



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

1.1 Product identifier

Product name : ABX Alphalyse 0.4L
Product code : 0906004
Product description : 0.4 L
Product type : Liquid.

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

ABX Alphalyse is a lysing solution intended for in vitro diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination on HORIBA Medical blood cell counters.

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.

Date of issue/Date of revision : 26/09/2017.

1/12

ABX Alphalyse 0.4L

SECTION 2: Hazards identification

Precautionary statements

- Prevention** : Not applicable.
- Response** : Not applicable.
- Storage** : Not applicable.
- Disposal** : Not applicable.
- Supplemental label elements** : Safety data sheet available on request.
- 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.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
<input checked="" type="checkbox"/> Dodecyltrimethylammonium chloride	EC: 203-927-0 CAS: 112-00-5	>=2,5 - <5	Xi; R36/37/38 N; R51/53 See Section 16 for the full text of the R-phrases declared above.	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Acute 1, H400 See Section 16 for the full text of the H statements declared above.	[1]

There are no additional 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 or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

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
- [5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

Date of issue/Date of revision : 26/09/2017.

2/12

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. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- 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** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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.

ABX Alphalyse 0.4L

SECTION 5: Firefighting measures

Hazardous thermal decomposition products : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 nitrogen oxides
 halogenated compounds

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 : 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).

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.

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.

Date of issue/Date of revision : 26/09/2017.

4/12

ABX Alphalyse 0.4L

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: 18 to 25°C (64,4 to 77°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.

- Other information** : Store away from light.

7.3 Specific end use(s)

- Recommendations** : Not available.
- 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

Date of issue/Date of revision : 26/09/2017.

5/12

SECTION 8: Exposure controls/personal protection

- 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.
- 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. [Clear aqueous solution]
- Colour** : Colourless.
- Odour** : Cyanide
- Odour threshold** : Not available.
- pH** : 9,5 to 10,5
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Non-flammable.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.

Date of issue/Date of revision : 26/09/2017.

6/12

ABX Alphalyse 0.4L

SECTION 9: Physical and chemical properties

- Relative density** : Not available.
- Solubility(ies)** : Easily soluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/ water** : Not available.
- Auto-ignition temperature** : Not applicable.
- 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.
- 10.5 Incompatible materials** : No specific data.
- Other information** : Extremely reactive or incompatible with the following materials: acids. ABX Basolyse, ABX Basolyse II
- 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

Route	ATE value
Oral	18726,6 mg/kg

Irritation/Corrosion

No known significant effects or critical hazards.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Date of issue/Date of revision : 26/09/2017.

7/12

ABX Alphalyse 0.4L

SECTION 11: Toxicological information

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.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

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.

Date of issue/Date of revision : 26/09/2017.

8/12

ABX Alphalyse 0.4L

SECTION 11: Toxicological information**Other information** : Not available.**SECTION 12: Ecological information****12.1 Toxicity**

Product/ingredient name	Result	Species	Exposure
ABX Alphalyse 0.4L dodecyltrimethylammonium chloride	EC50 1,01 to 9,99 mg/l	Daphnia	48 hours
	NOEC 1 mg/l	Daphnia	48 hours
	Acute EC50 190 µg/l Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute LC50 0,06 mg/l	Daphnia	48 hours

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.**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.

Date of issue/Date of revision : 26/09/2017.

9/12

ABX Alphalyse 0.4L

SECTION 13: Disposal considerations

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	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.
Additional information	-	-	-	-

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

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

Date of issue/Date of revision : 26/09/2017.

10/12

ABX Alphalyse 0.4L

SECTION 15: Regulatory information

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.
- 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** : Not determined.
- 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 : Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

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.	

Date of issue/Date of revision : 26/09/2017.

11/12

ABX Alphalyse 0.4L

SECTION 16: Other information

- Full text of abbreviated H statements** : H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H400 Very toxic to aquatic life.
- Full text of classifications [CLP/GHS]** : Acute Tox. 4, H302 ACUTE TOXICITY (oral) - Category 4
 Aquatic Acute 1, H400 ACUTE AQUATIC HAZARD - Category 1
 Eye Irrit. 2, H319 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
 Skin Irrit. 2, H315 SKIN CORROSION/IRRITATION - Category 2
- Full text of abbreviated R phrases** : R36/37/38- Irritating to eyes, respiratory system and skin.
 R51/53- Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Full text of classifications [DSD/DPD]** : Xi - Irritant
 N - Dangerous for the environment
- Date of printing** : 26/09/2017.
- Date of issue/ Date of revision** : 26/09/2017.

Version : 2

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.