



Safety Data Sheet

Valid as of Product for in vitro diagnostic use only
This version supersedes all earlier versions.
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1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product Name	B·R·A·H·M·S Free β hCG KRYPTOR
Article Number	809.075
Product Name	B·R·A·H·M·S Free β hCG KRYPTOR CAL
Article Number	80991
Product Name	B·R·A·H·M·S GM KRYPTOR QC
Article Number	88192

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

Use of the preparation:	Product for in vitro diagnostic 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

Product	REF	2.1 Classification of the substance or mixture	2.2 Label elements / 2.3 Other hazards
B·R·A·H·M·S Free β hCG KRYPTOR	809.075	No classification.	No label element. / No special remarkable hazard.
B·R·A·H·M·S Free β hCG KRYPTOR CAL	80991	No classification.	No label element. / No special remarkable hazard.
B·R·A·H·M·S GM KRYPTOR QC	88192	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 Free β hCG KRYPTOR

Component	Reagent	Ingredient	Concentration
Cryptate-CONJUGATE		Potassium fluoride (KF)	< 5 %
		Bovine serum albumine (BSA)	< 0.5 %
XL665-CONJUGATE		Potassium fluoride (KF)	< 5 %
		Bovine serum albumine (BSA)	< 0.5 %
DILUENT		New born calf serum	< 10 mL/vial
		? UHcb'7;	< 0.5 %
		Ethylenediaminetetraacetic acid (EDTA)	< 0.5 %

Accessories



B·R·A·H·M·S Free β hCG KRYPTOR CAL

Component	Reagent	Ingredient	Concentration
CALIBRATOR		BYk Vcfb WJZgYfi a	0.65 mL/vial
		? UHcb'7;	< 0.5 %

B·R·A·H·M·S GM KRYPTOR QC

Component	Reagent	Ingredient	Concentration
CONTROL 1		Human serum	2.0 mL/vial
		AFP Antigen	
		Free β hCG Antigen	
		PAPP-A Antigen	
		? UHcb'7;	< 0.5 %
CONTROL 2		Human serum	2.0 mL/vial
		AFP Antigen	
		Free β hCG Antigen	
		PAPP-A Antigen	
		? UHcb'7;	< 0.5 %
CONTROL 3		Human serum	2.0 mL/vial
		AFP Antigen	
		Free β hCG Antigen	
		PAPP-A Antigen	
		? UHcb'7;	< 0.5 %

Characterization of hazardous ingredients

CAS No.	Ingredient	Classification
7789-23-3	Potassium fluoride	Acute Tox. 3 H301: Toxic if swallowed. H311: Toxic in contact with skin. H331: Toxic if inhaled. P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P311: Call a POISON CENTER or doctor/physician.
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.

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
7789-23-3	Potassium fluoride (KF)	Inhalation	2.5 mg/m ³

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 Free β hCG KRYPTOR	809.075	Form: liquid Colour: not applicable Odour: odourless	not available
B·R·A·H·M·S Free β hCG KRYPTOR CAL	80991	Form: liquid Colour: not applicable Odour: odourless	not available
B·R·A·H·M·S GM KRYPTOR QC	88192	Form: solid (lyophilized) Colour: not applicable Odour: odourless	7.0 (reconstituted)

9.2 Other information

None

