classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 1 of 7

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

1.1 Product identifier

Brand name: Brucella abortus Antigen

Product no.: BA116VS

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

Identified use: In vitro diagnostic agent or component of an in vitro diagnostic agent

Discouraged uses: No other relevant information available.

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH Friedrich-Bergius-Ring 19 97076 Würzburg Germany

Tel. 0049 (0) 931 – 30 45 0 Fax 0049 (0) 931 – 30 45 100 Email dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer: 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 a.m. to 4:00 p.m.)

Section 2: Possible hazards

2.1 Classification of the substance or mixture

Classification per Regulation (EC) No. 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

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

2.3 Other hazards

This product contains chemically and/or physically inactivated biological agents and should be considered potentially infectious. The mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

Section 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Component **Phenol** (fraction: < 1 %):

EG no.: 203-632-7; INDEX no.: 604-001-00-2; CAS no.: 108-95-2

Classification (Regulation (EC) No. 1272/2008:

- Toxic in contact with skin, Category 3, H311
- Toxic if inhaled, Category 3, H331
- Toxic if swallowed, Category 3, H301
- Causes severe skin burns and eye damage, Category 1B, H314
- Suspected of causing genetic defects, Category 2, H341
- May cause damage to organs through prolonged or repeated exposure, Category 2, H373
- Toxic to aquatic life with long lasting effects, Category 2, H411

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 2 of 7

Section 4: First aid measures

4.1 Description of first aid measures

General instructions: Administer artificial respiration for irregular respiration or respiratory arrest.

Consult a doctor immediately.

After inhalation: Fresh air or administer oxygen. Consult a doctor.

After skin contact: Wash off with plenty of water. Remove contaminated clothing immediately.

Use skin disinfectant at the affected areas. Consult a doctor.

After eye contact: Flush eyes with plenty of water and intermittently lift the upper and lower

eyelids. Check for contact lenses and remove if present. Consult a doctor.

After swallowing: Rinse out mouth and drink plenty of water. Do not induce vomiting. Consult

a doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

Component Phenol (< 1 %):

Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. Spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, burning sensation, cough, wheezing, laryngitis, shortness of breath, headache, vomiting.

4.3 Indication of any immediate medical attention or special treatment needed

No information available.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Use extinguishing measures appropriate to the environment.

Unsuitable extinguishing media:

For this substance/mixture there are no limitations on extinguishing agents.

5.2 Special hazards related to this substance or mixture

Non-combustible. In case of fire may be liberated: May produce toxic fumes.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Self-contained breathing apparatus required when in the hazard area. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not inhale vapors/aerosols. Avoid contact with substance. Ensure adequate ventilation. Evacuate the danger zone, follow the emergency plan, consult specialists.

6.1.2 Information for emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

No specific procedures required.

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 3 of 7

6.3 Methods and materials for containment and cleaning up

Remove containers from the discharge area. Avoid discharging in sewer system, bodies of water, basements or closed areas. Take up material and put in appropriately labeled waste containers. Dispose of using an accredited waste disposal company. Clean.

6.4 Reference to other sections

Instructions for disposal see section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Avoid exposure. Follow the instructions on the label.

7.1.2 Hygiene measures

Change contaminated clothing immediately. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:

Store only in original container.

7.3 Specific end uses

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

Section 8: Limiting and monitoring exposure/ personal protective equipment

8.1 Parameters to be monitored

Component Phenol (< 1 %)

EG-Nr.	Workplace limit value		Peak limit	
CAS-Nr.	mL/m³ (ppm)	mg/m³	Exceeding factor	Comment
203-632-7	1	o	2 (11)	EU, H, 11
108-95-2	4	0	Z (II)	Ευ, π, 11

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures

Provide adequate ventilation.

8.2.2 Individual protection

Do not eat, drink or smoke when working. Wash hands before breaks and after working. Use ointment for preventive skin protection.

8.2.2.1 Eye/face protection

Safety goggles

8.2.2.2 Skin protection

Hand protection

Glove material, e.g. nitrile rubber or butyl rubber

The protective gloves must conform to the specifications of EC Directive 89/686/EEC and the related standard EN 374.

Other safety precautions

Protective clothing

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 4 of 7

8.2.2.3 Respiratory protection

Not necessary.

8.2.3 Limiting and monitoring environmental exposure

No specific procedures required.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance shape: liquid

Color: No information available

Odor No information available Odor threshold No information available No information available рΗ Melting point No information available **Boiling point** No information available Flash point No information available No information available **Evaporation rate** No information available Flammability (solid, gas) Lower explosion limit No information available Upper explosion limit No information available No information available Vapor pressure Vapor density No information available Relative density No information available No information available Water solubility at 20 °C Partition coefficient: n-octanol/water No information available

Auto-ignition temperature not applicable

Decomposition temperature

Viscosity, dynamic

Explosive properties

Oxidizing properties

No information available.

No information available.

No information available.

9.2 Other information

No other relevant information available.

Section 10: Stability and reactivity

10.1 Reactivity

No information available.

10.2 Chemical stability

The product is chemically stable under the specified storage conditions.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

Under fire conditions, formation of Sulphur oxides (SOx) possible.

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 5 of 7

Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Phenol (< 1 %), LD 50 (oral): 300 mg/kg

Calculated estimate of the acute oral toxicity ATE (mix): 120000 mg/kg

Acute inhalation toxicity

Phenol (< 1 %), LD 50 (inhalativ): ATE 3 mg/l/4h

Calculated estimate of the acute inhalativ toxicity ATE (mix): 200 mg/l/4h

Acute dermal toxicity

Phenol (< 1 %), LD 50 (dermal): 317 mg/kg

Calculated estimate of the acute dermal toxicity ATE (mix): 126800 mg/kg

Skin irritation

Phenol (< 1 %) additive, Category 1B

SCL: Category 1B: 3 % Category 1C: 3 % Category 2: 1 %

Eye irritation

No information available.

Sensitization

Phenol (< 1%), Category 2

SCL: Category 2: 10 % (general limit value)
The mixture is not classified in this category.

Germ cell mutagenicity

Phenol (< 1 %), Category 2

SCL: Category 2: 1 % (general limit value)

The mixture is not classified in this category.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure:

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

This product contains chemically inactivated biological agents and should be considered potentially infectious.

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 6 of 7

Section 12: Ecological information

Mixture

12.1 Toxicity

No information available.

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 Results of PBT and vPvB assessment

There is no PBT/vPvB assessment available because no chemical safety assessment is required/was conducted.

12.6 Other adverse effects

No information available.

Additional ecological information

Discharge into the environment must be avoided.

Section 13: Disposal considerations

Waste treatment methods

Dispose of leftover product in accordance with Directive 2008/98/EC on Waste and national and regional regulations. Do not mix with other waste. Treat uncleaned containers depending on the product.

Section 14: Transport information

- **14.1 ADR, IMDG, IATA** not classified as dangerous in the meaning of transport regulations
- 14.2 Proper UN shipping name not applicable
- 14.3 Transport hazard class not applicable
- 14.4 Packing group not applicable
- 14.5 Environmentally hazardous No
- **14.6** Special precautions for user *No*
- 14.7 Transport in bulk according to Annex II of the MARPOL Convention 73/78 and the IBC Code
 Not relevant

Section 15: Regulatory information

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

EU legislation none known National laws none known

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2017-12-01

Version: 201712_4_EN_2 replaces version dated: 2017-08-01

Page 7 of 7

15.2 Chemical safety assessment

A chemical safety assessment has not been conducted for this product.

Section 16: Other information

The information describes the product with reference to the applicable safety precautions. It is not an assurance of the properties of the product.