



# SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - Switzerland

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

### 1.1 Product identifier

Product name	Adult Bovine Serum Collected and Processed in New Zealand EMEA/CVMP/743/00 and EMA/CHMP/BWP/457920/2012 CONFORMING
Catalogue Number	SH30528
EC number	Not available.
CAS number	Not available.
Product description	Not available.
Product type	Liquid.
Other means of identification	Not available.

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

Not applicable.

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

#### Supplier

Cytiva Austria  
Krempelstr. 5  
4061 Pasching  
AUSTRIA  
Phone: +43 7229 64865

#### Hours of operation

Mo. - Fr.  
08.30 - 17.00

HyClone Laboratories  
925 West 1800 South  
Logan, Utah 84321  
Phone: (435) 792-8000

Cytiva Singapore  
1 Maritime Square #13-01  
Harbourfront Centre  
Singapore 099253

Person who prepared the SDS: sds\_author@cytiva.com

#### Switzerland

Cytiva Austria  
Krempelstr. 5  
4061 Pasching  
AUSTRIA  
Phone: +43 7229 64865

### 1.4 Emergency telephone number

Call INFOTRAC 24 Hour number:  
001-352-323-3500 (Call Collect).

#### National advisory body/Poison Centre

**Switzerland**

Schweizerisches Toxikologische  
Informationszentrum  
Freiestrasse 16  
8032 Zürich  
Tel.: +41 (1) 251 51 51

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

**Product definition** Mono-constituent substance

**Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]**

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

**2.2 Label elements****Hazard pictograms**

**Signal word** No signal word.

**Hazard statements** No known significant effects or critical hazards.

**Precautionary statements**

**Prevention** Not applicable.

**Response** Not applicable.

**Storage** Not applicable.

**Disposal** Not applicable.

**Supplemental label elements** Not applicable.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** Not applicable.

**Special packaging requirements**

**Containers to be fitted with child-resistant fastenings** Not applicable.

**Tactile warning of danger** Not applicable.

**2.3 Other hazards**

**Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII**

PBT	P	B	T	vPvB	vP	vB
N/A	N/A	N/A	N/A	N/A	N/A	N/A

**Other hazards which do not result in classification** None known.

**SECTION 3: Composition/information on ingredients****3.1 Substances** Mono-constituent substance

Product/ingredient name	Identifiers	%	<b><u>Classification</u></b>	
			Regulation (EC) No. 1272/2008 [CLP]	Type
-	-	100	Not classified.	[A]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

**Type**

- [A] Constituent  
 [B] Impurity  
 [C] Stabilising additive

Occupational exposure limits, if available, are listed in Section 8.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

<b>Eye contact</b>	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
<b>Skin contact</b>	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
<b>Protection of first-aiders</b>	No action shall be taken involving any personal risk or without suitable training.

**4.2 Most important symptoms and effects, both acute and delayed****Over-exposure signs/symptoms**

<b>Eye contact</b>	No specific data.
<b>Inhalation</b>	No specific data.
<b>Skin contact</b>	No specific data.
<b>Ingestion</b>	No specific data.

**4.3 Indication of any immediate medical attention and special treatment needed**

<b>Notes to physician</b>	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
<b>Specific treatments</b>	No specific treatment.

See toxicological information (Section 11)

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

<b>Suitable extinguishing media</b>	Use an extinguishing agent suitable for the surrounding fire.
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**Unsuitable extinguishing media** None known.

**5.2 Special hazards arising from the substance or mixture**

<b>Hazards from the substance or mixture</b>	In a fire or if heated, a pressure increase will occur and the container may burst.
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<b>Hazardous combustion products</b>	No specific data.
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**5.3 Advice for firefighters**

<b>Special precautions for fire-fighters</b>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
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<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
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## SECTION 6: Accidental release measures

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

**For non-emergency personnel** No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

**For emergency responders** If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### 6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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

**Small spill** Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

**Large spill** Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

### 6.4 Reference to other sections

See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

## SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 7.1 Precautions for safe handling

**Protective measures** Put on appropriate personal protective equipment (see Section 8).

**Advice on general occupational hygiene** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

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

Do not store above the following temperature: -10°C (14°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

### 7.3 Specific end use(s)

**Recommendations** For Further Manufacturing or Research Use. Not for Diagnostic or Therapeutic Use.

**Industrial sector specific solutions** Not available.

## SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

### 8.1 Control parameters

#### Occupational exposure limits

No exposure limit value known.

#### **Recommended monitoring procedures**

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

**DNELs/DMELs**

No DELs available.

**PNECs**

No PECs available.

**8.2 Exposure controls****Appropriate engineering controls**

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

**Individual protection measures****Hygiene measures**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection**

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

**Skin protection****Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

**Body protection**

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Other skin protection**

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection**

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

**Environmental exposure controls**

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties****Appearance**

<b>Physical state</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient: n-octanol/water</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.

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<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidising properties</b>	Not available.

**9.2 Other information**

<b>Burning time</b>	Not applicable.
<b>Burning rate</b>	Not applicable.
<b>Solubility in water</b>	Not available.

