

rHulnsulin Apollo Scientific

Chemwatch Hazard Alert Code: 2

Part Number: BITP1188 Version No: 1.1 Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878) Issue Date: 20/05/2022 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	rHulnsulin
Chemical Name	Not 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

Rele	evant identified uses	Not Available
U	lses 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	Whitefield 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 ^[1]	
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

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	rHulnsulin	Not Applicable	Not Applicable	Not Available

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	 If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	 If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

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

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	 Clean up all spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Sweep up, shovel up or

Page **4** of **13** rHulnsulin

	 Vacuum up (consider explosion-proof machines designed to be grounded during storage and use). Place spilled material in clean, dry, sealable, labelled container.
Major Spills	 Moderate hazard. CAUTION: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. Recover product wherever possible. IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal. ALWAYS: Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services.

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

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	 Lined metal can, lined metal pail/ can. Plastic pail. Polyliner drum. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known
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	Not Available

application of

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
rHulnsulin	Not Available	Not Available		Not Available
Ingredient	Original IDLH		Revised IDLH	
rHulnsulin	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.				
8.2.1. Appropriate engineering controls	 Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of: (a): particle dust respirators, if necessary, combined with an absorption cartridge; (b): filter respirators with absorption cartridge or canister of the right type; (c): fresh-air hoods or masks. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant. Type of Contaminant: 				
	direct spray, spray painting in shallow booths, drum filling, discharge (active generation into zone of rapid air motion)	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). Within each range the appropriate value depends on:	2.5-10 m/s (500-2000 f/min.)			
	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			

	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.
8.2.2. Individual protection measures, such as personal protective equipment	
Eye and face protection	 Safety glasses with side shields. Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] 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 have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the gloves and has to be observed 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 wathed and dired thoroughly. Application of a non-perfurmed molisturiesr is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: - Ifrequency and durability of glove type is dependent on usage. Important factors in the selection of gloves include: - Ifrequency and durability of glove type is dependent on usage. Important factors in the selection of gloves include: - Ifrequency and durability of glove type is dependent on usage. Important factors in the selection of gloves include: - Ifrequency and durability of glove type is dependent on usage. Important factors in the selection of gloves include: - Ifrequency and durability of glove material, - glove thickness and - deaterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). - When protonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.1 or national equivalent) is recommended. - When only biref contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.1 or national equivalent) - Contaminated gloves should be replaced. As defined in ASTM F-739-96 in any application, gloves are rated as: - Excellent when breakthrough time < 20 min - Good when breakthrough time < 20 min
	Gloves should be examined for wear and/ or degradation constantly.

Page 7 of 13 rHulnsulin

 Overalls. P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit. 	Other protection	 P.V.C apron. Barrier cream. Skin cleansing cream.
--	------------------	---

Respiratory 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	Divided 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

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. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.
Ingestion	The material has NOT 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.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	This material can cause eye irritation and damage in some persons.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.

at tasks as a Par	ΤΟΧΙΟΙΤΥ	IRRITATION
rHulnsulin	Not Available	Not Available
Legend:	 Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register 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	×

Part Number: BITP1188	Page 9 of 13		Issue Date: 20/05/2022
Version No: 1.1	 rHulnsulin		Print Date: 31/07/2023
	•	X – Data eitner not available €	or does not till the criteria tor classification assification

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

	Endpoint	Test Duration (hr)	Species	Value	Source
rHulnsulin	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? No				
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	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse
---------------------------------	--

	► Recycling
	Disposal (if all else fails)
	This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf
	life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use,
	and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.
	DO NOT allow wash water from cleaning or process equipment to enter drains.
	It may be necessary to collect all wash water for treatment before disposal.
	In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
	Where in doubt contact the responsible authority.
	Recycle wherever possible or consult manufacturer for recycling options.
	 Consult State Land Waste Management Authority for disposal.
	Bury residue in an authorised landfill.
	Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

14.1. UN number or ID	Net Applicable				
number	Not Applicable				
14.2. UN proper shipping name	Not Applicable				
14.3. Transport hazard	Class	Not Applicab	le		
class(es)	Subsidiary risk Not Applicable				
14.4. Packing group	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 Restrictio	n 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			
01035(05)	ERG Code Not Applicable			
14.4. Packing group	Not Applicable	Not Applicable		
14.5. Environmental hazard	Not Applicable			
	Special provisions		Not Applicable	
14.6. Special precautions for user	Cargo Only Packing Instructions		Not Applicable	
	Cargo Only Maximum Qty / Pack		Not Applicable	
	Passenger and Cargo Packing Instructions		Not Applicable	
	Passenger and Cargo Maximum Qty / Pack		Not Applicable	

Part Number: BITP1188	Page 11 of 13	Issue Date: 20/05/2022
Version No: 1.1	rHulnsulin	Print Date: 31/07/2023
	_	

 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			
14.2. UN proper shipping name	Not Applicable			
14.3. Transport hazard	IMDG Class	Not Applicable		
class(es)	IMDG Subrisk	Not Applicable		
14.4. Packing group	Not Applicable	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		
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

Not Applicable

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 in 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

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
Taiwan - TCSI	Not Available
Mexico - INSQ	Not Available
Vietnam - NCI	Not Available
Russia - FBEPH	Not Available
Legend:	Yes = All CAS declared ingredients are on the inventory 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	20/05/2022
Initial Date	20/05/2022

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
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value

rHulnsulin

LOD: Limit Of Detection OTV: Odour Threshold Value **BCF: BioConcentration Factors** BEI: Biological Exposure Index AIIC: Australian Inventory of Industrial Chemicals DSL: 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

Powered by AuthorITe, from Chemwatch.

