

# Recombinant Human Serum Albumin, Lipid Free Apollo Scientific

Part Number: **BITP2152** Version No: **1.1** Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

#### Chemwatch Hazard Alert Code: 2

Issue Date: **13/03/2023** Print Date: **31/07/2023** S.REACH.GBR.EN

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

#### **1.1. Product Identifier**

Product name	Recombinant Human Serum Albumin, Lipid Free	
Chemical Name	t Applicable	
Synonyms	Not Available	
Chemical formula	Not Applicable	
Other means of identification	Not Available	

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

Relevant identified uses	Use according to manufacturer's directions.	
Uses advised against	No specific uses advised against are identified.	

#### 1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific	
Address	/hitefield Road, Bredbury SK62QR United Kingdom	
Telephone	01614060505	
Fax	0161 406 0506	
Website	http://www.apolloscientific.co.uk/	
Email	sales@apolloscientific.co.uk	

#### 1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

#### **SECTION 2 Hazards identification**

#### 2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and	H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H315 - Skin Corrosion/Irritation Category 2, H319 - Serious Eye Damage/Eye Irritation Category 2
amendments <sup>[1]</sup>	
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### 2.2. Label elements

Hazard pictogram(s)	
Signal word	Warning

#### Hazard statement(s)

H335	May cause respiratory irritation.	
H315	Causes skin irritation.	
H319	Causes serious eye irritation.	

#### Supplementary statement(s)

Not Applicable

#### Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.	
P261	Avoid breathing dust/fumes.	
P280	Wear protective gloves, protective clothing, eye protection and face protection.	
P264	Wash all exposed external body areas thoroughly after handling.	

#### Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.		
P337+P313	If eye irritation persists: Get medical advice/attention.		
P302+P352	IF ON SKIN: Wash with plenty of water.		
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.		
P332+P313	If skin irritation occurs: Get medical advice/attention.		
P362+P364	Take off contaminated clothing and wash it before reuse.		

#### Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

#### Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

#### 2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

#### **SECTION 3 Composition / information on ingredients**

#### 3.1.Substances

See 'Composition on ingredients' in Section 3.2

#### 3.2.Mixtures

1. CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
Not Available	100	Recombinant Human Serum Albumin, Lipid Free	Not Applicable	Not Applicable	Not Available

Continued...

Legend: 1. Classified by Chernwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; \* EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

#### SECTION 4 First aid measures

#### 4.1. Description of first aid measures

Eye Contact	<ul> <li>If this product comes in contact with eyes:</li> <li>Wash out immediately with water.</li> <li>If irritation continues, seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>	
Skin Contact	<ul> <li>If skin or hair contact occurs:</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>	
Inhalation	<ul> <li>If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>Other measures are usually unnecessary.</li> </ul>	
Ingestion	<ul> <li>Immediately give a glass of water.</li> <li>First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>	

#### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

#### **SECTION 5 Firefighting measures**

#### 5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

#### 5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

#### 5.3. Advice for firefighters

Fire Fighting	<ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Use fire fighting procedures suitable for surrounding area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul>
Fire/Explosion Hazard	<ul> <li>Non combustible.</li> <li>Not considered a significant fire risk, however containers may burn.</li> </ul>

#### **SECTION 6 Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

See section 8

#### 6.2. Environmental precautions

See section 12

#### 6.3. Methods and material for containment and cleaning up

Minor Spills	<ul> <li>Clean up all spills immediately.</li> <li>Avoid contact with skin and eyes.</li> <li>Wear impervious gloves and safety glasses.</li> <li>Use dry clean up procedures and avoid generating dust.</li> <li>Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>Do NOT use air hoses for cleaning</li> <li>Place spilled material in clean, dry, sealable, labelled container.</li> </ul>

Major Spills	<ul> <li>Clear area of personnel and move upwind.</li> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Control personal contact with the substance, by using protective equipment and dust respirator.</li> <li>Prevent spillage from entering drains, sewers or water courses.</li> <li>Avoid generating dust.</li> <li>Sweep, shovel up. Recover product wherever possible.</li> <li>Put residues in labelled plastic bags or other containers for disposal.</li> <li>If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