**SECTION 10: Stability and reactivity**

<b>10.1 Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	No specific data.
<b>10.5 Incompatible materials</b>	No specific data.
<b>10.6 Hazardous decomposition products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

**SECTION 11: Toxicological information****11.1 Information on toxicological effects****Acute toxicity**

**Conclusion/Summary** Not available.

N/A

**Irritation/Corrosion**

**Conclusion/Summary** Not available.

**Sensitiser**

**Conclusion/Summary** Not available.

**Mutagenicity**

**Conclusion/Summary** Not available.

**Carcinogenicity**

**Conclusion/Summary** Not available.

**Reproductive toxicity**

**Conclusion/Summary** Not available.

**Teratogenicity**

**Conclusion/Summary** Not available.

**Specific target organ toxicity (single exposure)**

Not available.

**Specific target organ toxicity (repeated exposure)**

Not available.

**Aspiration hazard**

Not available.

**Information on likely routes of exposure** Routes of entry anticipated: Oral, Dermal.

**Potential acute health effects**

<b>Inhalation</b>	No known significant effects or critical hazards.
<b>Ingestion</b>	No known significant effects or critical hazards.
<b>Skin contact</b>	No known significant effects or critical hazards.
<b>Eye contact</b>	No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

Inhalation	No specific data.
Ingestion	No specific data.
Skin contact	No specific data.
Eye contact	No specific data.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Short term exposure**

Potential immediate effects	Not available.
Potential delayed effects	Not available.

**Long term exposure**

Potential immediate effects	Not available.
Potential delayed effects	Not available.

**Potential chronic health effects**

Not available.

Conclusion/Summary	Not available.
General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Teratogenicity	No known significant effects or critical hazards.
Developmental effects	No known significant effects or critical hazards.
Fertility effects	No known significant effects or critical hazards.
Other information	Not available.

**SECTION 12: Ecological information****12.1 Toxicity**

Conclusion/Summary	Not available.
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**12.2 Persistence and degradability**

Conclusion/Summary	Not available.
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**12.3 Bioaccumulative potential**

Not available.

**12.4 Mobility in soil**

Soil/water partition coefficient (K <sub>oc</sub> )	Not available.
Mobility	Not available.

**12.5 Results of PBT and vPvB assessment**

Product/ingredient name	PBT	P	B	T	vPvB	vP	vB
Adult Bovine Serum Collected and Processed in New Zealand EMEA/CVMP/743/00 and EMA/CHMP/BWP/457920/2012 CONFORMING	N/A	N/A	N/A	N/A	N/A	N/A	N/A

**12.6 Other adverse effects**

No known significant effects or critical hazards.

## SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 13.1 Waste treatment methods

#### Product

##### Methods of disposal

The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

##### Hazardous waste

Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

#### Packaging

##### Methods of disposal

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

##### Special precautions

This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

## SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not available.	Not available.	Not available.	Not available.
14.2 UN proper shipping name	Not available.	Not available.	Not available.	Not available.
14.3 Transport hazard class(es)	Not available.	Not available.	Not available.	Not available.
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

#### 14.6 Special precautions for user

**Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not available.

## SECTION 15: Regulatory information

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

#### EU Regulation (EC) No. 1907/2006 (REACH)

#### Annex XIV - List of substances subject to authorisation

##### Annex XIV

None of the components are listed.

##### Substances of very high concern

None of the components are listed.

#### Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

#### Other EU regulations



**Industrial emissions  
(integrated pollution  
prevention and control) - Air**

Not listed

**Industrial emissions  
(integrated pollution  
prevention and control) -  
Water**

Not listed

**Ozone depleting substances (1005/2009/EU)**

Not listed.

**Prior Informed Consent (PIC) (649/2012/EU)**

Not listed.

**Seveso Directive**

This product is not controlled under the Seveso Directive.

**National regulations**

**VOC content** Exempt.

**International regulations**

**Chemical Weapon Convention List Schedules I, II & III Chemicals**

Not listed.

**Montreal Protocol (Annexes A, B, C, E)**

Not listed.

**Stockholm Convention on Persistent Organic Pollutants**

Not listed.

**Rotterdam Convention on Prior Informed Consent (PIC)**

Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals**

Not listed.

**Inventory list**

<b>Europe</b>	Not determined.
<b>United States</b>	Not determined.
<b>Canada inventory</b>	Not determined.
<b>China</b>	Not determined.
<b>Japan</b>	<b>Japan inventory (ENCS):</b> Not determined. <b>Japan inventory (ISHL):</b> Not determined.

**15.2 Chemical safety assessment** This product contains substances for which Chemical Safety Assessments are still required.

## SECTION 16: Other information

 Indicates information that has changed from previously issued version.

**Abbreviations and acronyms**

ATE = Acute Toxicity Estimate  
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]  
 DMEL = Derived Minimal Effect Level  
 DNEL = Derived No Effect Level  
 EUH statement = CLP-specific Hazard statement  
 N/A = Not available  
 PBT = Persistent, Bioaccumulative and Toxic  
 PNEC = Predicted No Effect Concentration  
 RRN = REACH Registration Number  
 vPvB = Very Persistent and Very Bioaccumulative

**Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]**

Classification	Justification
Not classified.	

**Full text of abbreviated H statements** Not applicable.

**Full text of classifications [CLP/ GHS]** Not applicable.

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**Date of previous issue** 20 February 2017  
**Version** 2

**Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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