

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
---------------------	---------------------	--------------------------------

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) 2062204 : Twin Pack 1H + 1L (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 ABX hematology blood cell counters with the HORIBA ABX reagents.	
1.3. Company identification	
	HORIBA ABX - Rue du Caducée - Parc Euromédecine 34184 MONTPELLIER CEDEX 4 - FRANCE Tel: +33 (0) 4 67 14 15 16 Fax: +33 (0) 4 67 14 15 17 Email: documentation@fr.abx.fr
1.4. Emergency phone number	
	Contact the nearest first-aid station

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.

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
---------------------	---------------------	--------------------------------

3. Composition/information on ingredients					
3.1. Description of the kit					
	Contains human blood components.				
3.2. Hazardous ingredients (name, concentration)					
CAS N.	Name	Concentration	Symbol	Risk	Registration number
To the best of our knowledge, this product contains no hazardous ingredients as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 and by EU Directive 67/548/EEC.					

4. First-aid-measures	
Inhalation:	Respiratory protection not required if used according to package insert.
Skin contact:	Immediately wash affected area with soap and water and get medical attention. Other protective clothing or equipment : Lab coat.
Eye contact:	Immediately wash eyes, also under the eyelids, with water for at least 15 minutes. Get medical attention immediately.
Ingestion:	In case of ingestion get medical attention immediately.

5. Fire-fighting measures : Product non flammable	
Extinguishing media:	As appropriate for fire in surrounding materials.
Specific risks:	None.
Special protective equipment:	None.
Additional recommendations:	None.

6. Accidental release measures	
Personal precautions:	Wear gloves during spill clean up.
Environmental precautions:	Not determined.
Methods for cleaning/absorption:	Absorb spill using disposable towels or commercially available chemical spill kit absorbent material. Flood contaminated area with undiluted household bleach (5.5% sodium hypochlorite), then wipe clean. Contain absorbent waste in biohazard bag.

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
---------------------	---------------------	--------------------------------

7. Handling and storage	
7.1. Handling	
Technical measures:	Solutions containing human-sourced materials should be handled as if potentially infectious.
Precautions:	Not determined.
Handling recommendations:	Not determined.
7.2. Storage	
Technical measures:	Not determined.
Storage conditions:	To maintain the quality of the product, store the tubes in their original package at 2 to 8°C. Keep away from excessive heat (>30°C) and from cold (<2°C). DO NOT FREEZE. Unopened tubes that have been stored at 2-8°C are stable until the expiry date listed on the label. Do not use grossly contaminated or haemolysed control material. Opened tubes are stable for 16 sampling events over a maximum of 16 days ^a .
Incompatible materials:	Not determined.
Packaging materials:	Not determined.

a. Modification from index C to D : stability changed.

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:	Not determined.
Respiratory protection:	Not required if used according to package insert.
Hand protection:	Protective gloves.
Eye protection:	Safety goggles.
Skin protection:	Avoid contact with skin. When handling, use proper personal protective equipment.
Hygiene measures:	Do not eat, drink, or smoke where reagents are handled. Do not pipette by mouth, use mechanical pipetting device. Follow good laboratory practices. Wash thoroughly after handling.
8.2.2. Environmental exposure controls	
Not determined.	

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
---------------------	---------------------	--------------------------------

9. Physical and chemical properties

9.1. General information

Physical state:	Liquid.		
Colour:	Dark red.	Odour:	None.

9.2. Important health, safety and environmental information

pH:	Not determined.	Relative density:	Not determined.
Boiling point:	Not determined.	Solubility:	Soluble in water.
Flash point:	Not determined.	Partition coefficient:	Not determined.
Flammability (solid, gaz):	Not determined.	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.	
-----------------	--

10. Stability and reactivity

Conditions to avoid:	Not applicable.
Materials to avoid:	None.
Hazardous decomposition products:	None.
Other data:	Stable - Hazardous polymerisation will not occur.

11. Toxicological information

Acute toxicity:	No irritating effects. When used and handled according to labelled instructions, the product does not have any harmful effects.
Chronic toxicity:	This product contains antibiotics. People with know or suspected allergies should use appropriate safety precautions when handling. People that are allergic to antibiotics may experience eye, skin, and respiratory irritation.
Inhalation:	Not determined.
Skin contact:	Not determined.
Eye contact:	Not determined.
Ingestion:	Not determined.
Other data:	None.

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
---------------------	---------------------	--------------------------------

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:	Currently, no ecological effect has been identified. This product is not hazardous for water.
12.6. Other hazardous effects:	None.

13. Disposal considerations	
Surplus or waste (residues):	The product must be disposed of as a laboratory chemical according to local regulations.
Contaminated packaging:	Dispose of according to local regulations.

14. Transport information (International regulations)	
General information:	None.
By air (IATA):	Not applicable.
By land (ADR):	Not applicable.
By sea (IMDG):	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.	

ABX DIFFTROL	A91A00320DEN	Revision 08/09/2008
--------------	--------------	------------------------

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	
<p>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.</p> <p>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.</p>	
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.	