HORIBA Medical

SAFETY DATA SHEET

A91A00665F EN

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

1.1 Product identifier

Product name : ABX Pentra MultiCal

Product code : A11A01652

SAP Code : 1220001652

Product description : 10 X 3 mL (Lyophilised)

Product type : Powder.

Other means of identification : Not available.

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

Identified uses
Calibrator for the measurement of HORIBA Medical methods.

Uses advised against

Not applicable.

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 : +353 1 837 9964

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

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

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

2.2 Label elements

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SECTION 2: Hazards identification

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : Not applicable.

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

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification : May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

There are no 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, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

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.

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. 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.

4.2 Most important symptoms and effects, both acute and delayed

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SECTION 4: First aid measures

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 : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use dry chemical powder.

Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : May form explosible dust-air mixture if dispersed.

Hazardous combustion products : No specific data.

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.

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 the information in "For non-emergency personnel".

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SECTION 6: Accidental release 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 material for containment and cleaning up

Small spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. 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. 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.

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 oxidising 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. See Section 10 for incompatible materials before handling or use.Store away from light.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

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SECTION 8: Exposure controls/personal protection

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.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures : Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs 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

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, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles. Recommended: Tightly sealed goggles according to EN 166

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. > 8 hours (breakthrough time): Protective gloves according to EN 374

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.

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SECTION 8: Exposure controls/personal protection

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device according to EN 14387

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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Solid. [Powder.]

Colour : Yellowish.

Odour : Odourless.

Odour threshold : Not available.

Melting point/freezing point : Not available.

Initial boiling point and boiling range : Not available.

Flammability : May be combustible at high temperature.

Lower and upper explosion limit : Not applicable.

Flash point : Not applicable.

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not available.

pH : Not available.

Viscosity : Not applicable.

Solubility(ies) :

Media	Result
cold water hot water	Soluble Soluble

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Vapour pressure : Not available.

Relative density : Not available.

Vapour density : Not applicable.

Explosive properties : Not available.

Oxidising properties : Not available.

Particle characteristics

Median particle size : Not available.

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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:
oxidising 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Conclusion/Summary : Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
ABX Pentra MultiCal	5050,5	N/A	N/A	N/A	N/A

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

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SECTION 11: Toxicological information

Information on 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.

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 as well as 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

Not available.

Conclusion/Summary : Not available.

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.

Reproductive toxicity : No known significant effects or critical hazards.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

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SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary : Not available.

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

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Not available.

12.7 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. 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. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

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	IMDG	IATA
14.1 UN number or ID 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 : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Maritime transport in bulk according to IMO instruments : Not available.

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

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

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

Other EU regulations

Industrial emissions (integrated pollution prevention and control) - Air : Not listed

Industrial emissions (integrated pollution prevention and control) - Water : Not listed

Ozone depleting substances (1005/2009/EU)

Not listed.

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SECTION 15: Regulatory information

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia	:	All components are listed or exempted.
Canada	:	All components are listed or exempted.
China	:	All components are listed or exempted.
Eurasian Economic Union	:	**Russian Federation inventory**: All components are listed or exempted.
Japan	:	**Japan inventory (CSCL)**: All components are listed or exempted. **Japan inventory (ISHL)**: Not determined.
New Zealand	:	All components are listed or exempted.
Philippines	:	All components are listed or exempted.
Republic of Korea	:	All components are listed or exempted.
Taiwan	:	All components are listed or exempted.
Thailand	:	All components are listed or exempted.
Turkey	:	Not determined.
United States	:	All components are active or exempted.
Viet Nam	:	All components are listed or exempted.

15.2 Chemical safety assessment : Not applicable.

SECTION 16: Other information

Revision comments : New MSDS form.

Indicates information that has changed from previously issued version.

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SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

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

Not classified.

Full text of abbreviated H statements

Not applicable.

Full text of classifications [CLP/GHS]

Not applicable.

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Date of previous issue : No previous validation

Version : 3

Notice to reader

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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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