ppm
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	1000 mg/m³
Lithuania	OEL TWA (Legal Basis:HN 23:2011)	1000 mg/m³
Lithuania	OEL TWA (Legal Basis:HN 23:2011)	500 ppm
Lithuania	OEL STEL (Legal Basis:HN 23:2011)	1900 mg/m³
Lithuania	OEL STEL (Legal Basis:A-N 684)	1000 ppm
Netherlands	OEL TWA (Legal Basis:OWCRLV)	260 mg/m³
Netherlands	OEL STEL (Legal Basis:OWCRLV)	1900 mg/m³
Netherlands	OEL Chemical Category (Legal Basis:OWCRLV)	Skin notation
Norway	OEL TWA (Legal Basis:FOR-2020-04-06-695)	950 mg/m³
Norway	OEL TWA (Legal Basis:FOR-2020-04-06-695)	500 ppm
Norway	OEL STEL (Legal Basis:FOR-2020-04-06-695)	1187,5 mg/m³ (value calculated)
Norway	OEL STEL (Legal Basis:FOR-2020-04-06-695)	625 ppm (value calculated)
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	1900 mg/m³
Portugal	OEL TWA (Legal Basis:Portuguese Norm NP 1796:2014)	1000 ppm
Portugal	OEL Chemical Category (Legal Basis:Portuguese Norm NP 1796:2014)	A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans
Romania	OEL TWA (Legal Basis:Gov. Dec. No 1.218)	1900 mg/m³
Romania	OEL TWA (Legal Basis:Gov. Dec. No 1.218)	1000 ppm
Romania	OEL STEL (Legal Basis:Gov. Dec. No 1.218)	9500 mg/m³

Ethyl alcohol (64-17-5)		
Romania	OEL STEL (Legal Basis:Gov. Dec. No 1.218)	5000 ppm
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	960 mg/m³
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	500 ppm
Slovakia	OEL STEL (Legal Basis:Gov. Decree 33/2018)	1920 mg/m³
Slovenia	OEL TWA (Legal Basis:No. 79/19)	960 mg/m³
Slovenia	OEL TWA (Legal Basis:No. 79/19)	500 ppm
Slovenia	OEL STEL (Legal Basis:No. 79/19)	1920 mg/m³
Slovenia	OEL STEL (Legal Basis:No. 79/19)	1000 ppm
Spain	OEL STEL (Legal Basis:OELCAIS)	1910 mg/m³
Spain	OEL STEL (Legal Basis:OELCAIS)	1000 ppm
Sweden	OEL TLV (Legal Basis:AFS 2018:1)	1000 mg/m³
Sweden	OEL TLV (Legal Basis:AFS 2018:1)	500 ppm
Sweden	OEL STEL (Legal Basis:AFS 2018:1)	1900 mg/m³
Sweden	OEL STEL (Legal Basis:AFS 2018:1)	1000 ppm
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	1920 mg/m³
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	1000 ppm
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	960 mg/m³
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	500 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when flammable gases or vapours may be released. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection. Personal protective equipment should be chosen in accordance with Regulation (EU) 2016/425, CEN standards, and in discussion with the supplier of the protective equipment.

Materials for Protective Clothing : Chemically resistant materials and fabrics. Wear fire/flame resistant/retardant clothing.

Hand Protection : Wear protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Colour, Appearance : No data available

Odour : Alcohol-like

Odour Threshold : No data available

pH : No data available

Evaporation Rate : No data available

Melting Point : No data available

Freezing Point : No data available

Boiling Point : > 35 °C (95 °F)

Flash Point : > 23 °C (73,4 °F)

Auto-Ignition Temperature : ≥ 363 °C (685,4 °F)

Decomposition Temperature	: No data available
Flammability	: Flammable liquid
Vapour Pressure	: No data available
Relative Vapour Density At 20°C	: No data available
Relative Density	: No data available
Solubility	: Water: Partially miscible
Partition Coefficient n-Octanol/Water	: No data available
Viscosity	: No data available
Explosive Properties	: No data available
Oxidising Properties	: No data available
Explosive Limits	: No data available
Particle Aspect Ratio	: Not applicable
Particle Aggregation State	: Not applicable
Particle Agglomeration State	: Not applicable
Particle Specific Surface Area	: Not applicable
Particle Dustiness	: Not applicable

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reacts violently with strong oxidisers. Increased risk of fire or explosion.

