

according to Regulation (EC) No 1907/2006

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**Protein in PBS Buffer** 

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

# 1.1. Product identifier

Product name:	Protein in PBS Buffer
Article number:	AGX-5-000-0114 Clostridium difficile ToxA (C-term)
	AGX-5-000-0117 Clostridium difficile ToxB (C-term)
	AGX-5-000-0131 Borrelia burgdorferi OspC
	AGX-5-000-0132 Borrelia garinii OspC
	AGX-5-000-0135 Borrelia afzelii p39
	AGX-5-000-0139 Borrelia afzelii DbpA
	AGX-5-000-0140 Borrelia burgdorferi DbpA
	AGX-5-000-0141 Borrelia garinii DbpA
	AGX-5-000-0143 Borrelia afzelii OspA
	AGX-5-000-0190 Borrelia burgdorferi p41 (N-term)
	AGX-5-000-0198 Borrelia spielmanii DbpA
	AGX-5-000-0199 Borrelia spielmanii OspC
	AGX-5-000-0200 Borrelia afzelii OspC
	AGX-5-000-0204 Borrelia garinii p58
	AGX-5-000-0206 Borrelia afzelii VIsE
	AGX-5-000-0213 Clostridium difficile GDH
	AGX-5-000-0231 Borrelia garinii (Pbi) OspC
	AGX-5-000-0256 Clostridium difficile GDH
	AGX-5-000-0430 Rotavirus capsid VP6 (strain SA11)
	AGX-5-000-0443 Borrelia afzelii p83/100
	AGX-5-000-1043 SARS-CoV2 Nucleocapsid
REACH Registration Number:	not applicable

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

# Use of the substance/mixture

For research use and further manufacturing. Restricted to professional users.

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

Company name:	Seramun Diagnostica GmbH	
Street:	Spreenhagener Str. 1	
Place:	D-15754 Heidesee	
Telephone: E-mail:	+49 33767 791-10 quality@seramun.com	
1.4. Emergency telephone number:	+49 33767 791-10 from 9:00 am to 3:00 pm CET, excluding weekends and public holidays	

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

# Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

# 2.2. Label elements

# Labelling of packages where the contents do not exceed 125 ml

#### 2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

# **SECTION 3: Composition/information on ingredients**

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# 3.2. Mixtures

# Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

# **SECTION 4: First aid measures**

# 4.1. Description of first aid measures

## General information

When in doubt or if symptoms are observed, get medical advice.

#### After inhalation

Provide fresh air.

#### After contact with skin

Wash with plenty of water.

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing.

# After ingestion

Rinse mouth thoroughly with water.

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

No information available.

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

Treat symptomatically.

#### **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

#### Suitable extinguishing media

Foam Dry extinguishing powder Carbon dioxide (CO2)

#### Unsuitable extinguishing media

Full water jet

# 5.2. Special hazards arising from the substance or mixture

No known hazardous decomposition products.

# 5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

# **SECTION 6: Accidental release measures**

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

#### General advice

Use personal protection equipment.

#### For non-emergency personnel

Wear personal protection equipment (refer to section 8).

#### For emergency responders

Use personal protective equipment as required.

# 6.2. Environmental precautions

No special environmental measures are necessary.



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# 6.3. Methods and material for containment and cleaning up

#### For containment

Take up mechanically.

### For cleaning up

Wipe up with absorbent material (eg. cloth, fleece).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

## **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

# Advice on safe handling

Observe instructions for use.

Advice on protection against fire and explosion No special fire protection measures are necessary.

#### Advice on general occupational hygiene

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Take off contaminated clothing.

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

## Requirements for storage rooms and vessels

Keep container tightly closed. Keep cool. Keep/Store only in original container. Never return spills in original containers for re-use.

#### Hints on joint storage

Keep away from: Food and feedingstuffs

# Further information on storage conditions

storage temperature at <= -70 °C .

# 7.3. Specific end use(s)

For research use and further manufacturing. Restricted to professional users.

### **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

## Additional advice on limit values

To date, no national critical limit values exist.

# 8.2. Exposure controls

# Individual protection measures, such as personal protective equipment

### Eye/face protection

Eye protection: not required.

### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable material: NBR (Nitrile rubber)

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Thickness of the glove material >= 0.1 mm		
Breakthrough time: > 480 min		
Take recovery periods for skin regeneration.		
Skin protection		
Use of protective clothing.		
Respiratory protection		

Usually no personal respirative protection necessary.

# Thermal hazards

No special handling advices are necessary.

