

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Identity	CytoGam
Alternate Names	CytoGam

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

Intended use	See Technical Data Sheet.
Application Method	See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name	CSL Behring L.L.C. 1020 First Avenue PO Box 61501 King of Prussia, PA
---------------------	--

Emergency

24 hour Emergency Telephone No.	Emergency Response: (800) 424-9300 Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C.	(610) 878-4000

2. Hazard identification of the product

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

No applicable CLP categories.

Classification according to 67/548/EEC or 1999/45/EC.

No applicable DPD categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

According to Regulation (EC) No 1272/2008

[Prevention]:

No CLP prevention statements

[Response]:

No CLP response statements

[Storage]:

No CLP storage statements

[Disposal]:

No CLP disposal statements
See Technical Data Sheet.

2.3. Other hazards

This product contains no PBT/vPvB chemicals.

3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Non-Hazardous Ingredients

- Cytomegalovirus Immune Globulin Intravenous (Human) (CMV-IVIG) 2.5g
- Sucrose, USP
- Sodium Chloride, USP
- Aminoacetic acid (glycine), USP
- Water For Injection, USP

4. First aid measures

4.1. Description of first aid measures

- | | |
|-------------------|---|
| General | In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. |
| Inhalation | Remove to fresh air. |
| Eye | Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser. |
| Ingestion | Drink water. Obtain medical attention if feeling ill. |

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

Overview Potential Health Effects
 This product is a biologic prepared from purified antibodies obtained from human plasma tested and found to be negative for anti-HIV antibodies and for Hepatitis B and C viruses. This product is further subjected to a solvent detergent virus inactivation procedure to enhance product safety. However, the risk of infectivity due to known or as yet unknown pathogens cannot be totally eliminated from this product.

No adverse health effects anticipated with normal handling and use in appropriate medical setting. Medical implications of therapeutic use are described in product package insert or may be found in the Physicians' Desk Reference.

Emergency Overview:
 This product is a sterile prescription pharmaceutical. It is to be administered only at the order of a licensed physician. This product is safe when used for its intended purpose and administered as directed by a physician. In addition, no adverse health effects are anticipated as a result of incidental contact or exposure to this product by those handling it or administering it in a therapeutic setting. More detailed information is available in the product package insert. Please report adverse events in patients using this product to the manufacturer at the telephone number listed above.

- Eye
No data. No adverse health effects reported nor anticipated.
- Skin Contact
No data. No adverse health effects reported nor anticipated.
- Skin Absorption

This product is not absorbed through the skin.
Ingestion
Not intended for oral use. Expected to be relatively non-toxic if ingested.
Chronic Effects/Carcinogenicity
None known or anticipated under normal handling and exposure conditions.
See section 2 for further details.

5. Fire-fighting measures

5.1. Extinguishing media

Product is not flammable. The only potential fire hazard would involve packaging material

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

5.3. Advice for fire-fighters

Fire fighting personnel should respond with appropriate protective clothing, firefighting gear, and breathing equipment as trained. All other personnel should exit the area and proceed to a gathering point in an area unaffected by the fire and smoke.

Hazardous Combustion Products: Packaging material fire may produce carbon monoxide and other gaseous asphyxiants plus airborne particulate matter.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Large Spill

Absorb spills with material suitable for aqueous solutions and dispose in solid waste container, or mop spilled material with detergent/water or bleach/water solution and dispose in sanitary sewer. Ventilate area, if desired.

Small Spill

Clean area of spill with wetted toweling and dispose in solid waste container, or follow procedure for large spills.

7. Handling and storage

7.1. Precautions for safe handling

General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.
 Storage and transportation temperatures should not fall below 2C and not exceed 8C.
 Incompatible materials: No data available.
 Keep container closed tightly.
 Store locked up or accessible to authorized persons or their representatives only.

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls

Respiratory	Not Applicable
Eyes	Not Applicable
Skin	Not Applicable
Engineering Controls	Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

Other Work Practices Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

Appearance	Clear Liquid
Odor	None
Odor threshold	Not Measured
pH	6.8 +/- 0.4
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Complete
Partition coefficient n-octanol/water (Log Kow)	Not Measured

Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

None

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No hazardous decomposition data available.

11. Toxicological information

Acute toxicity

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable

Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Disposal Information

Not classified as hazardous waste. Observe all federal, state, and local regulations.

Waste Disposal Methods

Waste must be disposed in accordance with federal, state and local environmental regulations. Uncontaminated product may be disposed by flushing down the sanitary sewer, or by mixing with a liquid sorbent and then placing mixture in the solid waste container for disposal. Incineration is the preferred method of disposal for any contaminated product.

14. Transport information

DOT (Domestic Surface

IMO / IMDG (Ocean

ICAO/IATA

	Transportation)	Transportation)	
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user			
	No further information		

15. Regulatory information

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

EU Legislation

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

National Legislation

None noted.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

The information contained herein is based upon data considered true and accurate. CSL Behring makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

End of Document