10.2. Chemical Stability

Flammable liquid and vapour. May form flammable or explosive vapour-air mixture.

10.3. Possibility of Hazardous Reactions

Hazardous polymerisation will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, heat, hot surfaces, sparks, open flames, incompatible materials, and other ignition sources.

10.5. Incompatible Materials

Acids. Alkali metals. Halogens. Oxidisers.

10.6. Hazardous Decomposition Products

Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Hazard Classes As Defined In Regulation (EC) No 1272/2008

Likely Routes of Exposure	: Inhalation; Dermal; Oral; Eye contact
Acute Toxicity (Oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Ethyl alcohol (64-17-5)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124,7 mg/l/4h

Skin Corrosion/Irritation	: Not classified (Based on available data, the classification criteria are not met)
Eye Damage/Irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Single Exposure)	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity (Repeated Exposure)	: Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard	: Not classified (Based on available data, the classification criteria are not met)
Symptoms/Injuries After Inhalation	: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact	: Prolonged exposure may cause skin irritation.
Symptoms/Injuries After Eye Contact	: May cause eye irritation.

Symptoms/Injuries After Ingestion : Ingestion may cause adverse effects. May cause headache, dizziness, drowsiness, and loss of coordination.

Chronic Symptoms : Repeated exposure may cause skin dryness or cracking.

11.2. Information On Other Hazards

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to humans as it does not meet the criteria set out in section A of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

Component	
Ethyl alcohol (64-17-5)	This chemical is considered to have endocrine-disrupting properties with respect to animals and humans in the foetus, liver, producing changes to development, physiology, morphology as it meets the criteria set out in section A of Regulation (EU) 2017/2100, and/or the criteria set out in Regulation (EU) 2018/605. This conclusion is based on evidence from studies and data obtained from a literature search conducted on this chemical, and shows a link between the effects above and endocrine activity, which is relevant for humans.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Hazardous To The Aquatic Environment, Short–Term (Acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous To The Aquatic Environment, Long–Term (Chronic) : Not classified (Based on available data, the classification criteria are not met)

Ethyl alcohol (64-17-5)	
LC50 Fish	11200 mg/l
EC50 Crustacea	9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
ErC50 Algae	1000 mg/l
NOEC Chronic Crustacea	9,6 mg/l

12.2. Persistence and Degradability

Immobilized rProtein Solutions	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Immobilized rProtein Solutions	
Bioaccumulative Potential	Not established.

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0,35 at 24 °C (at pH 7.4)

12.4. Mobility in Soil

Immobilized rProtein Solutions	
Ecology - Soil	Leaches if exposed to water.

12.5. Results of PBT and vPvB Assessment

Does not contain any PBT/vPvB substances >= 0.1% assessed in accordance with REACH Annex XVIII

12.6. Endocrine Disrupting Properties

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

12.7. Other Adverse Effects

Other Adverse Effects : None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Treatment Methods : Product contaminated with biological materials should preferably be incinerated.

Sewage Disposal Recommendations : Do not dispose of waste into sewer.

Product/Packaging Disposal Recommendations : Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information : Handle empty containers with care because residual vapours are flammable.

