Safety data sheet according to 29 CFR 1910.1200

Alpha Biosciences - Bile Salts # 3 B02-126

SECTION 1: IDENTIFICATION

1.1 GHS Product identifier: Alpha Biosciences - Bile Salts # 3

B02-126

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

Emergency phone number: 1.4

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture:

NFPA:

Health Hazards: 2 Flammability Hazards: 0 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. 2: Eye irritation, Category 2, H319 Skin Irrit, 2: Skin irritation, Category 2, H315

STOT SE 3: Respiratory tract toxicity, single exposure, Category 3, H335

2.2 **Label elements:**

NFDA-



29 CFR 1910.1200:

Warning



Hazard statements:

Acute Tox. 4: H302 - Harmful if swallowed Eye Irrit. 2: H319 - Causes serious eye irritation Skin Irrit. 2: H315 - Causes skin irritation

STOT SE 3: H335 - May cause respiratory irritation

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/eye protection/face protection

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 contents and / or their container according to the separated collection system used in your municipality

Substances that contribute to the classification

sodium 3-a,12-a-dihydroxy-5-β-cholan-24-oate (CAS: 302-95-4); Sodium cholate (CAS: 361-09-1)

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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:

Non-applicable

3.2 Mixtures:

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 $\S1910.1200$. Therefore, in accordance with Appendix D to $\S1910.1200$, the product contains:

	Identification Chemical name/Classification		Concentration
		sodium 3-α,12-α-dihydroxy-5-β-cholan-24-oate	
CAS:	302-95-4	Acute Tox. 4: H302; STOT SE 3: H335 - Warning	50 - <75 %
CAC	261 00 1	Sodium cholate	FO 47F 0/
CAS:	361-09-1	Eye Irrit. 2: H319; Skin Irrit. 2: H315; STOT SE 3: H335 - Warning	50 - <75 %

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

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:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

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:

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SECTION 5: FIRE-FIGHTING MEASURES (continued)

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

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:

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

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.

 $\hbox{C.-}$ 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

Minimum Temp.: 35.6 °F

Maximum Temp.: 86 °F

Maximum time: 60 Months

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 and vapours	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. 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

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application

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



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

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

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: Not available Color: Not available Odor: Not available Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: Non-applicable * Vapour pressure at 68 °F: Non-applicable * Non-applicable * Vapour pressure at 122 °F: 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 * Non-applicable * Concentration: 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 * Non-applicable * Solubility properties: Decomposition temperature: Non-applicable * Melting point/freezing point: Non-applicable * Explosive properties: Non-applicable * Oxidising properties: Non-applicable * Flammability:

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

*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)

Upper flammability limit: Non-applicable *

Explosive:

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

9.2 Other information:

Surface tension at 68 °F:

Refraction index:

Non-applicable *

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: Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.
- C- Contact with the skin and the eyes (acute effect):
 - Contact with the skin: Produces skin inflammation.
 - Contact with the eyes: Produces eye damage after contact.

- CONTINUED ON NEXT PAGE -

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

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

Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

- 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
sodium 3-a,12-a-dihydroxy-5-β-cholan-24-oate	LD50 oral	1370 mg/kg	Rat
CAS: 302-95-4	LD50 dermal	Non-applicable	
	LC50 inhalation	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Ecotoxicity (aquatic and terrestrial, where available):

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

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

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
 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** Non-applicable

to Annex II of MARPOL 73/78 and the IBC Code):

Transport of dangerous goods by sea:

With regard to IMDG 39-18:

14.1 UN number: Non-applicable
 14.2 UN proper shipping name: Non-applicable
 14.3 Transport hazard class(es): 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** Non-applicable

to Annex II of MARPOL 73/78 and the IBC Code):

Transport of dangerous goods by air:

With regard to IATA/ICAO 2020:

14.1 UN number: Non-applicable
 14.2 UN proper shipping name: Non-applicable
 14.3 Transport hazard class(es): 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 Non-applicable to Annex II of MARPOL

73/78 and the IBC Code):

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SECTION 15: REGULATORY INFORMATION

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

SARA Title III - Toxic Chemical Release Inventory Reporting (Section 313): Non-applicable

California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986); Non-applicable

The Toxic Substances Control Act (TSCA): sodium 3-a,12-a-dihydroxy-5-β-cholan-24-oate; Sodium cholate

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): sodium 3-a,12-a-dihydroxy-5-β-cholan-24-oate; Sodium cholate

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 substances release notification under CERCLA sections 102-103 (40 CFR Part 302): 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:

The Toxic Substances Control Act (TSCA)

Occupational Safety and Health Standards (1910 Subpart Z - Toxic and Hazardous Substances)

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

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:

H335: May cause respiratory irritation

H315: Causes skin irritation

H302: Harmful if swallowed

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. 2: H319 - Causes serious eye irritation Skin Irrit. 2: H315 - Causes skin irritation

STOT SE 3: H335 - May cause respiratory irritation

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



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END OF SAFETY DATA SHEET

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