# **Environmental exposure controls**

No special environmental measures are necessary.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state:	Liquid		
Colour:	colourless		
Odour:	odourless		
			Test method
Changes in the physical state			
Melting point/freezing point:		not determined	
Boiling point or initial boiling point and boiling range:		100 C	Calculation method.
Flash point:		380 °C	Calculated flash point.
Flammability			
Solid/liquid:		not determined	
Explosive properties The product is not: Explosive.			
Lower explosion limits:		not determined	
Upper explosion limits:		not determined	
Auto-ignition temperature:		not determined	
Decomposition temperature:		not determined	
pH-Value (at 20 °C):		7.2-7.4	Experimental data
Viscosity / kinematic:		not determined	
Water solubility: (at 20 °C)		not determined	
Solubility in other solvents not determined			
Partition coefficient n-octanol/water:		not applicable	
Vapour pressure: (at 20 °C)		not determined	
Vapour pressure: (at 50 °C)		not determined	
Density (at 20 °C):		1.01 g/cm <sup>3</sup>	Calculation method.
Relative vapour density:		not determined	
Particle characteristics:		not applicable	
2. Other information			

<u>9.2</u>

Information with regard to physical hazard classes



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Oxidizing properties

The product is not: oxidising.

# Other safety characteristics

# Solid content:

# **Further Information**

not determined

No known hazardous decomposition products.

# **SECTION 10: Stability and reactivity**

# 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

# 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

### 10.4. Conditions to avoid

Keep away from heat.

# 10.5. Incompatible materials

No information available.

## 10.6. Hazardous decomposition products

No known hazardous decomposition products.

# **SECTION 11: Toxicological information**

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

# Acute toxicity

Based on available data, the classification criteria are not met.

# **ATEmix calculated**

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

# Irritation and corrosivity

Based on available data, the classification criteria are not met.

### Sensitising effects

Based on available data, the classification criteria are not met.

# Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

# STOT-single exposure

Based on available data, the classification criteria are not met.

# STOT-repeated exposure

Based on available data, the classification criteria are not met.

# Aspiration hazard

Based on available data, the classification criteria are not met.

### Information on likely routes of exposure

No information available.

### Additional information on tests

There are no data available on the preparation/mixture itself.

# 11.2. Information on other hazards

# Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

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# **Further information**

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

# **SECTION 12: Ecological information**

# 12.1. Toxicity

# The product is not: Ecotoxic.

# 12.2. Persistence and degradability

The single components are biodegradable.

### 12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

# 12.4. Mobility in soil

The product has not been tested.

# 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

# 12.7. Other adverse effects

No information available.

# **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

### **Disposal recommendations**

Dispose of waste according to applicable legislation.

### List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

# List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

### List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

#### Contaminated packaging

Non-contaminated packages may be recycled.

# **SECTION 14: Transport information**

# Land transport (ADR/RID)

 14.1. UN number or ID number:

 14.2. UN proper shipping name:

 14.3. Transport hazard class(es):

 14.4. Packing group:

 Inland waterways transport (ADN)

14.1. UN number or ID number: 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.

No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.



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14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.	
14.4. Packing group:	No dangerous good in sense of this transport regulation.	
Marine transport (IMDG)		
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.	
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.	
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.	
14.4. Packing group:	No dangerous good in sense of this transport regulation.	
Air transport (ICAO-TI/IATA-DGR)		
14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.	
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.	
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.	
14.4. Packing group:	No dangerous good in sense of this transport regulation.	
14.5. Environmental hazards		
ENVIRONMENTALLY HAZARDOUS:	No	
14.6. Special precautions for user		
No dangerous good in sense of this transport regulation.		
14.7. Maritime transport in bulk according to IMO instruments		
No dangerous good in sense of this transport regulation.		
SECTION 15: Regulatory information		
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture		

EU regulatory information	
Information according to 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)
National regulatory information	
Water hazard class (D):	non-hazardous to water
15.2. Chemical safety assessment	

#### Chemical safety assessments for substances in this mixture were not carried out.

# **SECTION 16: Other information**

#### Abbreviations and acronyms

CLP: Classification, labelling and Packaging REACH: Registration, Evaluation and Authorization of Chemicals GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals **UN: United Nations** CAS: Chemical Abstracts Service DNEL: Derived No Effect Level DMEL: Derived Minimal Effect Level PNEC: Predicted No Effect Concentration ATE: Acute toxicity estimate LC50: Lethal concentration, 50% LD50: Lethal dose, 50% LL50: Lethal loading, 50% EL50: Effect loading, 50% EC50: Effective Concentration 50% ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration BCF: Bio-concentration factor PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

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ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) RID: Regulations concerning the international carriage of dangerous goods by rail ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures) IMDG: International Maritime Code for Dangerous Goods EmS: Emergency Schedules MFAG: Medical First Aid Guide IATA: International Air Transport Association ICAO: International Civil Aviation Organization MARPOL: International Convention for the Prevention of Marine Pollution from Ships IBC: Intermediate Bulk Container SVHC: Substance of Very High Concern For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

# **Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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