Ecology - Waste Materials : Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
Not regulated per Special Provision 144	Not regulated per Special Provision 144	Not regulated per Special Provision A58	Not regulated per Special Provision 144	Not regulated per Special Provision 144
14.1. UN Number or ID Number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN Proper Shipping Name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport Hazard Class				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing Group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental Hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special Precautions For User

No additional information available

14.7. Maritime Transport in Bulk According to IMO instruments

Not applicable

SECTION 15: REGULATORY INFORMATION

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

15.1.1. EU-Regulations

15.1.1.1. REACH Annex XVII Information

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:

3(a) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F	Immobilized rProtein Solutions ; Ethyl alcohol
40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.	Ethyl alcohol

15.1.1.2. REACH Candidate List Information

Contains no substance(s) listed on the REACH Candidate List

15.1.1.3. POP (2019/1021) - Persistent Organic Pollutants Information

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

15.1.1.4. PIC Regulation EU (649/2012) - Export and Import of Hazardous Chemicals Information

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

15.1.1.5. REACH Annex XIV Information

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

15.1.1.6. Substances Depleting the Ozone layer (1005/2009) Information

No additional information available

15.1.1.7. EC Inventory Information

Ethyl alcohol (64-17-5)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.1.8. Other Information

No additional information available

15.1.2. National Regulations

No additional information available

15.1.3. International Inventory Lists

Ethyl alcohol (64-17-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active
Listed on the Canadian DSL (Domestic Substances List)
Listed on the Canadian IDL (Ingredient Disclosure List)
Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on KECL/KECI (Korean Existing Chemicals Inventory)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on the Japanese ISHL (Industrial Safety and Health Law)
Listed on INSQ (Mexican National Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)
Listed on the NCI (Vietnam - National Chemical Inventory)

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Date of Preparation or Latest Revision : 27/10/2023

Data Sources : Information and data obtained and used in the authoring of this safety data sheet could come from database subscriptions, official government regulatory body websites, product/ingredient manufacturer or supplier specific information, and/or resources that include substance specific data and classifications according to GHS or their subsequent adoption of GHS.

Other Information : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Full Text of H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.

Classification and Procedure Used to Derive the Classification for Mixtures According to Regulation (EC) 1272/2008 [CLP]:

Flam. Liq. 3	On basis of test data

Indication of Changes

No additional information available

Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists
ADN – European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road
ATE - Acute Toxicity Estimate
BCF - Bioconcentration Factor
BEI - Biological Exposure Indices (BEI)
BOD – Biochemical Oxygen Demand
CAS No. - Chemical Abstracts Service Number
CLP – Classification, Labeling and Packaging Regulation (EC) No 1272/2008
COD – Chemical Oxygen Demand
EC – European Community
EC50 - Median Effective Concentration
EEC – European Economic Community
EINECS – European Inventory of Existing Commercial Chemical Substances
EmS-No. (Fire) - IMDG Emergency Schedule Fire
EmS-No. (Spillage) - IMDG Emergency Schedule Spillage
EU – European Union
ErC50 - EC50 in Terms of Reduction Growth Rate
GHS – Globally Harmonized System of Classification and Labeling of Chemicals
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
IBC Code - International Bulk Chemical Code
IMDG - International Maritime Dangerous Goods
IPRV - Ilgalaikio Poveikio Ribinis Dydis
IOELV – Indicative Occupational Exposure Limit Value
LC50 - Median Lethal Concentration
LD50 - Median Lethal Dose
LOAEL - Lowest Observed Adverse Effect Level
LOEC - Lowest-Observed-Effect Concentration
Log Koc - Soil Organic Carbon-water Partitioning Coefficient
Log Kow - Octanol/water Partition Coefficient
Log Pow - Ratio of the equilibrium concentration (C) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, in this case octanol and water
MAK – Maximum Workplace Concentration/Maximum Permissible Concentration
MARPOL - International Convention for the Prevention of Pollution
NDS - Najwyzsze Dopuszczalne Stezenie
NDSCh - Najwyzsze Dopuszczalne Stezenie Chwilowe
NDSP - Najwyzsze Dopuszczalne Stezenie Pulapowe
NOAEL - No-Observed Adverse Effect Level
NOEC - No-Observed Effect Concentration
NRD - Nevirsytinas Ribinis Dydis
NTP – National Toxicology Program
OEL - Occupational Exposure Limits
PBT - Persistent, Bioaccumulative and Toxic
PEL - Permissible Exposure Limit
pH – Potential Hydrogen
REACH – Registration, Evaluation, Authorisation, and Restriction of Chemicals
RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
SADT - Self Accelerating Decomposition Temperature
SDS - Safety Data Sheet
STEL - Short Term Exposure Limit
STOT - Specific Target Organ Toxicity
TA-Luft - Technische Anleitung zur Reinhaltung der Luft
TEL TRK – Technical Guidance Concentrations
ThOD – Theoretical Oxygen Demand
TLM - Median Tolerance Limit
TLV - Threshold Limit Value
TPRD - Trumpalaikio Poveikio Ribinis Dydis
TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern
TRGS 552 – Technische Regeln für Gefahrstoffe - N-Nitrosamine
TRGS 900 - Technische Regel für Gefahrstoffe 900 – Arbeitsplatzgrenzwerte
TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische Grenzwerte
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
VOC – Volatile Organic Compounds
VLA-EC - Valor Límite Ambiental Exposición de Corta Duración
VLA-ED - Valor Límite Ambiental Exposición Diaria
VLE – Valeur Limite D'exposition
VME – Valeur Limite De Moyenne Exposition
vPvB - Very Persistent and Very Bioaccumulative
WEL – Workplace Exposure Limit
WGK - Wassergefährdungsklasse

