

# Safety Data Sheet

According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue Number: 1 Effective Date: 13 September 2023 Review Date: 13 September 2026

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

### 1.1. Product identifier

Product Form Product Name Product Code(s) Synonyms : Mixture

: Exo**HERO**®

: EH0001001A & EH0010001B

: ExoHERO<sup>®</sup> 1 (EH0001001A) - 1mL; ExoHERO<sup>®</sup> 10 (EH0010001B) - 10mL

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

### 1.2.1. Relevant identified uses

Main use category Use of the substance/mixture

- : Professional use.
- : Bioseparation material for purification of therapeutic proteins.

### 1.2.2. Uses advised against

Restrictions on use

: Use only for intended applications.

### **1.3. Details of the supplier of the safety data sheet**

### Supplier

Astrea Bioseparations Ltd The Freeport Ballasalla IM9 2AP – Isle of Man T +44 (0) 151 351 4650 <u>Sales@Astrea-bio.com</u>

## **1.4. Emergency telephone number**

**Emergency Number** 

: +44 (0) 151 351 4650 GMT English (0900-1700hrs Mon-Fri)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Cardiff Centre) University Hospital Llandough	Penlan Road CF64 2XX	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Edinburgh Centre) Royal Infirmary of Edinburgh	Little France Crescent EH16 4SA	0344 892 0111	Only for healthcare professionals
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER	+44 20 7188 7188	N/A
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre	16/17 Framlington Place Newcastle-upon-Tyne NE2 4AB	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA	0344 892 0111	Only for healthcare professionals

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SECTION 2: Hazards identificati	ion
2.1. Classification of the substance	or mixture
Classification according to Regulation (	EC) No. 1272/2008 [CLP]
Flammable liquids, Category 3 Full text of H- and EUH-statements: see se	H226 ection 16.
Adverse physicochemical, human healt No additional information available.	h and environmental effects
2.2. Label elements	
Labelling according to Regulation (EC)	No. 1272/2008 [CLP]
Hazard pictograms (CLP)	GHS02
Signal word (CLP)	: Warning
Hazard statements (CLP) Precautionary statements (CLP)	<ul> <li>H226 - Flammable liquid and vapour.</li> <li>P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</li> <li>P233 - Keep container tightly closed.</li> <li>P280 - Wear protective clothing, eye protection, face protection, protective gloves.</li> <li>P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.</li> <li>P403+P235 - Store in a well-ventilated place. Keep cool.</li> <li>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</li> </ul>
Extra phrases	: Exemption for inner packaging where the contents do not exceed 10ml.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII. This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII. Contains no PBT/vPvB substances  $\geq$  0.1% assessed in accordance with REACH Annex XIII.

Component	
	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII. This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

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

## 3.1. Substances

Not applicable.

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Name	Product identifier	%	Classification according to R egulation (EC) No. 1272/2008 [CLP]
Ethanol	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5 REACH-no: 01-2119457610- 43	< 24	Flam. Liq. 2, H225
ull text of H- and EUH-statements: see section 16.	· · ·		·
ECTION 4: First aid measures			
.1. Description of first aid measures			
irst-aid measures after inhalation irst-aid measures after skin contact irst-aid measures after eye contact irst-aid measures after ingestion	<ul><li>and water. If symptoms persist ca</li><li>Remove contact lenses, if presen a doctor.</li></ul>	nd wash it befo III a doctor. t and easy to o	ore reuse. Gently wash with plenty of soap do. Continue rinsing. If symptoms persist c vomiting. Drink plenty of water. Get me
.2. Most important symptoms and effects,	both acute and delayed		
ymptoms/effects after inhalation ymptoms/effects after skin contact ymptoms/effects after eye contact ymptoms/effects after ingestion	<ul> <li>At high concentrations, the vapou</li> <li>Prolonged or repeated contact matrix</li> <li>Redness, itching, tears.</li> <li>Gastrointestinal complaints.</li> </ul>		
.3. Indication of any immediate medical at	tention and special treatment ne	eded	
reat symptomatically.			
ECTION 5: Firefighting measures			
.1. Extinguishing media			
uitable extinguishing media Insuitable extinguishing media	<ul> <li>Dry chemical, CO<sub>2</sub>, dry sand, or a</li> <li>Do not use a heavy water stream.</li> </ul>		nt foam.
.2. Special hazards arising from the subst	ance or mixture		
re hazard azardous decomposition products in case of fire	: Heating may cause a fire. : On combustion, forms: carbon ox	ides (CO and (	CO <sub>2</sub> ).
.3. Advice for firefighters			
refighting instructions rotection during firefighting	<ul><li>Avoid release to the environment.</li><li>Wear recommended personnel pr</li></ul>		ment.
ECTION 6: Accidental release measur	res		
1. Personal precautions, protective equip	ment and emergency procedure	es	
eneral measures	: Avoid contact with skin and eyes. surfaces, sparks, open flames an		ne vapours. Keep away from heat, hot n sources. No smoking.

