

SAFETY DATA SHEET

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

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

1.1 Product identifier

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

<u>Supplier</u> Cytiva Austria

Kremplstr. 5 4061 Pasching AUSTRIA

Phone: +43 7229 64865

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

United Kingdom (UK) Cytiva Austria

Kremplstr. 5 4061 Pasching AUSTRIA

Phone: +43 7229 64865

1.4 Emergency telephone number

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

Hours of operation

Mo. - Fr.

08.30 - 17.00

National advisory body/Poison Centre

Article Number SH30528 Page: 1/10

Kdult Bovine Serum Collected and Processed in New Zealand EMEA/CVMP/743/00 and EMA/

CHMP/BWP/457920/2012 CONFORMING

United Kingdom (UK) National Poison Information Centre

Medical Toxicology Unit Avalonley Road London SE14 5ER Tel.: +44 (171)635 91 91

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

PreventionNot applicable.ResponseNot applicable.StorageNot applicable.DisposalNot applicable.Supplemental label elementsNot applicable.

Annex XVII - Restrictions on the Not applicable.

manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

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 \sqrt{N}/A N/A N/A N/A N/A N/A N/A

Other hazards which do not None known.

result in classification

SECTION 3: Composition/information on ingredients

3.1 Substances Mono-constituent substance

			<u>Classification</u>	
Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Туре
-	-	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.

Article Number SH30528 Page: 2/10

Adult Bovine Serum Collected and Processed in New Zealand EMEA/CVMP/743/00 and EMA/

CHMP/BWP/457920/2012 CONFORMING

<u>Type</u>

[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

Eye contact 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.

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical

attention if symptoms occur.

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get

medical attention if symptoms occur.

Ingestion 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.

Protection of first-aidersNo 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

Eye contactNo specific data.InhalationNo specific data.Skin contactNo specific data.IngestionNo specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically. Contact poison treatment specialist immediately if large quantities have

been ingested or inhaled.

Specific treatments No specific treatment.

See toxicological information (Section 11)

SECTION 5: Firefighting measures

5.1 Extinguishing media

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or In a fire or if heated, a pressure increase will occur and the container may burst.

mixture

Hazardous combustion

products

No specific data.

5.3 Advice for firefighters

Special precautions for fire-

fighters

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.

Special protective equipment

for fire-fighters

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.

Article Number SH30528 Page: 3/10

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No action shall be taken involving any personal risk or without suitable training. Evacuate For non-emergency personnel

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".

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

6.2 Environmental Inform the relevant authorities if the product has caused environmental pollution (sewers, precautions

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.

Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, Large spill

> 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).

hygiene

Advice on general occupational 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

To 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 wellventilated 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)

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

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.

Article Number SH30528 Page: 4/10

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

Physical state Liquid.

Colour Not available. Odour Not available. **Odour threshold** Not available. Not available. Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Flash point Not available. **Evaporation rate** Not available Flammability (solid, gas) Not available Upper/lower flammability or Not available

explosive limits

Vapour pressure Not available. Not available. Vapour density Relative density Not available. Solubility(ies) Not available. Partition coefficient: n-octanol/ Not available.

water

Auto-ignition temperature Not available. **Decomposition temperature** Not available.

> Article Number SH30528 Page: 5/10

ViscosityNot available.Explosive propertiesNot available.Oxidising propertiesNot available.

9.2 Other information

Burning timeNot applicable.Burning rateNot applicable.Solubility in waterNot available.

SECTION 10: Stability and reactivity

10.1 Reactivity No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability The product is stable.

10.3 Possibility of hazardous

reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid No specific data.10.5 Incompatible materials No specific data.

10.6 Hazardous Under normal conditions of storage and use, hazardous decomposition products should not be

decomposition products 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.

<u>Sensitiser</u>

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 Routes of entry anticipated: Oral, Dermal.

exposure

Potential acute health effects

InhalationNo known significant effects or critical hazards.IngestionNo known significant effects or critical hazards.Skin contactNo known significant effects or critical hazards.Eye contactNo known significant effects or critical hazards.

Article Number SH30528 Page: 6/10

Symptoms related to the physical, chemical and toxicological characteristics

InhalationNo specific data.IngestionNo specific data.Skin contactNo specific data.Eye contactNo 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.

GeneralNo known significant effects or critical hazards.CarcinogenicityNo known significant effects or critical hazards.MutagenicityNo known significant effects or critical hazards.TeratogenicityNo known significant effects or critical hazards.Developmental effectsNo known significant effects or critical hazards.Fertility effectsNo known significant effects or critical hazards.

Other information Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary Not available.

12.2 Persistence and degradability

Conclusion/Summary Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

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Soil/water partition coefficient Not available.

 (K_{oc})

Mobility Not available.

12.5 Results of PBT and vPvB assessment

Product/ingredient name PBT P B T

Adult Bovine Serum Collected N/A N/A N/A N/A

and Processed in New Zealand

EMEA/CVMP/743/00 and EMA/
CHMP/BWP/457920/2012

12.6 Other adverse effects No known significant effects or critical hazards.

Article Number SH30528 Page: 7/10

vPvB

N/A

vΡ

N/A

vΒ

N/A

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 Not applicable. manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Other EU regulations

Article Number SH30528 Page: 8/10

Adult Bovine Serum Collected and Processed in New Zealand EMEA/CVMP/743/00 and EMA/

CHMP/BWP/457920/2012 CONFORMING

Industrial emissions Not listed (integrated pollution

prevention and control) - Air

Not listed

(integrated pollution prevention and control) -

Industrial emissions

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.

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

Europe Not determined. **United States** Not determined. Canada inventory Not determined. China Not determined.

Japan inventory (ENCS): Not determined. Japan

Japan inventory (ISHL): 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/ Not applicable.

GHS]

Article Number SH30528 Page: 9/10

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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.

Article Number SH30528 Page: 10/10

SH30528