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 2°C and not exceed 8°C.
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

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

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
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
14.1. UN number
Not Applicable

14.2. UN proper shipping name
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

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


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.

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