#### 6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

#### **SECTION 7 Handling and storage**

#### 7.1. Precautions for safe handling

Safe handling	<ul> <li>Limit all unnecessary personal contact.</li> <li>Wear protective clothing when risk of exposure occurs.</li> <li>Use in a well-ventilated area.</li> <li>Avoid contact with incompatible materials.</li> <li>When handling, DO NOT eat, drink or smoke.</li> <li>Keep containers securely sealed when not in use.</li> <li>Avoid physical damage to containers.</li> <li>Always wash hands with soap and water after handling.</li> <li>Work clothes should be laundered separately.</li> <li>Use good occupational work practice.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
Fire and explosion protection	See section 5
Other information	<ul> <li>Store in original containers.</li> <li>Keep containers securely sealed.</li> <li>Store in a cool, dry area protected from environmental extremes.</li> <li>Store away from incompatible materials and foodstuff containers.</li> <li>Protect containers against physical damage and check regularly for leaks.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>For major quantities:</li> <li>Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).</li> <li>Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul>

#### 7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul> <li>Lined metal can, lined metal pail/ can.</li> <li>Plastic pail.</li> <li>Polyliner drum.</li> <li>Packing as recommended by manufacturer.</li> <li>Check all containers are clearly labelled and free from leaks.</li> </ul>
Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed. None known <ul> <li>Moisture sensitive</li> <li>Store at-20°c</li> </ul>
Hazard categories in accordance with Regulation (EC) No 1272/2008	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available

#### 7.3. Specific end use(s)

See section 1.2

### SECTION 8 Exposure controls / personal protection

#### 8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

\* Values for General Population

#### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available						

Not Applicable

#### Emergency Limits

Ingredient	TEEL-1	TEEL-2		TEEL-3
Recombinant Human Serum Albumin, Lipid Free	Not Available	Not Available		Not Available
Ingredient	Original IDLH		Revised IDLH	
Recombinant Human Serum Albumin, Lipid Free	Not Available		Not Available	

#### 8.2. Exposure controls

	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.				
	<ul> <li>Local exhaust ventilation is required where solids are har large, a certain proportion will be powdered by mutual fric</li> <li>If in spite of local exhaust an adverse concentration of the considered.</li> </ul>	ction.			
	considered. Such protection might consist of:				
	(a): particle dust respirators, if necessary, combined with an absorption cartridge;				
8.2.1. Appropriate	<ul><li>(b): filter respirators with absorption cartridge or canister of th</li><li>(c): fresh-air hoods or masks.</li></ul>	ie ngni type,			
engineering controls	Air contaminants generated in the workplace possess varying velocities" of fresh circulating air required to effectively remov		ine the "capture		
		ve the contaminant.	Air Croad		
	Type of Contaminant:		Air Speed:		
	direct spray, spray painting in shallow booths, drum filling, d discharge (active generation into zone of rapid air motion)	conveyer loading, crusher dusts, gas	1-2.5 m/s (200-500 f/min.)		
	grinding, abrasive blasting, tumbling, high speed wheel ger velocity into zone of very high rapid air motion).	nerated dusts (released at high initial	2.5-10 m/s (500-2000 f/min.)		
	Within each range the appropriate value depends on:				
	Lower end of the range	Upper end of the range			
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents			
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity			
	3: Intermittent, low production.	3: High production, heavy use			
	4: Large hood or large air mass in motion	4: Small hood-local control only			

