

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 PRODUCT IDENTIFIER

PRODUCT NAME:

Borrelia afzelii OspC dimeric

CATALOG NUMBER:

AGX-5-001-0710-0/AGX-5-001-0710-1

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

The product is for use in research and manufacturing only.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Seramun Diagnostica GmbH

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15754 Heidesee

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1.4 EMERGENCY TELEPHONE NUMBER

Phone: +49 33767-791-10 available only during office hours.

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

This product does not need to be classified according to the European Regulation (EC) 1272/2008. The product should be handled with the usual care for all chemicals, in order to avoid synergistic effects.

2.2 LABEL ELEMENTS

Labels according European regulation (EC) 1272/2002 (CLP):

Pictogram none

Signal word none

Hazard Statement(s) none

Precautionary Statement(s) none

Supplemental Hazard Statements none

This product does not need to be labeled in accordance with EC directives or respective national laws.

2.3 OTHER HAZARDS

Chemicals bear specific risks. That's why these are only handled by qualified staff in compliance with health and safety regulations. None of the components is listed as PBT or vPvB relevant.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Aqueous solution of *Borrelia afzelii* OspC dimeric. The product is a mixture.

3.2 MIXTURES

The recombinant protein is a biological substance and therefore not subject for safety regulations of chemicals. The recombinant protein is solved in an appropriate buffer. Concentration of dangerous

components according to regulation (EC) 1272/2008 are below the concentration limits mentioned in the law.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration.

Consult a physician.

In case of skin contact

Wash off with plenty of water. Consult a physician.

In case of eye contact

Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

If swallowed

Never give anything by mouth to an unconscious person.

Rinse mouth with water, drink about 300 ml water, consult a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No data available.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available.

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media

Use water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The product itself is difficult to ignite; extinguishing measures should therefore be prepared for an environmental fire.

In case of fire toxic vapors, e.g. nitric oxide and carbon monoxide, can be released.

5.3 ADVICE FOR FIREFIGHTERS

Wear breath protective mask and protective clothes if necessary during fire fighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Keep away from drains. Avoid contamination of water or soil.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Suck up with inert absorbance material and dispose as waste. Keep in a suitable, closed container.

6.4 REFERENCE TO OTHER SECTIONS

For personal protection see chapter 8.

For disposal considerations see chapter 13.

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

No smoking, eating, drinking, chewing gum or storage of food or beverages in the working laboratories. Wash hands after work. Remove safety clothing before entering a refreshment room.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store tightly closed at a cool dry place. Reseal opened bottles carefully and store in an upright position.

Recommended storage temperature: -70°C or below

Storage classification: 12 (non flammable liquids)

segregate from: class 1 (explosives)
class 4.1A (flammable solids)
class 4.3 (dangerous when wet)
class 5 (oxidizing substances)
class 6.2 (infectious)
class 7 (radioactive)

Further advises:

Separate from foodstuffs.

Protect from unauthorized access.

7.3 SPECIFIC END USE(S)

Use only in accordance to the Product Data Sheet.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

If the product is used in a laboratory with adequate ventilation, no air pollution is to be expected.

8.2 EXPOSURE CONTROLS

Consider the usual good hygiene and safety practice by handling chemicals.

Personal protective equipment

Eye/face protection: Safety glasses with side shields conforming to EN 166 (EC), NIOSH (US)

Skin protection: protective gloves of nitril rubber (thickness min. 0.28 mm, AQL1,5) or nature latex (thickness min. 0.22 mm, AQL 1,5), satisfying the norm EN 374

Body protection: impermeable protective clothing, the kind of protective equipment has to be selected depending from concentration and amount of dangerous substance at the specific workplace.

