

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product name : ABX Pentra MultiCal
Product code : A11A01652
Product description : 10 X 3 mL (Lyophilised)

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

Calibrator for the measurement of HORIBA Medical methods.

1.3 Details of the supplier of the safety data sheet

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
BP 7290
34184 MONTPELLIER CEDEX 4 - FRANCE
Tel: +33 (0) 4 67 14 15 16
Fax: +33 (0) 4 67 14 15 17

e-mail address of person responsible for this SDS : documentation.med@horiba.com

1.4 Emergency telephone number**National advisory body/Poison Centre**

Telephone number United Kingdom (UK) : +44 (0)20 7771 5310

Supplier

Telephone number : + 800 67 14 15 16

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Product definition : Mixture

Classification according to Directive 1999/45/EC [DPD]

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Not classified.

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard symbol or symbols :

Indication of danger : Not applicable.

Risk phrases : This product is not classified according to EU legislation.

Safety phrases : Not applicable.

2.3 Other hazards

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SECTION 2: Hazards identification

- Other hazards which do not result in classification** : Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat. Fine dust clouds may form explosive mixtures with air.
- Biological Hazard** : Human source material. Treat as potentially infectious. Each serum donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HbsAg, HCV and antibody to HIV 1/2. Because no known test method can offer complete assurance that infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.
- Animal source material. Treat as potentially infectious because there is no approved test done on this reagent.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
tetramethylammonium chloride	EC: 200-880-8 CAS: 75-57-0	1-3	T; R25 Xn; R21 See Section 16 for the full text of the R-phrases declared above.	Acute Tox. 2, H300 Acute Tox. 4, H312 See Section 16 for the full text of the H statements declared above.	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
 [2] Substance with a workplace exposure limit
 [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
 [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

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SECTION 4: First aid measures

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

- Eye contact** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

Flammability : May be combustible at high temperature.

5.1 Extinguishing media

Suitable extinguishing media : Use dry chemical powder.

Unsuitable extinguishing media : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : Fine dust clouds may form explosive mixtures with air.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

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SECTION 5: Firefighting measures

- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

6.2 Environmental precautions

- : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor.
Wash contaminated area with disinfectant.
- Large spill** : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Avoid creating dusty conditions and prevent wind dispersal. Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material.

SECTION 7: Handling and storage

Advice on general occupational hygiene

: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

: Store between the following temperatures: 2 to 8°C (35,6 to 46,4°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures

: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Derived effect levels

No DELs available.

Predicted effect concentrations

No PECs available.

8.2 Exposure controls

Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Individual protection measures

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SECTION 8: Exposure controls/personal protection

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. If operating conditions cause high dust concentrations to be produced, use dust goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Solid. [Powder.]
- Colour** : Yellowish.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability** : May be combustible at high temperature.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : Not available.
- Solubility(ies)** : Soluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water** : Not available.

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SECTION 9: Physical and chemical properties

Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Prevent dust accumulation.
10.5 Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
tetramethylammonium chloride	LD50 Oral	Rat	50 mg/kg	-

Irritation/Corrosion

No known significant effects or critical hazards.

Sensitisation

No known significant effects or critical hazards.

Mutagenicity

No known significant effects or critical hazards.

Carcinogenicity

No known significant effects or critical hazards.

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SECTION 11: Toxicological information**Reproductive toxicity**

No known significant effects or critical hazards.

Teratogenicity

No known significant effects or critical hazards.

Information on the likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

No known significant effects or critical hazards.

- General** : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Other information : Not available.

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SECTION 11: Toxicological information**SECTION 12: Ecological information****12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
tetramethylammonium chloride	Acute LC50 462000 ug/L Fresh water	Fish - Pimephales promelas - 33 days - 21,8 mm - 0,147 g	96 hours

Conclusion/Summary : Substance slightly hazardous to water and ground water.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods**Product**

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

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SECTION 14: Transport information

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
14.6 Special precautions for user	Not available.	Not available.	Not available.	Not available.
Additional information	-	-	-	-

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.
 on the manufacture,
 placing on the market and
 use of certain dangerous
 substances, mixtures and
 articles

Other EU regulations

Europe inventory : All components are listed or exempted.

Black List Chemicals : Not listed

Priority List Chemicals : Not listed

Integrated pollution prevention and control list (IPPC) - Air : Not listed

Integrated pollution prevention and control list (IPPC) - Water : Not listed

International regulations

Chemical Weapons Convention List Schedule I Chemicals : Not listed

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SECTION 15: Regulatory information

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

15.2 Chemical Safety Assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Revision comments : New MSDS form.

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements : H300 Fatal if swallowed.
 H312 Harmful in contact with skin.

Full text of classifications [CLP/GHS] : Acute Tox. 2, H300 ACUTE TOXICITY: ORAL - Category 2
 Acute Tox. 4, H312 ACUTE TOXICITY: SKIN - Category 4

Full text of abbreviated R phrases : R25- Toxic if swallowed.
 R21- Harmful in contact with skin.

Full text of classifications [DSD/DPD] : T - Toxic
 Xn - Harmful

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Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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