

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

Product name : ABX Pentra RF Cal
Product code : A11A01618
Product description : 5 X 1 mL (5 levels)

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

Calibrator for the measurement of rheumatoid factor (RF) by latex-enhanced immunoturbidimetric assay.

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

Not classified.

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 pictograms :

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

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SECTION 2: Hazards identification

| | |
|------------------------------------|-------------------|
| Storage | : Not applicable. |
| Disposal | : Not applicable. |
| Supplemental label elements | : Not applicable. |

2.3 Other hazards

Other hazards which do not result in classification : Not available.

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.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

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

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. 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. |

4.2 Most important symptoms and effects, both acute and delayedPotential acute health effects

| | |
|---------------------|---|
| Eye contact | : No known significant effects or critical hazards. |
| Inhalation | : No known significant effects or critical hazards. |
| Skin contact | : No known significant effects or critical hazards. |
| Ingestion | : No known significant effects or critical hazards. |

Over-exposure signs/symptoms

| | |
|---------------------|---------------------|
| Eye contact | : No specific data. |
| Inhalation | : No specific data. |
| Skin contact | : No specific data. |

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SECTION 4: First aid measures

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

Flammability : May be combustible at high temperature.

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition 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.

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. 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".

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).

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SECTION 6: Accidental release measures

- Other information** : This preparation contains a small amount of sodium azide. Sodium azide is harmful to aquatic organisms and can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Prevent preparation from entering the drain and water intakes in the environment. If preparation enters the drain, flush with large amounts of water to prevent azide build up. Follow proper disposal procedures.

6.3 Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Wash contaminated area with disinfectant.

- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Note: see section 1 for emergency contact information and section 13 for waste disposal.

- 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).
- 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 10°C (35,6 to 50°F). Store in accordance with local regulations. 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. 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.

- Recommendations** : Due to sodium azide, incompatible with acid and some metals. Forms explosion-sensitive compounds.

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 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 : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

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.

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 | : Liquid. |
| Colour | : Yellowish. |
| Odour | : Odourless. |
| Odour threshold | : Not available. |
| pH | : 7,5 |
| 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. |
| 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 | : No specific data. |
| Recommendations | : This reagent contains sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product. |
| 10.5 Incompatible materials | : No specific data. |

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SECTION 10: Stability and reactivity

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

No known significant effects or critical hazards.

Acute toxicity estimates

Not available.

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.

Reproductive toxicity

No known significant effects or critical hazards.

Teratogenicity

No known significant effects or critical hazards.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

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 : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

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SECTION 11: Toxicological information

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 : No known significant effects or critical hazards.

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.

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

PBT : Not applicable.

vPvB : Not applicable.

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

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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.

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

**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

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

| Classification | Justification |
|-----------------|---------------|
| Not classified. | |

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SECTION 16: Other information

Full text of abbreviated H statements : Not applicable.

Full text of classifications [CLP/GHS] : Not applicable.

Full text of abbreviated R phrases : Not applicable.

Full text of classifications [DSD/DPD] : Not applicable.

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Version : 1

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.