

MATERIAL SAFETY DATA SHEET

ABX Pentra MultiCal - A91A00665-

2004/02/02

1. Product and company identification

1.1 Identification of the product:

Product name: ABX Pentra MultiCal
Product code: Ref. ABX ==> A11A01652

1.2 Company identification: ABX Diagnostics - rue du Caducée - Parc Euromédecine –
34184 MONTPELLIER CEDEX 4 – FRANCE
TEL (33) 4 67 14 15 16 FAX (33) 4 67 14 15 17

1.3 Emergency phone number: Contact the nearest first-aid station

2. Composition/information on ingredients

Chemical nature: Lyophilised calibrator: 10 x 3 mL
Human serum
Human and animal Tissues extracts
Bovine serum albumin
Tetramethylammoniumchloride < 3% Symbol : T Risk sentence : R21-25

Hazardous ingredients:

(name, concentration)

Dangerous preparation according to 67/548/EEC - 99/45/EEC (Yes/No) : No

3. Hazards identification

Most important hazards:

This substance is prepared from human serum. All products derived from blood are prepared exclusively from the blood of donors tested individually by an FDA-approved method and found to be negative for HbsAg and antibodies to HCV and HIV1/HIV2. Nevertheless it is impossible to reach complete information about the possibility of disease transmission, please handle as potentially infectious.

This substance is particularly stable and no toxic in normal conditions of use. The usual hygienic measures taken when handling biological material should be observed.

Specific risks:

For Human: Effect of acute exposure
Eyes contact: May cause irritation
Skin contact: May cause irritation, may be harmful
Inhalation: May cause irritation, may be harmful
Ingestion: May be harmful
For Environment: Substance slightly dangerous to water and ground water.

4. First-aid measures

Inhalation:

Provide fresh air. If breathing is difficult, obtain medical attention.

Skin contact:

Immediately flush area with plenty of water and treat the contacted skin with skin-disinfectant.

Eye contact:

Immediately flush eyes with water for at least 15 minutes.

Ingestion:

Requires medical control. Instructions for physician: Symptomatic treatment by a physician.

5. Fire-fighting measures

Extinguishing media:

No restriction.

Specific risks:

N/A

Special protective equipment:

N/A

Additional recommendations:

Dangerous decomposition is not anticipated.

6. Accidental release measures

Personal precautions:

Environmental precautions:

Damage limitation: Special measures to limit damage are not necessary.

Methods for cleaning / absorption:

After spillage: sweep up spilled substance in dry condition, avoiding dust formation.

Absorbent material: not necessary.

Disposal measure: Dispose according to national or local regulations.

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7. Handling and storage

7.1 Handling:

Technical measures: Combustible substance.
Precautions: No restriction.
Handling recommendations: Open and handle vessels carefully.

7.2 Storage:

Technical measures: N/A.
Storage conditions: Store tightly closed at 2-8°C.
Incompatible materials: No restriction.
Packaging materials: No restriction.

8. Exposure controls/personal protection

Specific control parameters: N/A.
Technical measures: Follow standard laboratory practices concerning manipulation of human origin products.
Respiratory protection: None.
Hand protection: Yes, wear one-way gloves, wash hands after handling.
Eye protection: Yes, wear protective goggles.
Skin protection: Yes, wear protective clothes.
Hygiene measures: Disinfect workplace and hands after work.

9. Physical and chemical properties

Physical state:	Solid (powder)	Auto-flammability:	No data available.
Colour:	Yellowish.	Explosive properties:	No data available.
Odour:	No data available.	Oxidizing properties:	No data available.
pH :	6.9	Vapour pressure:	No data available.
Boiling point:	No data available.	Relative density:	No data available.
Melting point:	No data available.	Solubility:	Soluble in water.
Flashing point:	Cannot be determined.	Partition coefficient:	No data available.
Flammability (solid, gas) :	No data available.	Other data:	

10. Stability and reactivity

Conditions to avoid: N/A.
Materials to avoid: N/A.
Hazardous decomposition products: None.
Other data: Hazardous reaction: none known when used appropriately.

11. Toxicological information

Acute toxicity: Presence of Tetramethylammoniumchloride. See §3.
Chronic toxicity:
(sensitization, carcinogenicity, mutagenicity, teratogenicity, etc)
Inhalation:
Skin contact:
Eye contact:
Ingestion:
Other data: This substance is prepared from human serum. All products derived from blood are prepared exclusively from the blood of donors tested individually by an FDA-approved method and found to be negative for HbsAg and antibodies to HCV and HIV1/HIV2. Nevertheless it is impossible to reach complete information about the possibility of disease transmission, please handle as potentially infectious.

12. Ecological information

Mobility: No data yet available.
Degradability: No data yet available.
Bioaccumulative potential: No data yet available.
Ecotoxicity: No data yet available.
Other hazardous effects: Substance slightly hazardous to water and ground water. Disposal procedures have to be respected (see §13).

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13. Disposal considerations

Surplus or waste (residues):

This must be disposed of in compliance with antipollution and other laws of the country concerned.

Contaminated packaging:

Dispose of empty packs via local recycling or waste disposal routes _ if necessary, clean them beforehand.

14. Transport information (International regulations)

By land:

N/A.

By river:

N/A.

By air:

N/A.

By sea:

N/A.

General information:

This product is not subject to current regulations for transportation of hazardous goods.

15. Regulatory information

Labelling according to EEC directives

Symbols:

This product must not be labelled, in accordance with EEC directives 67/548 and 99/45.

R phrases:

N/A.

S phrases:

N/A.

Substances:

N/A.

Other regulatory requirements:

In no way does this information exempt the user from knowing about or applying all the national or international regulations relating to his/her activity.

16. Other information

This product is intended for IN VITRO diagnostic use only.

NOT FOR USE IN HUMANS.

This sheet is a complement to instructions for use but does not replace them. Information contained herewith is based on our current knowledge of the product, at the date shown, and is correct to the best of our knowledge.

Furthermore, the user's attention is drawn to the dangers of using this product for anything other than its intended use.

The user must accept the sole responsibility and take precautions accordingly for the use of this product.