



Safety Data Sheet

Product for Service use only

Valid as of This version supersedes all earlier versions. 0
01.12.2022

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

1.1 Product identifier

Product Name **B-R-A-H-M-S Service Test-Kit KRYPTOR SYSTEMS**
Article Number **89977/89978N**

Component Name B-R-A-H-M-S Service Test-Kit KRYPTOR
Article Number 89968

Component Name B-R-A-H-M-S AFP CRYPTATE KRYPTOR
Article Number 00004

Component Name B-R-A-H-M-S Calibrator Service Test-Kit KRYPTOR
Article Number 89911N

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

Use of the preparation: Product for Service use only
Uses advised against: all other use

1.3 Details of the supplier of the safety data sheet

see above

1.4 Emergency telephone number

phone: +49 (0) 3302/883 300
e-mail: service@brahms.de

2 Hazards identification

Components	REF	2.1 Classification of the substance or mixture	2.2 Label elements / 2.3 Other hazards
B-R-A-H-M-S Service Test-Kit KRYPTOR	89968	No classification.	No label element. / No special remarkable hazard.
B-R-A-H-M-S AFP CRYPTATE KRYPTOR	00004	No classification.	No label element. / No special remarkable hazard.
B-R-A-H-M-S Calibrator Service Test-Kit KRYPTOR	89911N	No classification.	No label element. / No special remarkable hazard.

3 Composition/information on ingredients

3.1 Substances

not applicable

3.2 Mixtures

Kit

B·R·A·H·M·S Service Test-Kit KRYPTOR

Component	Reagent	Ingredient	Concentration
Cryptate-CONJUGATE		Bovine serum albumine (BSA)	< 0.5 % (reconstituted)
XL665-CONJUGATE		Bovine serum albumine (BSA)	< 0.5 % (reconstituted)
DILUENT		New born calf serum	10.7 mL/vial
		ProClin 150	< 0.1 %
		Ethylenediaminetetraacetic acid (EDTA)	< 0.5 %

Accessories



B·R·A·H·M·S AFP CRYPTATE KRYPTOR


Component	Reagent	Ingredient	Concentration
Cryptate-CONJUGATE		Bovine serum albumine (BSA)	< 0.5 % (reconstituted)

B·R·A·H·M·S Calibrator Service Test-Kit KRYPTOR

Component	Reagent	Ingredient	Concentration
Calibrator		New born calf serum	1.0 mL/vial (reconstituted)
		Human Antigen	275 ng/vial (reconstituted)

Characterization of hazardous ingredients

CAS No.	Ingredient	Classification
9048-46-8	Bovine serum albumine	 No hazard labelling required Potentially harmful and infectious, respectively.
/	New born calf serum	 No hazard labelling required Potentially harmful and infectious, respectively.

CAS No.	Ingredient	Classification
/	ProClin 150	Skin Corr. 1C Skin Sens. 1 Eye Dam. 1 Aqua. Acute 1 Aqua. Chron. 1 H314: Causes severe skin burns and eye damage. H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
60-00-4	Ethylenediaminetetraacetic acid	Eye Irrit. 2 H319: Causes serious eye irritation. P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
/	Human Antigen	 No hazard labelling required Potentially harmful and infectious, respectively.

4 First aid measures

4.1 Description of first aid measures

General statements

Contamination

Inhalation

Ingestion

- Avoid every contact with eyes, skin and clothing.
- Remove contaminated clothing.
- Flush eyes or skin with plenty of water immediately at least 15 min.
- Supply for fresh air.
- If not breathing, give artificial respiration.
- At breathing problems supply oxygen.
- Secure, that the person is conscious.
- Immediately call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None

4.3 Indication of any immediate medical attention and special treatment needed

Show this Safety Data Sheet to physician or emergency ward.

5 Firefighting measures

5.1 Extinguishing media

5.2 Special hazards arising from the substance or mixture

5.3 Advice for firefighters

- No information available
- No information available
- Put on breath protecting equipment, wear protecting clothing to prevent from contact with skin and eyes.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.2 Environmental precautions

6.3 Methods and material for containment and cleaning up

- Avoid substance contact.
- Prevent from getting into sewage, water, ground.
- Remove pollutes with absorbing paper.
- Clean the polluted place with disinfecting solution.
- All the material used for cleaning up must be disposed of as infectious laboratory waste.

7 Handling and storage

7.1 Precautions for safe handling

Advices for safe handling

Precautions

- No special measures necessary at proper use.
- Do not pipet by mouth.
- When using do not eat, drink or smoke.
- Wear suitable one-way rubber gloves at work.
- Avoid every splash and formation of aerosols.
- Further advices see point 8.
- Raw materials of human or animal origin contained in the reagents have been tested with approved kits and found negative for the anti-HIV 1, anti-HIV 2, anti-HCV antibodies and the HBs antigen. However as it is impossible to strictly guarantee that such products will not transmit hepatitis, the HIV virus, or any other viral infection, all raw materials of human or animal origin including the samples to be assayed must be treated as potentially infectious.