Limit Value Legal Basis*

*Includes the below and any related regulations/provisions, and subsequent amendements

EU - 2019/1831 EU in accor. with 98/24/EC - Directive 2019/1831/EU of October 24, 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 2000/39/EC.

EU - 2019/1243/EU, and 98/24/EC) - Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and amendment Regulation (EU) 2019/1243.

Austria - BGBl. II Nr. 254/2018 - Ordinance on Limit Values for Workplace Substances and on Carcinogens from the Federal Ministry of Economics and Labour, Published in 2003, Appendix 1: Substance List, Published through: Ministry of Economics and Labour of the Republic of Austria amended through the Government Gazette II (BGBL. II) No 119/2004) & BGBl. II No. 242/2006, BGBl. II No. 243/2007, lastly changed through BGBl. I Nr. 51/2011), BGBl. II Nr. 186/2015, BGBl. II Nr. 288/2017 amended by BGBl. II Nr. 254/2018.

Austria - BLV BGBl. II Nr. 254/2018 - Ordinance on health monitoring at the workplace 2008, published through BGBl. II Nr. 224/2007 by Austria Minister for Labor and Social Affairs, Lastly changed through BGBl. II Nr. 254/2018

Belgium - Royal Decree 21/01/2020 - Royal decree amending title 1 relating to chemical agents in Book VI of the code of well-being at work, with regard to the list of limit values of exposure to chemical agents and title 2 relating to carcinogens, mutagens and reprotoxics of Book VI of the code of well-being at work (1)

Bulgaria - Reg. No. 13/10 -

Regulation No. 13 of December 30, 2003 on the Protection of Workers from Hazards Related to Exposure to Chemical Agents at Work Labor Code, Annex No.1 Limit values of chemical agents in the air of the working environment, and Annex № 2 Biological limit values of chemical agents and their metabolites (bio markers of exposure) or bio markers of effect Amended by: 71/2006, 67/2007, 2/2012, 46/2015, 73/2018, 5/2020), and Regulation No.10 of September 26, 2003 on the Protection of Workers from the Risks Associated with Exposure to Carcinogens and Mutagens at Work Annex No.1 Occupational Exposure Limits, Amended by: 8/2004, 46/2015, 5/2020

