

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

### 1.1 Product identifier

**Product name** : BFTROL  
**Product code** : 1300039405  
**Product description** : ("2" & "3"): 2 x 3 mL  
**Product type** : Liquid.

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

Control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA Medical hematology blood cell counters for leucocytes (WBC) and erythrocytes (RBC) in body fluids.

### 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** : +44 (0)20 7771 5310  
**United Kingdom (UK)**

#### 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

**Signal word** : No signal word.  
**Hazard statements** : No known significant effects or critical hazards.

#### Precautionary statements

**Date of issue/Date of revision** : 17/07/2017.

1/11

**BFTROL**

## SECTION 2: Hazards identification

- 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.

### 2.3 Other hazards

**Other hazards which do not result in classification** : None known.

**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

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. 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 delayed

#### Potential acute health effects

**Date of issue/Date of revision** : 17/07/2017.

2/11

**BFTROL**

## SECTION 4: First aid measures

- 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.
- 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 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".

**Date of issue/Date of revision** : 17/07/2017.

**3/11**

**BFTROL**

## 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).
- 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. 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).
- 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 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.

**Date of issue/Date of revision** : 17/07/2017.

4/11

**BFTROL**

## SECTION 7: Handling and storage

**Industrial sector specific solutions** : Not available.

## SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker or exposure or environmental releases.

### 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 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** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

#### 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.

#### 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.

**Date of issue/Date of revision** : 17/07/2017.

5/11

**BFTROL**

## SECTION 8: Exposure controls/personal protection

- 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** : Red. [Dark]
- Odour** : Weak up to odourless.
- Odour threshold** : Not available.
- pH** : 6 to 8
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability** : Non-flammable.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : Not available.
- Solubility(ies)** : Not available.
- 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.

**Date of issue/Date of revision** : 17/07/2017.

6/11

BFTROL

## 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.  
**Other information** : Reactive or incompatible with the following materials: metals.
- 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

**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.

**Date of issue/Date of revision** : 17/07/2017.

7/11

**BFTROL**

## SECTION 11: Toxicological information

**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.

### 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

**Conclusion/Summary** : Not available.  
**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.

**Date of issue/Date of revision** : 17/07/2017.

8/11

**BFTROL**

## SECTION 12: Ecological information

### 12.4 Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : 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. 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 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

	<b>ADR/RID</b>	<b>ADN</b>	<b>IMDG</b>	<b>IATA</b>
<b>14.1 UN number</b>	Not regulated.	Not regulated.	Not regulated.	Not regulated.
<b>14.2 UN proper shipping name</b>	-	-	-	-
<b>14.3 Transport hazard class(es)</b>	-	-	-	-
<b>14.4 Packing group</b>	-	-	-	-

**Date of issue/Date of revision** : 17/07/2017.

**9/11**

**BFTROL**

**SECTION 14: Transport information**

<b>14.5 Environmental hazards</b>	No.	No.	No.	No.
<b>Additional information</b>	-	-	-	-

**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.

**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 (SVHC)**

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.

**Seveso II Directive**

This product is not controlled under the Seveso II Directive.

**International regulations**

**Chemical Weapon Convention List Schedules I, II & III Chemicals**

Not listed.

**Montreal Protocol (Annexes A, B, C, E)**

Not listed.

**Stockholm Convention on Persistent Organic Pollutants**

Not listed.

**Rotterdam Convention on Prior Inform Consent (PIC)**

Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals**

Not listed.

**International lists**

**National inventory**

**Australia** : All components are listed or exempted.

**Canada** : All components are listed or exempted.

**China** : All components are listed or exempted.

**Date of issue/Date of revision** : 17/07/2017.

**BFTROL**

**SECTION 15: Regulatory information**

- Japan** : All components are listed or exempted.
- Malaysia** : 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.
- United States** : **United States inventory (TSCA 8b)**: All components are listed or exempted.

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

**SECTION 16: Other information**

**Revision comments** : Not available.

✔ 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]  
 DMEL = Derived Minimal Effect Level  
 DNEL = Derived No Effect Level  
 EUH statement = CLP-specific Hazard statement  
 PBT = Persistent, Bioaccumulative and Toxic  
 PNEC = Predicted No Effect Concentration  
 RRN = REACH Registration Number  
 vPvB = Very Persistent and Very Bioaccumulative

**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** : 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.

**Date of printing** : 17/07/2017.

**Date of issue/ Date of revision** : 17/07/2017.

**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.

**Date of issue/Date of revision** : 17/07/2017.