7.2 Conditions for safe storage, including any incompatibilities

Conditions for safe storage specific design for storage rooms and containers

- Keep container tightly closed.
- Keep only in the original container.
- Store in a cool dry place (2...8 °C).

7.3 Specific end use(s)

See Instruction for Use.

8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with occupational exposure limits

CAS No.	Ingredient	Type	Value
-	-	-	-

8.2 Exposure controls

Personal protective equipment

Respirator protection

Hand protection

Eye protection

Body protection

General protective and sanitary measures

- Required if dust and aerosols are generated.
- Wear suitable gloves.
- Wear eye/face protection.
- Wear suitable protective clothing.
- Safety shower.
- Eyewash.
- When using do not eat, drink or smoke.
- Change contaminated clothing immediately.
- Wash hands after work.
- Preventive skin protection is recommended.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Only the physical and chemical properties relevant for and applicable to the respective product are indicated.

Product	REF	Appearance	pH
B-R-A-H-M-S Service Test-Kit KRYPTOR	89968	Form: solid (lyophilized) Colour: not applicable Odour: odourless	not available (reconstituted)
B-R-A-H-M-S AFP CRYPTATE KRYPTOR	00004	Form: solid (lyophilized) Colour: not applicable Odour: odourless	not available (reconstituted)
B-R-A-H-M-S Calibrator Service Test-Kit KRYPTOR	89911N	Form: liquid Colour: not applicable Odour: odourless	not available

9.2 Other information

None

10 Stability and reactivity

10.1 Reactivity

- No information available

10.2 Chemical stability

- No information available

10.3 Possibility of hazardous reactions

- None.

10.4 Conditions to avoid

- Strong heating.

10.5 Incompatible materials

- No information available

10.6 Hazardous decomposition products

- In case of fire liberation of dangerous decomposition products (hydrogen fluoride) possible.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity of hazardous ingredients

Ingredient	Parameter	Type	Value	Species
-	-	-	-	-

Product	Reagent	Toxicological advice	Supplementary advice
B-R-A-H-M-S Service Test-Kit KRYPTOR	89968	not applicable	No hazardous substance according to applicable regulations.
B-R-A-H-M-S AFP CRYPTATE KRYPTOR	00004	not applicable	No hazardous substance according to applicable regulations.
B-R-A-H-M-S Calibrator Service Test-Kit KRYPTOR	89911N	not applicable	No hazardous substance according to applicable regulations.

12 Ecological information

12.1 Toxicity

Acute toxicity of hazardous ingredients

Ingredient	Parameter	Value	Species	Period
-	-	-	-	

12.2 Persistence and degradability

- No information available

12.3 Bioaccumulative potential

- No information available

12.4 Mobility in soil

- No information available

12.5 Results of PBT and vPvB assessment

- No information available

12.6 Other adverse effects

- Prevent from getting into sewage, water, ground.
- Ecotoxic effects of the product are not to be expected.
- Quantitative data on the ecological effect of this product are not available.
- No ecological problems are to be expected when the product is handled and used with due care and attention.

13 Disposal considerations

13.1 Waste treatment methods

Product

- The product must be disposed of as a laboratory chemical according to local regulations.
- Please contact responsible authority.
- Used reagents plates and reagent kits dispose of as potential infectious laboratory waste.

Contaminated packaging

- Dispose of according to local regulations.
- Recommendation: Remove residues. Empty containers should be returned to local recyclers.

Pollutes

- Remove pollutes with absorbing paper.
- All the material used for cleaning up must be disposed of as laboratory waste.

14 Transport information

No dangerous article according to applicable transport regulations (ADR/RID; DGR and IMDG code).

15 Regulatory information

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

This SDS complies with Regulation (EC) No 1907/2006. IVD is labelled according to EC Directives.

15.2 Chemical safety assessment

No information available

16 Other information

16.1 Additional information

Content Changes versus previous versions

- content alignment

Recommended range of applications

- not available

Working restrictions

- for Service use only

16.2 Abbreviations

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
Acute Tox. 3	Acute toxicity 3
Aquatic Chronic 2	Hazardous to the aquatic environment, Aquatic Chronic 2
DGR	Dangerous Goods Regulations
Eye Irrit. 2	Serious eye damage/eye irritation, Eye Irrit. 2
IMDG	International Maritime Code for Dangerous Goods
Ox. Liq. 3	Oxidising liquid 3
RID	Regulations concerning the International carriage of Dangerous goods by Rail
Resp. Sens. 1	Respiratory/skin sensitization 1
STOT SE 3	Specific target organ toxicity — single exposure SE-3
Skin Corr. 1B	Skin corrosion/irritation 1B

The information provided in this Safety Data Sheet shall only apply to the material described herein. It shall not apply to the processing of this material and/or its use together with other materials. It does not represent a guarantee of the properties of the material and is not the subject of any guarantee liabilities. With regard to contractual arrangements, only the specifications referred there to shall be applicable. B·R·A·H·M·S GmbH shall not be responsible for any consequences of the use of this information.