Croatia - OG No. 91/2018 - Regulation on the Protection of Workers from Exposure to Hazardous Chemicals at Work, the Limit Values of Exposure and the Biological Limit Values. Official Gazette No. 91 of October 12, 2018

Cyprus - KDP 16/2019 - Government of Cyprus Cabinet of Ministers Regulation 268/2001 - Safety and Health in the Working Environment (Chemical Substances) Article 38, As amended by Regulation 16/2019 and Cabinet of Ministers Regulation 153/2001 - Safety and Health in the Working Environment (Chemical Substances-Carcinogens), as amended by Regulation 493/2004 - Safety and Health in the Working Environment (Chemical Substances - Carcinogens) AND Law 47(I) 2000 - Occupational Health and Safety (Asbestos), as amended by Decree 316/2006.

Czech Republic - Reg. 41/2020 - Regulation 41/2020 amending Regulation 361/2007 of Coll. establishing Occupation Exposure Limits as amended

Czech Republic - Decree No. 107/2013 - Decree No. 107/2013 Coll., amending Decree No. 432/2003 Coll., laying down the conditions for the application of the work into categories, limit values for the parameters of biological exposure tests, collection of biological material conditions for the implementation of biological exposure tests and requirements for reporting work with asbestos and biological agents

Denmark - BEK No. 698 of 28/05/2020 - Order on Limit Values for Substances and Materials, The Statutory Order No. 507 of May 17, 2011, Appendix 1 - Limits for air pollution, etc. and Appendix 3 - Biological Exposure Values, Amended by: No. 986 of October 11, 2012, No. 655 of May 31, 2018, No. 1458 December 13, 2019, No. 698 of May 28, 2020

Estonia - Regulation No. 105 - Health and Safety Requirements for the Use of Dangerous Chemicals and Materials Containing Them and Occupational Exposure Limits to Chemical Agents

Government of the Republic, Regulation No. 105 of 20 March 2001, Amended 17 October 2019, and 17 January, 2020.

Finland - HTP-ARVOT 2020 - Concentrations Known to be Hazardous, 654/2020 OEL values 2020 Publications of Ministry of Social Affairs and Health 2020:24 Annexes1, 2 and 3.

France - INRS ED 984 - Occupational Exposure Limit Values to Chemical Agents in France Published 2016 by the INRS National Institute of Research and Safety Health and safety of work, revised, updated by: Decree 2016-344, JORF No 0119, and Decree 2019-1487.

France - Decree 2009-1570 - Decree 2009-1570 of December 15, 2009, relative to the control of chemical risk on workplaces.

Germany - TRGS 900 - Occupational Exposure Limits, Technical Rules for Dangerous Substances, latest amendment March, 2020

Germany - TRGS 903 - Biological Threshold Limits (BGW-Values), Technical

Greece - PWHSE - Occupational Exposure Limits - Protection of workers' health and safety from exposure to certain chemical substances during the workday, (latest amendment 82/2018) and Occupation Exposure Limits - Protection of workers' health and safety from exposure to certain carcinogenic and mutagenic chemical substances (latest amendment 26/2020), and Presidential Decree 212/2006 - Protection of workers that are exposed to asbestos.

Hungary - Decree 05/2020 - 5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers from the risks related to chemical agents

Ireland - 2020 COP - 2020 Code of Practice for the Chemical Agents Regulations, Schedule 1

Italy - Decree 81 - Title IX, Annex XLIII and XXXVIII, Professional Exposure Limits and Annex XXXIX Mandatory Biological Limit Values and Health Monitoring, Article 1, Law 123 of August 3, 2007, Legislative Decree 81 of April 9, 2008, Last amended: January 2020

Italy - IMDFN1 - Ministerial Decree of August 20, 1999 Final Note (1)

Latvia - Reg. No. 325 - Cabinet of Ministers Regulation No. 325 - Labour Protection Requirements when Coming in Contact with Chemical Substances at Workplaces, Amended by Cabinet of Ministers Regulation No. 92, 163, 407 and No. 11.