Respiratory protection: not required, if handled according to the intended use. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

Environmental exposure controls: Keep away from drains, water or soil.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Description	liquid product
Colour	clear solution
Odour	odourless
pH-value	pH 7.5-8.5
boiling point	not determined

Flash point	not determined
Explosive properties	none
Oxidizing properties	none
Vapour pressure	not determined
Relative density	not determined
Solubility	complete soluble/miscible in water
Water solubility	complete soluble/miscible
Viscosity	not determined

9.2 OTHER INFORMATION

No further dangerous properties known.

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No data available.

10.2 CHEMICAL STABILITY

Stable under recommended storage at -70°C or below.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No hazardous reactions are to be expected.

10.4 CONDITIONS TO AVOID

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

10.5 INCOMPATIBLE MATERIALS

Complex forming agents, heavy metal salts will not cause a dangerous reaction, but may destroy the quality of the product.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Dangerous decomposition products are not known.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

(a) acute toxicity

The mixtures are not classified to be toxic (see chapter 15.1).

(b) skin corrosion/irritation

No information available.

(c) serious eye damage/irritation

No information available.

(d) respiratory or skin sensitization

Sensitization or allergic reaction cannot be completely excluded.

(e) germ cell mutagenicity

No information available.

(f) carcinogenicity

No information available.

(g) reproductive toxicity

No information available.

(h) STOT-single exposure

No specific target organ toxicant because no component is known as specific target organ toxicant.

(i) STOT-repeated exposure

No specific target organ toxicant because no component is known as specific target organ toxicant.

(j) aspiration hazard

No information available.

11.2 FURTHER TOXICOLOGICAL INFORMATION

Quantitative data on the toxicity of the mixture is not available.

Calculation of ATE according to (EC) 1272/2008, Appendix I: see section 15.1.

Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

The mixture is not classified to be toxic to water organisms, calculated $L(E)C_{50} > 100$ mg/l (see chapter 15.1).

12.2 PERSISTENCE AND DEGRADABILITY

No data available.

12.3 BIOACCUMULATIVE POTENTIAL

No data available.

12.4 MOBILITY IN SOIL

No data available.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

None of the components is listed as PBT or vPvB relevant.

12.6 OTHER ADVERSE EFFECTS

No further effects known.

If used appropriately, no ecological problems are to be expected.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product:

Disposal should be made in accordance with national and local regulations and laws.

Packaging:

Emptied packaging can be given to local recycling or waste disposal.

14. TRANSPORT INFORMATION

14.1 UN NUMBER

ADR/RID: -

IMDG: -

IATA: -

14.2 UN PROPER SHIPPING NAME

ADR/RID: No dangerous goods

IMDG: No dangerous goods

IATA: No dangerous goods

14.3 TRANSPORT HAZARD CLASS(ES)

ADR/RID: - IMDG: - IATA: -

14.4 PACKING GROUP

ADR/RID: - IMDG: - IATA: -

14.5 ENVIRONMENTAL HAZARDS

ADR/RID: No IMDG: Marine pollutant no IATA: No

14.6 SPECIAL PRECAUTIONS FOR USER

No data available

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE

The product will be shipped only in approved card boxes.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet meets the requirements of the Regulations (EC) 453/2010 to amending Regulation (EC) 1907/2006.

The calculated toxicity (ATE) of the mixture according (EC) 1272/2008, Annex I in mg/kg body weight:

>2,000 - no classification (see chapter 16.)

According (EC) 1272/2008, Annex I no classification as hazardous to water.

(calculated L(E)C₅₀ of the mixture: >100 mg/l)

Water endangering class according to VwVwS (Germany): Water endangering class 1

15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

16. OTHER INFORMATION

Categories of the Acute Toxicity (ATE) according EC 1272/2008:

Category 1	0< ATE ≤5	(oral in mg/kg body weight)
Category 2	5< ATE ≤50	(oral in mg/kg body weight)
Category 3	50< ATE ≤300	(oral in mg/kg body weight)
Category 4	300< ATE ≤2,000	(oral in mg/kg body weight)

Further information:

The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action.

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Changes with respect to the previous version:

- no previous version