

Safety data sheet

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

Valid from: 20170627

Version: 201607_13_1 replaces version dated: 20150305

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

1.1 Product identifier

Brand name: Complement
Product no.: 9001 and 9001.5

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

Identified use: In vitro diagnostic agent or component of 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 info@virion-serion.de

1.4 Emergency telephone number

Manufacturer: 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)

Section 2: Possible hazards

2.1 Classification of the substance or mixture

Classification per Regulation (EC) No. 1272/2008

Repr. 1B, H360FD: May damage fertility. May damage the unborn child.

2.2 Label elements

Hazard pictogram(s):
GHS08 Health hazard



Signal word: **Hazard**

H statements:

H360FD: May damage fertility. May damage the unborn child.

P statements:

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P308+P313 If exposed or concerned: Get medical advice/attention. P405 Store locked up.

P501 Dispose of contents/container in accordance with the local / regional / national / international regulations.

Additional information

Only for commercial use

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2.3 Other hazards

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

Section 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Hazardous ingredients

Boric acid

EINECS: 200-210-4; Index number: 005-007-00-2; CAS no. 1004-35-3;

Proportion: >15%

SVHC

10043-35-3 Boric acid

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

Repr. 1A, H360FD May damage fertility. May damage the unborn child.

Section 4: First aid measures

4.1 Description of first aid measures

General information: Remove the affected person to fresh air
Do not leave affected person unattended.
After inhalation: Fresh air or administer oxygen. Consult a doctor.
After skin contact: Immediately wash with soap and water and rinse well.
After eye contact: Flush eye with running water for several minutes while holding the eyelid open. Consult a doctor immediately.
After swallowing: Consult a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention or special treatment needed

No information available.

Section 5: Firefighting measures

5.1 Extinguishing media

CO₂, dry powder or water mist spray. Fight larger fires with water mist spray or alcohol-containing foam.

5.2 Special hazards related to this substance or mixture

No other relevant information available.

5.3 Advice for firefighters

Special protective equipment for firefighters

Do not inhale explosion and fire gasses.

Further data

Fire residues and contaminated extinguishing water must be disposed of in accordance with legal requirements.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

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Ensure there is adequate ventilation. Prevent dust formation. Wear personal protective clothing.

6.1.2 Information for emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

Do not allow discharge into the sewerage system or bodies of water.

6.3 Methods and materials for containment and cleaning up

Remove mechanically.

Dispose of contaminated material as waste in accordance with section 13.

6.4 Reference to other sections

See section 7 for information about safe handling. See section 8 for information about personal protective equipment. See section 13 for information about disposal.

Section 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Handle and open container with care. Prevent dust formation.

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. Store away from food.

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

Constituents with workplace-related limit values that must be monitored

Boric acid (CAS no. 10043-35-3)	
MWC	AGW long-term value 0.5 mg/m ³ 2 (I), AGS, Y, 10

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures

Ensure good general ventilation at the workplace.

8.2.2 Individual protection

The usual safety measures for handling chemicals must be observed.

Keep away from food, beverages and feed.

Immediately remove all contaminated clothing.

Wash hands before breaks and after working.

Pregnant women must avoid inhalation and skin contact.

8.2.2.1 Eye/face protection

Well-sealed safety goggles.

8.2.2.2 Skin protection

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Hand protection

Protective gloves

Glove material

The selection of a suitable glove depends not only on the material but also on other quality features and varies from manufacturer to manufacturer. Because the product is a preparation containing a number of substances, the resistance of glove materials cannot be predicted in advance and must therefore be tested prior to use.

Penetration time of the glove material

The exact penetration time must be specified by the glove manufacturer and must be observed.

Other safety precautions

Select suitable protection equipment for the workplace depending on the concentration and volume of the hazardous substance.

8.2.2.3 Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.3 Limiting and monitoring environmental exposure

Do not allow discharge into the sewerage system or bodies of water. Discharge into the environment must be avoided.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	shape: solid pellet Color: white
Odor	characteristic
Odor threshold	no information available
pH	no information available.
Melting point	no information available
Boiling point	no information available.
Flash point	no information available.
Evaporation rate	no information available
Flammability (solid, gas)	The product is not self-igniting
Lower explosion limit	no information available.
Upper explosion limit	no information available.
Vapor pressure	no information available.
Vapor density	no information available.
Relative density	no information available
Water solubility at 20 °C	soluble
Partition coefficient: n-octanol/water	no information available.
Auto-ignition temperature	not applicable
Decomposition temperature	no information available
Viscosity, dynamic	no information available.
Explosive properties	The product is not at risk of exploding.
Oxidizing properties	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 with proper use and under the specified storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

Potential formation of toxic pyrolysis products.

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Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

10043-35-3 Boric acid Oral LD50 2660 mg/kg (rat)

Acute oral toxicity

No information available.

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

Irritates skin and mucous membranes.

Eye irritation

Irritant effect

Sensitization

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

Repr. 1A, May damage fertility. May damage the unborn child.

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.

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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

Water hazard class 1 (self-assessment): slightly water hazardous. Do not allow undiluted product or larger quantities to discharge into ground water, water bodies or sewerage system.

Section 13: Disposal considerations

13.1 Procedure for handling waste:

European Waste Catalog:

Dispose of contents / container in accordance with the local / regional / national / international regulations.

Uncleaned packaging:

Recommendation: Dispose of in accordance with regulatory requirements.

Section 14: Transport information

14.1 UN number ADR, ADN, IMDG, IATA not classified as dangerous goods as per ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

14.2 Proper UN shipping name ADR, ADN, IMDG, IATA not applicable

14.3 Transport hazard class ADR, ADN, IMDG, IATA not applicable

14.4 Packing group ADR, ADN, IMDG, IATA not applicable

14.5 Environmental hazard no

14.6 Special precautions for users no

14.7 Transport in bulk according to Annex II of the MARPOL Convention 73/78 and the IBC Code
Not relevant

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Section 15: Regulatory information

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

National regulations:

Water hazard class: WGK 1 (self-classification): slightly hazardous to water.

Other regulations, restrictions and prohibitive ordinances:

Substances of very high concern (SVH C) as defined by REACH, article 57:
10043-35-3 Boric acid

15.2 Chemical safety assessment

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

Section 16: Other information

Full text of hazard warnings in section 3.2:

H statements:

H360FD May damage fertility. May damage the unborn child.

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