: For further information refer to section 8: "Exposure controls/personal protection".

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6.	1	.2.	For	emergency	responders
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Protective equipment

: For further information refer to section 8: "Exposure controls/personal protection".

## 6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up		
For containment Methods for cleaning up	<ul> <li>Collect spillage.</li> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Contain or absorb spilled liquid with earth or other absorbent material. After cleaning, flush traces away with water.</li> </ul>	
Other information	: This material and its container must be disposed of as hazardous waste.	

### 6.4. Reference to other sections

SECTION 8. SECTION 11. SECTION 13.

SECTION 7: Handling and sto	brage
7.1. Precautions for safe handlin	ıg
Precautions for safe handling	: Avoid contact with skin and eyes. Do not breathe vapours. Keep out of reach of children. Vapours may cause fire/explosion if source of ignition is present. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use only non- sparking tools.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Use barrier cream. Take off immediately all contaminated clothing and wash it before reuse.
7.2. Conditions for safe storage,	including any incompatibilities
Storage conditions	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a well-ventilated place. Keep container tightly closed. Keep cool.
Incompatible products	: Keep away from food, drink and animal feedingstuffs.
Storage temperature	: 2 – 30 °C

7.3. Specific end use(s)

Bioseparation material for purification of therapeutic proteins.

# **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Ethanol (64-17-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m <sup>3</sup>
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

### 8.1.2. Recommended monitoring procedures

No additional information available.

### 8.1.3. Air contaminants formed

#### No additional information available.

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### 8.1.4. DNEL and PNEC

Ethanol (64-17-5)		
DNEL/DMEL (Workers)		
Acute - local effects, inhalation	1900 mg/m <sup>3</sup>	
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day	
Long-term - systemic effects, inhalation	950 mg/m³	
DNEL/DMEL (General population)		
Acute - local effects, inhalation	950 mg/m³	
Long-term - systemic effects, oral	87 mg/kg bodyweight/day	
Long-term - systemic effects, inhalation	114 mg/m³	
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day	
PNEC (Water)		
PNEC aqua (freshwater)	960 µg/L	
PNEC aqua (marine water)	790 μg/L	
PNEC aqua (intermittent, freshwater)	2.75 mg/l	
PNEC (Sediment)		
PNEC sediment (freshwater)	3.6 mg/kg dwt	
PNEC sediment (marine water)	2.9 mg/kg dwt	
PNEC (Soil)		
PNEC soil	630 μg/kg dw	
PNEC (Oral)		
PNEC oral (secondary poisoning)	380 – 720 mg/kg food	
PNEC (STP)		
PNEC sewage treatment plant	580 mg/l	

### 8.1.5. Control banding

No additional information available.

### 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Good standard of general ventilation. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

### 8.2.2. Personal protection equipment

### Personal protection equipment symbol(s):



### 8.2.2.1. Eye and face protection

Eye protection:

Do not wear contact lenses. Chemical goggles or safety glasses. EN 166.

#### 8.2.2.2. Skin protection

### Skin and body protection: Lab coat.

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## Hand protection:

Hexyl-rubber protective gloves. Neoprene/viton®. EN 374.

### 8.2.2.3. Respiratory protection

### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Wear a respirator conforming to EN140 with Type A/P2 filter or better.

### 8.2.2.4. Thermal hazards

No additional information available.

### 8.2.3. Environmental exposure controls

No additional information available.

# SECTION 9: Physical and chemical properties

# 9.1. Information on basic physical and chemical properties

Physical state	: Solid fiber suspended in liquid.
Colour	: White.
Appearance	: Non-woven fiber, retained in plastic housing – Fiber is suspended in liquid.
Odour	: A Icohol.
Odour threshold	: 180 ppm
Melting point	: 260 °C
Freezing point	: Not available.
Boiling point	: > 86 °C
Flammability	: Not available.
Explosive limits	: Not available.
Lower explosion limit	: 3.3 vol % For ethanol at 100%
Upper explosion limit	: 19 vol % For ethanol at 100%
Flash point	: 34 °C Extrapolated from information in "Fire Protection Guide to Hazardous Materials", 13th
	Ed., page 325-57 (2002) & NIH.
Auto-ignition temperature	: 365 °C For ethanol at 100%
Decomposition temperature	: Not available.
pH	: Not available.
Viscosity, kinematic	: Not available.
Solubility	: Not available.
Partition coefficient n-octanol/water (Log Kow)	: Not available.
Vapour pressure	: Not available.
Vapour pressure at 50°C	: Not available.
Density	: Not available.
Relative density	: 959.3 at 20°C
Relative vapour density at 20°C	: Not available.
Particle characteristics	: Not applicable.

# 9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

9.2.2. Other safety characteristics

No additional information available.

