

**Alpha Biosciences - Oxbile
O15-103**

SECTION 1: IDENTIFICATION

1.1 GHS Product identifier: Alpha Biosciences - Oxbile
O15-103
Bile, extract

CAS: 8008-63-7

Other means of identification:

Non-applicable

1.2 Recommended use of the chemical and restrictions on use:

Relevant uses: Culture medium

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party:

Alpha Biosciences, Inc.
3651 Clipper Mill Road
21211 Baltimore - Maryland - USA
Phone: 410.467.9983 - Fax: 410.467.5088
www.alphabiosciences.com

1.4 Emergency phone number:

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture:

NFPA:

Health Hazards: 2
Flammability Hazards: 1
Instability Hazards: 0
Special Hazards: Non-applicable

29 CFR 1910.1200:

Classification of this product has been carried out in accordance with paragraph (d) of § 1910.1200.

Acute Tox. 4: Acute toxicity if swallowed, Category 4, H302
Eye Irrit. 2A: Eye irritation, Category 2A, H319
Skin Irrit. 2: Skin irritation, Category 2, H315
Skin Sens. 1: Sensitisation, skin, Category 1, H317

2.2 Label elements:

NFPA:



29 CFR 1910.1200:

Warning



Hazard statements:

Acute Tox. 4: H302 - Harmful if swallowed.
Eye Irrit. 2A: H319 - Causes serious eye irritation.
Skin Irrit. 2: H315 - Causes skin irritation.
Skin Sens. 1: H317 - May cause an allergic skin reaction.

Precautionary statements:

P101: If medical advice is needed, have product container or label at hand.
P102: Keep out of reach of children.
P264: Wash thoroughly after use.
P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501: Dispose of the contents/containers according to the local, state and federal regulations.

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SECTION 2: HAZARD(S) IDENTIFICATION (continued)

2.3 Hazards not otherwise classified (HNOC):

Non-applicable


SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances:

Chemical description: Mixture of substances

Components:

Remaining components are non-hazardous and/or present at amounts below reportable limits. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200. Therefore, in accordance with Appendix D to § 1910.1200, the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 8008-63-7	Bile, extract Acute Tox. 4: H302; Eye Irrit. 2A: H319; Skin Irrit. 2: H315; Skin Sens. 1: H317 - Warning	 100 %

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixtures:

Non-applicable

SECTION 4: FIRST-AID MEASURES

4.1 Description of necessary measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. In the case of loss of consciousness do not administrate anything orally unless supervised by a doctor. Rinse out the mouth and throat, as they may have been affected during ingestion. Keep the person affected at rest.

4.2 Most important symptoms/effects, acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of immediate medical attention and special treatment needed, if necessary:

Non-applicable

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Suitable (and unsuitable) extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

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SECTION 5: FIRE-FIGHTING MEASURES (continued)

Unsuitable extinguishing media:

Non-applicable

5.2 Specific hazards arising from the chemical:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Special protective equipment and precautions for fire-fighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

As in any fire, prevent human exposure to fire, smoke, fumes or products of combustion. Only properly trained personnel should be involved in firefighting. Evacuate nonessential personnel from the fire area. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

For emergency responders:

See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and materials for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current standards 29 CFR 1910 Occupational Safety and Health Standards. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

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SECTION 7: HANDLING AND STORAGE (continued)

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace:


Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

8.2 Appropriate engineering controls:


A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protection Equipment. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation, the information on clothing performance must be combined with professional judgment, and a clear understanding of the clothing application, to provide the best protection to the worker. All chemical protective clothing use must be based on a hazard assessment to determine the risks for exposure to chemicals and other hazards. Conduct hazard assessments in accordance with 29 CFR 1910.132.


B.- Respiratory protection

Pictogram	PPE	Remarks
 Mandatory respiratory tract protection	Filter mask for gases, vapours and particles	Replace when an increase in resistance to breathing is observed and/or a smell or taste of the contaminant is detected. Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29CFR).

