

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

1.1 Product identifier

Product name : ABX Alphalyse 360mL
Product code : 0906014
SAP Code : 1210906014
Product description : 360 mL
Product type : Liquid.
Other means of identification : Not available.

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

Identified uses

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.

Uses advised against

Not applicable.

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 : +353 1 837 9964

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.

SECTION 2: Hazards identification

Ingredients of unknown toxicity : 2,7 percent of the mixture consists of component(s) of unknown acute dermal toxicity
2,7 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

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

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.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.
Tactile warning of danger : Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
dodecyltrimethylammonium chloride	EC: 203-927-0 CAS: 112-00-5	≤5	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.	ATE [Oral] = 500 mg/kg M [Acute] = 10	[1]

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SECTION 3: Composition/information on ingredients

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, vPvBs or Substances of equivalent concern, 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

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

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. 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

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.
- Hazardous combustion products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

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SECTION 5: Firefighting measures

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 spilled 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 spilled 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 material 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.

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

SECTION 7: Handling and storage

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. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

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.

Biological exposure indices

No exposure indices known.

Recommended monitoring procedures : 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. Recommended: Tightly sealed goggles according to EN 166

Skin protection

SECTION 8: Exposure controls/personal 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. > 8 hours (breakthrough time): Protective gloves according to EN 374
- 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** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device according to EN 14387
- 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

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Liquid. [Clear aqueous solution]
- Colour** : Colourless.
- Odour** : Cyanide
- Odour threshold** : Not available.
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flammability** : Non-flammable.
- Lower and upper explosion limit** : Not available.
- Flash point** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not available.
- pH** : 9,5 to 10,5
- Viscosity** : Not available.
- Solubility(ies)** :

Media	Result
cold water	Easily soluble
hot water	Easily soluble

- Solubility in water** : Not available.
- Partition coefficient: n-octanol/ water** : Not applicable.
- Vapour pressure** : Not available.
- Relative density** : Not available.
- Vapour density** : Not available.

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SECTION 9: Physical and chemical properties

- Explosive properties** : Not available.
Oxidising properties : Not available.
Particle characteristics
Median particle size : Not applicable.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Conclusion/Summary : Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
ABX Alphalyse 360mL dodecyltrimethylammonium chloride	18726,6 500	N/A N/A	N/A N/A	N/A N/A	N/A N/A

Irritation/Corrosion

Conclusion/Summary : Not available.

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)

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SECTION 11: Toxicological information

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on 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 as well as 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

Not available.

- 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.
- Reproductive toxicity** : No known significant effects or critical hazards.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

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SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
ABX Alphalyse 360mL	EC50 1,01 to 9,99 mg/l NOEC 1 mg/l	Daphnia Daphnia	48 hours 48 hours
dodecyltrimethylammonium chloride	Acute EC50 200 µg/l Fresh water Acute LC50 0,06 mg/l	Algae - Navicula pelliculosa Daphnia	96 hours 48 hours

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

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Not available.

12.7 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 2008/98/EC.

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.

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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 or ID 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 : **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.

14.7 Maritime transport in bulk according to IMO instruments : Not available.

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

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

Industrial emissions (integrated pollution prevention and control) - Air : Not listed

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SECTION 15: Regulatory information

Industrial emissions : Not listed

(integrated pollution prevention and control) -

Water

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : All components are listed or exempted.

Canada : All components are listed or exempted.

China : All components are listed or exempted.

Eurasian Economic Union : **Russian Federation inventory**: All components are listed or exempted.

Japan : **Japan inventory (CSCL)**: All components are listed or exempted.

Japan inventory (ISHL): 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.

Thailand : Not determined.

Turkey : Not determined.

United States : All components are active or exempted.

Viet Nam : All components are listed or exempted.

15.2 Chemical safety assessment : Not applicable.

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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]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

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

Not classified.

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	ACUTE TOXICITY - Category 4
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Eye Irrit. 2	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Skin Irrit. 2	SKIN CORROSION/IRRITATION - Category 2

Date of printing : 31/01/2023

Date of issue/ Date of revision : 31/01/2023

Date of previous issue : No previous validation

Version : 3

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.