# SECTION 10: Stability and reactivity

# 10.1. Reactivity

## None.

# 10.2. Chemical stability

Stable under normal conditions of use.

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## 10.3. Possibility of hazardous reactions

None under normal use.

### 10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

### 10.5. Incompatible materials

Strong oxidizing agents. Strong acids.

### 10.6. Hazardous decomposition products

Toxic fumes may be released. On combustion, forms: carbon oxides (CO and CO<sub>2</sub>).

## **SECTION 11: Toxicological information**

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

Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation) Additional information Ethanol (64-17-5)	<ul> <li>Not classified.</li> <li>Not classified.</li> <li>Not classified.</li> <li>Gastrointestinal complaints.</li> </ul>
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
Skin corrosion/irritation Additional information Serious eye damage/irritation Additional information Respiratory or skin sensitisation Germ cell mutagenicity Carcinogenicity Reproductive toxicity STOT-single exposure Additional information STOT-repeated exposure	<ul> <li>Not classified.</li> <li>Prolonged or repeated contact may cause skin to become dry.</li> <li>Not classified.</li> <li>Redness, itching, tears.</li> <li>Not classified.</li> </ul>
Ethanol (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
Aspiration hazard	: Not classified.

### 11.2. Information on other hazards

No additional information available.

# SECTION 12: Ecological information

## 12.1. Toxicity

Hazardous to the aquatic environment, short-term	: Not classified.
(acute)	
Hazardous to the aquatic environment, long-term	: Not classified.
(chronic)	

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Ethanol (64-17-5)	
LC50 - Fish [1]	11.2 – 14.2 g/l
EC50 - Crustacea [1]	5.012 g/l
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic crustacea	9.6 mg/l Freshwater
NOEC chronic algae	1.58 g/l Marine

## 12.2. Persistence and degradability

Exo <b>HERO</b> ®	
Persistence and degradability	Product is biodegradable.
Ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	100 %
12.3. Bioaccumulative potential	
Exo <b>HERO</b> ®	
Bioaccumulative potential	There is no bioaccumulation.
Ethanol (64-17-5)	
Partition coefficient n-octanol/water (Log Kow)	-0.35 at 20-24°C
Bioaccumulative potential	There is no bioaccumulation.

# 12.4. Mobility in soil

Exo <b>HERO</b> ®	
Ecology - soil	Miscible with water. May spread in water systems.
Ethanol (64-17-5)	
Ecology - soil	Soluble in water.

# 12.5. Results of PBT and vPvB assessment

Exo <b>HERO</b> ®	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.	
Component	

Ethanol (64-17-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.
	This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

# 12.6. Endocrine disrupting properties

No additional information available.

## 12.7. Other adverse effects

No additional information available.

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

### 13.1. Waste treatment methods

Waste treatment methods

: This material and its container must be disposed of as hazardous waste.

## **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID: IMDG ΙΑΤΑ ADN RID ADR 14.1. UN number or ID number Not regulated Not regulated Not regulated Not regulated Not regulated 14.2. UN proper shipping name Not regulated Not regulated Not regulated Not regulated Not regulated 14.3. Transport hazard class(es) Not regulated Not regulated Not regulated Not regulated Not regulated 14.4. Packing group Not regulated Not regulated Not regulated Not regulated Not regulated 14.5. Environmental hazards Not regulated Not regulated Not regulated Not regulated Not regulated No supplementary information available.

### 14.6. Special precautions for user

**Special transport precautions** 

: Special provision 144 – An aqueous solution containing not more than 24% alcohol by volume is not subject to the requirements of ADR.

Overland transport Not regulated.

Transport by sea Not regulated.

Air transport Not regulated.

**Inland waterway transport** Not regulated.

Rail transport Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

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

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

### 15.1.1. EU-Regulations

#### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions).

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### **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List).

### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List.

### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals).

#### **POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants).

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer).

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors).

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances).

### 15.1.2. National regulations

No additional information available.

## 15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out: Ethanol

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

#### Indication of changes:

Formulation updated, no change in classification.

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS-No.	Chemical Abstract Service number.
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
DMEL	Derived Minimal Effect level.
DNEL	Derived-No Effect Level.
EC50	Median effective concentration.
EC-No.	European Community number.
ΙΑΤΑ	International Air Transport Association.
	IBC Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IMO).
IMDG	International Maritime Dangerous Goods.
LC50	Median lethal concentration.
LD50	Median lethal dose.
NOAEL	No-Observed Adverse Effect Level.
РВТ	Persistent Bioaccumulative Toxic.
PNEC	Predicted No-Effect Concentration.

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Abbreviations and acronyms:	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail.
vPvB	Very Persistent and Very Bioaccumulative.

Data sources

: ECHA (European Chemicals Agency). Supplier's safety documents.

Full text of H- and EUH-statements:	
Flam. Liq. 2	Flammable liquids, Category 2.
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.