C.- Specific protection for the hands

Pictogram	PPE	Remarks
 Mandatory hand protection	Protective gloves against minor risks	Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional /industrial users, we recommend using chemical protection gloves. Use gloves in accordance with manufacturer's use limitations and OSHA standard 1910.138 (29CFR)



D.- Ocular and facial protection

Pictogram	PPE	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. Use this PPE in accordance with manufacturer's use limitations and OSHA standard 1910.133 (29CFR)

E.- Bodily protection

Pictogram	PPE	Remarks
	Work clothing	Replace before any evidence of deterioration.
	Anti-slip work shoes	Replace before any evidence of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 68 °F:	Solid
Appearance:	Powdery
Color:	Beige
Odor:	Characteristic
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 68 °F:	Non-applicable *
Vapour pressure at 122 °F:	Non-applicable *
Evaporation rate at 68 °F:	Non-applicable *

Product description:

Density at 68 °F:	Non-applicable *
Relative density at 68 °F:	Non-applicable *
Dynamic viscosity at 68 °F:	Non-applicable *
Kinematic viscosity at 68 °F:	Non-applicable *
Kinematic viscosity at 104 °F:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 68 °F:	Non-applicable *
Partition coefficient n-octanol/water 68 °F:	Non-applicable *
Solubility in water at 68 °F:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Explosive (Solid):

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable *
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9.2 Other information:

Information with regard to physical hazard classes:

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *
Other safety characteristics:	
Surface tension at 68 °F:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	LD50 oral	500 mg/kg (ATEi)	
Bile, extract	LD50 dermal	Non-applicable	
CAS: 8008-63-7	LC50 inhalation	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity (aquatic and terrestrial, where available):

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SECTION 12: ECOLOGICAL INFORMATION (continued)

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Disposal methods:

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations. In case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See epigraph 6.2.

Regulations related to waste management:

Legislation related to waste management:

40 CFR Part 261- IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to 49 CFR on the Transport of Dangerous Goods:

14.1 UN number: Non-applicable

14.2 UN proper shipping name: Non-applicable

14.3 Transport hazard class(es): Non-applicable

Labels: Non-applicable

14.4 Packing group, if applicable: Non-applicable

14.5 Marine pollutant: No

14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises

Physico-Chemical properties: see section 9

14.7 Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 39-18:

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SECTION 14: TRANSPORT INFORMATION (continued)

- | | |
|--|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group, if applicable: | Non-applicable |
| 14.5 Marine pollutant: | No |
| 14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises | |
| Special regulations: | Non-applicable |
| EmS Codes: | |
| Physico-Chemical properties: | see section 9 |
| Limited quantities: | Non-applicable |
| Segregation group: | Non-applicable |
| 14.7 Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): | Non-applicable |

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:

- | | |
|--|----------------|
| 14.1 UN number: | Non-applicable |
| 14.2 UN proper shipping name: | Non-applicable |
| 14.3 Transport hazard class(es): | Non-applicable |
| Labels: | Non-applicable |
| 14.4 Packing group, if applicable: | Non-applicable |
| 14.5 Marine pollutant: | No |
| 14.6 Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises | |
| Physico-Chemical properties: | see section 9 |
| 14.7 Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): | Non-applicable |

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations specific for the product in question:

Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): Non-applicable
 California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986): Non-applicable
 The Toxic Substances Control Act (TSCA) : Bile, extract
 Massachusetts RTK - Substance List: Non-applicable
 New Jersey Worker and Community Right-to-Know Act: Non-applicable
 New York RTK - Substance list: Non-applicable
 Pennsylvania Worker and Community Right-to-Know Law: Non-applicable
 CANADA-Domestic Substances List (DSL): Bile, extract
 CANADA-Non-Domestic Substances List (NDSL): Non-applicable
 NTP (National Toxicology Program): Non-applicable
 Minnesota - Hazardous substances ERTK: Non-applicable
 Rhode Island - Hazardous substances RTK: Non-applicable
 OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096): Non-applicable
 Hazardous Air Pollutants (Clean Air Act): Non-applicable
 CALIFORNIA LABOR CODE - The Hazardous Substances List: Non-applicable
 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantities: Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

Take into consideration other applicable federal, state, and local laws and local regulations.

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This safety data sheet has been designed in accordance with Appendix d to §1910.1200 - Safety data sheets

Texts of the legislative phrases mentioned in section 2:

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

29 CFR 1910.1200:

Acute Tox. 4: H302 - Harmful if swallowed.

Eye Irrit. 2A: H319 - Causes serious eye irritation.

Skin Irrit. 2: H315 - Causes skin irritation.

Skin Sens. 1: H317 - May cause an allergic skin reaction.

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

Occupational Safety & Health Administration (OSHA).

Abbreviations and acronyms:

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

IARC: International Agency for Research on Cancer

Date of compilation: 4/27/2022

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END OF SAFETY DATA SHEET