<ul> <li>8.2.1. Individual processing processing</li> <li>8.2.2. Individual processing processing</li> <li>9.2.2. Individual processing processing</li> <li>9.2.2. Individual processing</li> <li>9.2.2. Individual processing</li> <li>9.2.2.2. Individual processing</li> <li>9.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2</li></ul>		Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.
<ul> <li>* Chemical gogles (JASN25 1337.1, EN166 or national equivalent)</li> <li>* Chemical registrop pose a special tenses may aboot and concentrate initiants. A written policy document, describing the vesting of lenses or restrictions on use, should be created or each workplace or task. This should be include a review of lens abootton and adoption for the class of dhenicistics in use and an account of high specification. Medical and first-aid personnel should be trained to rearrow and a suitable equipment should be trained separate. Jean equipment of the site of the class of dhenicistics in use and an account of high specification. Medical and first-aid personnel should be trained and suitable equipment should be trained separate. Jean equipment of the series of the site of the should be the method be removed in a clean environment only after workers have washed hands throughly. [CDC NIOSH Current Intelligence Bulletin 59].</li> <li>Skin protection</li> <li>Skin protection of suitable gives does not only depend on the material, but also on further marks of quality which vary from manifecture in manufacture. Where the chemical is a parametion of several substances. The resistance of the gives material can not be calculated in advance and has therefore to be checked prot to the application. The exact track through through time for substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has to be checked prot to the application. There and the substances has the dependent on usage. Important hands has to be observed where mating a final checke.</li> <li>* Foreunal hysions is a sey element of effecting hand cance. Development on the subs</li></ul>	measures, such as personal protective	
<ul> <li>Hands/feet protection</li> <li>Hands/feet protection</li> <li>Hands/feet protection</li> <li>Personal pagical stability and characterize and pass terafores to be checked substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be obtained from the manufacturer of the protective gloves and has to be obtained from the manufacturer of the protective gloves and has to be obtained from the manufacturer of the protective gloves, hands should be washed and drid thoroughly. Application of a non-perfundem misturiser is recommended.</li> <li>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:         <ul> <li>inequency and duration of contact.</li> <li>chemical resistance of glove material.</li> <li>glove thickness and</li> <li>dexterity</li> </ul> </li> <li>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, ASINZ5 2161.10 r antional equivalent).</li> <li>When onybeing of the contact is expended. A SINZ5 2161.10.1 or national equivalent) is recommended.</li> <li>Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-farm use.</li> <ul> <li>Contaminated gloves abuild be replaced.</li> <li>As defined in ASIN F.733-96 in any application, gloves are rated as:</li> <li>Excellent when breakthrough time &gt; 20 min</li> <li>Fair when breakthrough time &gt; 20 min</li> <li>Fair when breakthrough time &gt; 20 min</li> <li>Foor wheng glove material data should be requaintered.</li></ul></ul>	Eye and face protection	<ul> <li>Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]</li> <li>Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers</li> </ul>
Hands/feet protection       namufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material is an other calculated in advance and has therefore to be checked prior to the application. The exact breadt through time for substances has to be obtained from the manufacturer of the protective gloves, and has to be desired when making a final choice.         Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.         Suitability and durality of glove type is dependent on usage. Important factors in the selection of gloves include: <ul> <li>- frequency and duration of contact.</li> <li>- chemical resistance of glove material.</li> <li>- glove thickness and</li> <li>- dustrity</li> </ul> Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). <ul> <li>- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 374, AS/NZS 2161.1.01 or national equivalent) is recommended.</li> <li>- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time &gt; 20 min</li> <li>- Contaminated gloves should be replaced.</li> <li>As defined in ASTM F.733-96 in any application, gloves are rated as:</li> <li>- Excellent tweb threakthrough time &gt; 20 min</li> <li>- Foor when glove motekthrough time &gt; 20 min</li> <li>- Foor when glove motekthrough time &gt; 20 min</li> <li>- Foor when glove motekthro may time c. 20 min</li> <li>-</li></ul>	Skin protection	See Hand protection below
<ul> <li>fluorocaoutchouc.</li> <li>polyvinyl chloride.</li> <li>Gloves should be examined for wear and/ or degradation constantly.</li> </ul>	Hands/feet protection	<ul> <li>manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</li> <li>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</li> <li>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</li> <li>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</li> <li>trequency and duration of contact,</li> <li>chemical resistance of glove material.</li> <li>glove thickness and</li> <li>dexterity</li> <li>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</li> <li>When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.</li> <li>Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.</li> <li>Contaminated gloves should be replaced.</li> <li>As defined in ASTM F-739-96 in any application, gloves are rated as:</li> <li>Excellent when breakthrough time &gt; 480 min</li> <li>God when breakthrough time &gt; 20 min</li> <li>Fair when breakthrough time &gt; 20 min</li> <li>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, glove selection filt cass. For example:</li> <li>Chornid the gloves will be dependent on the exact composition of the g</li></ul>
		<ul> <li>fluorocaoutchouc.</li> <li>polyvinyl chloride.</li> </ul>

No special equipment needed when handling small quantities.

