

ABX Difftrol	A91A00320EEN	Revision 05/10/2011
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1. Product and company identification

1.1. Identification of the product

Product name:	ABX Difftrol
Product code:	2062203 : Twin Pack 2N (2 x 3ml vial + value sheet) 2062207 : Twin Pack 2L (2 x 3ml vial + value sheet) 2062208 : Twin Pack 2H (2 x 3ml vial + value sheet) 2062011 : Vial Low Level (1 x 3ml vial) 2062012 : Vial Normal Level 3ml (1 x 3ml vial) 2062013 : Vial High Level 3ml (1 x 3ml vial)

1.2. Use of the product

ABX Difftrol is a tri-level control intended for in vitro diagnostic use and designed for use in monitoring the accuracy and precision of the HORIBA Medical hematology blood cell counters with the HORIBA Medical reagents.

1.3. Company identification

	HORIBA ABX SAS - Rue du Caducée - Parc Euromédecine - BP7290 34184 MONTPELLIER CEDEX 4 - FRANCE Tel: + 33 (0) 4 67 14 15 16 Fax: + 33 (0) 4 67 14 15 17 Email: documentation.med@horiba.com
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1.4. Emergency phone number

Company :	+ 800 67 14 15 16
French official advisory body :	ORFILA (INRS) : + 33 (0) 1 45 42 59 59

2. Hazards identification

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

Most important hazards:	Non applicable.
Specific risks	Potentially biohazardous material. Handle as if potentially infectious.

3. Composition/information on ingredients

3.1. Description of the kit

	ABX Difftrol contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.
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3.2. Hazardous ingredients (name, concentration)

CAS No.	EC No. (EINECS/ELINCS/NLP)	Name	Concentration	Symbol	Risk	REACH No.
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This preparation does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU legislation.

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4. First-aid-measures

Inhalation:	Supply fresh air; consult a doctor in case of complaints.
Skin contact:	Immediately wash skin with soap and water.
Eye contact:	Immediately wash eyes, also under the eyelids, with water for at least 15 minutes.
Ingestion:	Rinse mouth out with water if the victim is conscious, otherwise call doctor.

5. Fire-fighting measures :

Extinguishing media:	This product is non-flammable.
Specific risks:	None determined.
Special protective equipment:	No special measures required.
Additional recommendations:	None.

6. Accidental release measures

Personal precautions:	Wear laboratory gloves and protective goggles.
Environmental precautions:	Neutralise product before discarding.
Methods for cleaning/absorption:	After neutralisation, absorb the product and rinse the whole area with water.

7. Handling and storage

7.1. Handling

Technical measures:	Avoid contact with the skin, eyes. Laboratory gloves and protective goggles.
Precautions:	Always handle the product in a well-ventilated area.
Handling recommendations:	Not determined.

7.2. Storage

Technical measures:	Not determined.
Storage conditions:	To maintain the quality of the product, do not freeze. ABX Difftrol vials should be tightly capped and stored at 2-8°C when not in use. ABX Difftrol is stable for 16 sampling events over a maximum of 16 days, after a vial has been opened, if it is properly handled and promptly refrigerated after each use. ABX Difftrol in unopened vials that have been stored at 2-8°C are stable until the expiration date listed on the label.
Incompatible materials:	Not determined.
Packaging materials:	Not determined.

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8. Exposure controls/personal protection	
8.1. Exposure limit values	
Specific control parameters:	Not determined.
8.2. Exposure controls	
8.2.1. Occupational exposure controls	
Technical measures:	ABX Difftrol should be handled in the same manner as a human blood sample. Eye wash, safety shower, laboratory gloves, goggles in case of prolonged contact.
Respiratory protection:	Not determined.
Hand protection:	Protective gloves.
Eye protection:	Safety goggles.
Skin protection:	Lab coat.
Hygiene measures:	Follow good laboratory practices.
8.2.2. Environmental exposure controls	

9. Physical and chemical properties			
9.1. General information			
Physical state:	Liquid.		
Colour:	Dark Red.	Odourless:	Little to none.
9.2. Important health, safety and environmental information			
pH:	Neutral.	Relative density:	Not determined.
Boiling point:	Not determined.	Solubility:	Miscible with water.
Flash point:	Not determined.	Partition coefficient:	Not determined.
Flammability (solid, gaz):	Non-flammable.	Viscosity:	Not determined.
Explosive properties:	Not determined.	Vapour density:	Not determined.
Oxidizing properties:	Not determined.	Evaporation rate:	Not determined.
9.3. Other information			
Not determined.			

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10. Stability and reactivity

Conditions to avoid:	Expiry date.
Materials to avoid:	This reagent contains less than 0.1% of sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
Hazardous decomposition products:	Not determined.
Other data:	None.

11. Toxicological information

Acute toxicity:	Not determined.
Chronic toxicity:	Not determined.
Inhalation:	Not determined.
Skin contact:	Not determined.
Eye contact:	Not determined.
Ingestion:	Not determined.
Other data:	None.

12. Ecological information

12.1. Ecotoxicity:	Not determined.
12.2. Mobility:	Not determined.
12.3. Degradability:	Not determined.
12.4. Bioaccumulative potential:	Not determined.
12.5. Results of PBT assessment:	None.
12.6. Other hazardous effects:	Not determined.

13. Disposal considerations

Surplus or waste (residues) Contaminated packaging	This reagent contains less than 0.1% of sodium azide as preservative. It is advisable to avoid or reduce the generation of waste products wherever possible. Empty containers may contain product residues. Discard all waste, unused products, and contaminated packaging in accordance with current legislation. If you are in any doubt over the regulations, further information can be obtained from the competent authorities.
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14. Transport information (International regulations)

By air (IATA):	Shipping name: UN number: Risk category: Packing group: <i>I</i>	Not applicable.
By land (European ADR):	Shipping name: UN number: Risk category: Packing group:	Not applicable.
By sea (IMDG):	Shipping name: UN number: Risk category: Packing group: Marine polluante: Yes/No	Not applicable.

15. Regulatory information

Symbols:	None.	
R phrases:	None.	
S phrases:	None.	
Substances:	None.	
Specific provisions and related laws:	None.	
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

16.1. List of relevant R phrases

None.

16.2. Recommended restriction on use

See specific information given in the product user information.

16.3. Further information

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.

16.4. Sources of key data

This document has been compiled with information extracted from documents given by our raw material suppliers.

16.5. Revision

The sections that have been modified from the previous version are indicated by a vertical line on the left side of the table.