Lithuania - HN 23:2011 - Lithuanian Hygiene Standard HN 23:2011 Occupational Exposure Limit Values, Amended by Order V-695/A1-272.

Luxembourg - A-N 684 - Grand-Ducal Regulation of 20 July 2018 amending the Grand-Ducal Regulation of 14 November 2016 concerning the protection of the safety and health of employees against the risks associated with chemical agents in the workplace. Official journal of the Grand-Duke of Luxembourg, A-N°684 of 2018

Malta - MOSHAA Ch. 424 - Malta Occupational Health and Safety Authority Act: Chapter 424 as amended by: Legal Notice 353, 53, 198, and 57.

Netherlands- OWCRLV - Occupational Working Conditions Regulation, Limit Values for substances harmful to health, Annex XVIII, Updated from August 1, 2020.

Norway - FOR-2020-04-060695 - Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents, FOR-2011-12-06-1358, Updated by: FOR-2020-04-06-695, FOR-2020-03-23-402, FOR-2018-12-20-2186, FOR-2018-08-21-1255, FOR-2017-12-20-2353.

Poland - Dz. U. 2020 Nr. 61 - Regulation of the Minister of Family, Labor and Social Policy of June 12, 2018 on the Highest Allowable Concentrations and Intensities of Factors Harmful to Health in the Work Environment Dz.U. 2018 Nr. 1286 of June 12, 2018, Annex 1 - List of values of the highest permissible chemical concentrations and dust factors harmful to health in the work environment, amended by: Dz. U. 2020 Nr. 61.

Portugal - Portuguese Norm NP 1796:2014 - Occupational exposure limits and biological exposure indices to chemical agents. Table 1 - Occupational exposure limits and biological exposure indices to chemical agents (OELs), Law Decree 35/2020.

Romania - Gov. Dec. No 1.218 - Governmental Decision No. 1.218 from 06/09/2006 on the minimum health and safety requirements for protection of workers from the risks related to exposure to chemical agents, Annex No. 1 Mandatory National Occupational Exposure Limit Values for Chemical Agents. Amended by Decision no. 157, 584, 359, and 1.

Slovakia - Gov. Decree 33/2018 - Government Decree of Slovak Republic 33/2018 on January 17, 2018 amending Government Decree of Slovak Republic 355/2006 about protection of health of employees when working with chemical agents

Slovenia - No. 79/19 - Regulation for protection of workers against risks related to carcinogenic or mutagenic substances exposure. Annex III - Classification and binding levels of carcinogenic or mutagenic substances for occupational exposure. The Official Journal of the Republic of Slovenia, No. 101/2005. Amended by 38/15, 79/19. Regulation for protection of workers against risks related to exposure to chemical substances at the workplace. Republic of Slovenia, No. 100/2001 . Annex I - List of Binding Occupational Exposure Limit Values. Amended by 39/05, 53/07, 102/10, 38/15, 78/18, 78/19

Spain - AFS 2018:1 - NATIONAL INSTITUTE FOR HEALTH AND SAFETY AT WORK. Occupational exposure limits for chemical agents in Spain. Tables 1 and 3. Latest edition Feb. 2019

Sweden - AFS 2018:1 - Statute Book of the Swedish Work Environment Authority, AFS 2018:1

The Swedish Work Environment Authority's Ordinance and General Guidance on Hygienic Limit Values

Switzerland - OLVSNAIF - Occupational Limit Values 2020 Swiss National Accident Insurance Fund. List of Biological Limit Values (BAT-Werte) and List of MAK Values.

Rules for Dangerous Substances, latest amendment March, 2020
Gibraltar - LN. 2018/131 - Factories (Control of Chemical Agents at Work) Regulations 2003 LN. 2003/035, amended by LN. 2008/035, LN. 2008/050, LN. 2012/021, LN. 2015/143, LN. 2018/181.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

EU GHS SDS (2020/878)