OTHERWISE:
Overalls.

- Barrier cream.
- Eyewash unit.

#### **Respiratory protection**

Other protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

#### \* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 deqC)

· Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.

• The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

• Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.

• Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.

• Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

 $\cdot$  Use approved positive flow mask if significant quantities of dust becomes airborne.

· Try to avoid creating dust conditions.

#### 8.2.3. Environmental exposure controls

See section 12

#### **SECTION 9** Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available

Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

#### 9.2. Other information

Not Available

#### **SECTION 10 Stability and reactivity**

10.1.Reactivity	See section 7.2	
10.2. Chemical stability	Product is considered stable and hazardous polymerisation will not occur.	
10.3. Possibility of hazardous reactions	See section 7.2	
10.4. Conditions to avoid	See section 7.2	
10.5. Incompatible materials	See section 7.2	
10.6. Hazardous decomposition products	See section 5.3	

#### **SECTION 11 Toxicological information**

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on toxicological effects

Recombinant Human	TOXICITY	IRRITATION	
Chronic	Long-term exposure to the product is not thought to produce chrousing animal models); nevertheless exposure by all routes shoul		
Eye	Although the material is not thought to be an irritant (as classified transient discomfort characterised by tearing or conjunctival redr		
Skin Contact	The material is not thought to produce adverse health effects or using animal models). Nevertheless, good hygiene practice require used in an occupational setting.		
Ingestion	The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.		
Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.		

	Serum Albumin, Lipiu Free	Not Available	Not Available
Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value of Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of che			
		Onless ourerwise specified data extracted non NTECS - Negist	er of Toxic Effect of chemical Substances

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	✓	Reproductivity	×
Serious Eye Damage/Irritation	×	STOT - Single Exposure	*
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×

Legend:

X – Data either not available or does not fill the criteria for classification

 Data available to make classification

#### 11.2 Information on other hazards

#### 11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

#### 11.2.2. Other information

See Section 11.1

#### **SECTION 12 Ecological information**

#### 12.1. Toxicity

Recombinant Human Serum Albumin, Lipid Free	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:         Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity           4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data					

#### 12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air		
	No Data available for all ingredients	No Data available for all ingredients		

#### 12.3. Bioaccumulative potential

Ingredient	Bioaccumulation	
	No Data available for all ingredients	

#### 12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

#### 12.5. Results of PBT and vPvB assessment

	Р	В	т		
Relevant available data	Not Available	Not Available	Not Available		
PBT	×	×	×		
vPvB	×	×	×		
PBT Criteria fulfilled?	PBT Criteria fulfilled?				
vPvB				No	

#### 12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

#### 12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

#### **SECTION 13 Disposal considerations**

#### 13.1. Waste treatment methods

Product / Packaging disposal	<ul> <li>Recycle wherever possible or consult manufacturer for recycling options.</li> <li>Consult State Land Waste Management Authority for disposal.</li> <li>Bury residue in an authorised landfill.</li> <li>Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
Waste treatment options	Not Available
Sewage disposal options	Not Available

#### **SECTION 14 Transport information**

 Marine Pollutant
 NO

 HAZCHEM
 Not Applicable

#### Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number or ID number	Not Applicable			
14.2. UN proper shipping name	Not Applicable	Not Applicable		
14.3. Transport hazard	Class	Not Applicab	le	
class(es)	Subsidiary risk	Not Applicab	le	
14.4. Packing group	Not Applicable	Not Applicable		
14.5. Environmental hazard	Not Applicable			
	Hazard identifica	tion (Kemler)	Not Applicable	
	Classification co	de	Not Applicable	
14.6. Special precautions	Hazard Label		Not Applicable	
for user	Special provisions		Not Applicable	
	Limited quantity		Not Applicable	
	Tunnel Restriction	on Code	Not Applicable	

#### Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable			
14.2. UN proper shipping name	Not Applicable			
	ICAO/IATA Class	Not Applicable		
14.3. Transport hazard class(es)	ICAO / IATA Subrisk	Not Applicable		
0.000(00)	ERG Code	Not Applicable		
14.4. Packing group	Not Applicable	Not Applicable		
14.5. Environmental hazard	Not Applicable			
	Special provisions		Not Applicable	
	Cargo Only Packing Ir	nstructions	Not Applicable	
	Cargo Only Maximum	Qty / Pack	Not Applicable	
14.6. Special precautions for user	Passenger and Cargo	Packing Instructions	Not Applicable	
	Passenger and Cargo Maximum Qty / Pack		Not Applicable	
	Passenger and Cargo Limited Quantity Packing Instructions		Not Applicable	
	Passenger and Cargo Limited Maximum Qty / Pack		Not Applicable	

#### Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	Not Applicable		
14.2. UN proper shipping name	Not Applicable	Not Applicable		
14.3. Transport hazard	IMDG Class	Not Applicable		
class(es)	IMDG Subrisk N	Not Applicable		
14.4. Packing group	Not Applicable			
14.5. Environmental hazard	Not Applicable			
	EMS Number	Not Applicable		
14.6. Special precautions for user	Special provisions	Not Applicable		
	Limited Quantities	Not Applicable		

#### Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	Not Applicable			
14.2. UN proper shipping name	Not Applicable				
14.3. Transport hazard class(es)	Not Applicable Not Applicable				
14.4. Packing group	Not Applicable				
14.5. Environmental hazard	Not Applicable				
	Classification code	Not Applicable			
	Special provisions	Not Applicable			
14.6. Special precautions for user	Limited quantity	Not Applicable			
	Equipment required	Not Applicable			
	Fire cones number	Not Applicable			

#### 14.7. Maritime transport in bulk according to IMO instruments

#### 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

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Not Applicable
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#### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
14.7.3. Transport in bulk i	n accordance with the IGC Code

## Product name Ship Type

#### **SECTION 15 Regulatory information**

#### 15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

#### Information according to 2012/18/EU (Seveso III):

Seveso Category	Not Available
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#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

#### ECHA SUMMARY

Not Applicable

#### **National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Not Available
Canada - DSL	Not Available
Canada - NDSL	Not Available
China - IECSC	Not Available
Europe - EINEC / ELINCS / NLP	Not Available
Japan - ENCS	Not Available
Korea - KECI	Not Available
New Zealand - NZIoC	Not Available
Philippines - PICCS	Not Available
USA - TSCA	Not Available

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#### Recombinant Human Serum Albumin, Lipid Free

National Inventory	Status
Taiwan - TCSI	Not Available
Mexico - INSQ	Not Available
Vietnam - NCI	Not Available
Russia - FBEPH	Not Available
	Yes = All CAS declared ingredients are on the inventory
Legend:	No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

#### **SECTION 16 Other information**

Revision Date	13/03/2023
Initial Date	23/02/2023

#### Full text Risk and Hazard codes

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

#### **Definitions and abbreviations**

PC - TWA: Permissible Concentration-Time Weighted Average PC - STEL: Permissible Concentration-Short Term Exposure Limit IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit. IDLH: Immediately Dangerous to Life or Health Concentrations ES: Exposure Standard OSF: Odour Safety Factor NOAEL :No Observed Adverse Effect Level LOAFL Lowest Observed Adverse Effect Level TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value **BCF: BioConcentration Factors BEI: Biological Exposure Index** AIIC: Australian Inventory of Industrial Chemicals DSI · Domestic Substances List NDSL: Non-Domestic Substances List IECSC: Inventory of Existing Chemical Substance in China EINECS: European INventory of Existing Commercial chemical Substances ELINCS: European List of Notified Chemical Substances NLP: No-Longer Polymers ENCS: Existing and New Chemical Substances Inventory KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals PICCS: Philippine Inventory of Chemicals and Chemical Substances TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas NCI: National Chemical Inventory FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

#### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H335	Expert judgement
Skin Corrosion/Irritation Category 2, H315	Expert judgement
Serious Eye Damage/Eye Irritation Category 2, H319	Expert judgement

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