



# MATERIAL SAFETY DATA SHEET

## DC-TROL Level 1

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** DC-TROL Level 1

**Product Number:** SM-052

**Synonym(s):** DC-Trol Multi-Analyte Control

**Product Use:** For in vitro diagnostic use in quality control.

**Description:** Lyophilized powder mixture containing human serum, salts, buffers, and trace amounts of antibiotics, drugs, hormones and enzymes.

**Corporate Headquarters**

**Genzyme Corporation**

500 Kendall Street  
Cambridge, MA 02142  
USA

**Phone:** 617-252-7500

**Distributor**

**Genzyme Diagnostics**

50 Gibson Drive  
Kings Hill, West Malling  
Kent, ME19 4AF  
UK

**Phone:** 44 (0) 1732 220022

**Distributor**

**Genzyme Diagnostics P.E.I. Inc.**

70 Watts Ave.  
Charlottetown, PE C1E 2B9  
CANADA

**Phone:** 800-332-1042

**Distributor**

**Genzyme Diagnostics**

31 New York Avenue  
Framingham, MA 01701-9322  
USA

**Phone:** 800-332-1042

**Emergency Telephone Numbers**

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 800-424-9300  
**CHEMTREC (Outside U.S.):** 703-527-3887

### 2. HAZARDS IDENTIFICATION

**Precautionary Statements:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May cause irritation to skin, eyes and respiratory tract. May be harmful if inhaled, absorbed or swallowed. Avoid contact with eyes and skin. Do not ingest or inhale. The human serum in this preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions. Preparation appearance: off-white lyophilized powder.

**Routes of Exposure:**

Occupational exposure routes may include eye contact, skin contact, skin absorption and inhalation.

**Potential Health Effects:**

<b>Inhalation</b>	No data available. Inhalation may cause respiratory tract irritation and may result in systemic effects.
<b>Eye</b>	No data available. Eye exposure may cause irritation, redness and watering.
<b>Skin</b>	No data available. Skin contact may be irritating. Possible systemic effects from skin absorption are unknown.
<b>Ingestion</b>	No data available.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	Unknown.



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### Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

### Potential Environmental Effects:

No data available.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Human serum	Not Assigned	Not Assigned	35 - 50
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Alpha lactose	5989-81-1	Not Assigned	20 - 30
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Lysine bicarbonate	Not Assigned	Not Assigned	10 - 15
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
HEPES, Free Acid	7365-45-9	230-907-9	2.5 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium chloride	7647-14-5	231-598-3	2.5 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium acetate trihydrate	6131-90-4	Not Assigned	2.5 - 5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
D-glucose	50-99-7	200-075-1	1 - 2.5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Cholesterol, bovine-source	57-88-5	200-353-2	1 - 2.5
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Triglyceride extract	Not Assigned	Not Assigned	1 - 2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Urea	57-13-6	200-315-5	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Potassium chloride	7447-40-7	231-211-8	< 1
<b>EC R-Phrases:</b> R36	<b>EC Hazard Class:</b> Xi		
Calcium chloride dihydrate	10035-04-8	233-140-8	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Lactic acid	79-33-4	201-196-2	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Magnesium chloride hexahydrate	7791-18-6	Not Assigned	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Salicylic acid	69-72-7	200-712-3	< 1
<b>EC R-Phrases:</b> R22, R36/38	<b>EC Hazard Class:</b> Xn		
Valproic acid	1069-66-5	213-961-8	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		



## MATERIAL SAFETY DATA SHEET

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#### 4. FIRST AID MEASURES

**General Advice:**

In the event of occupational exposure, follow company-specific bloodborne pathogen post-exposure requirements.

**Inhalation:**

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

**Eye Contact:**

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

**Skin Contact:**

In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

**Ingestion:**

In case of ingestion, contact a poison control center and seek immediate medical attention.

#### 5. FIRE FIGHTING MEASURES

**Flammable Properties:**

Material may burn when exposed to sufficient heat.

**Suitable Extinguishing Media:**

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

Irritating or highly toxic gases may be generated by combustion.

**Standard Protective Equipment and Precautions for Firefighters:**

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:**

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid generating or inhaling dust. Ensure adequate ventilation. Wash hands thoroughly after handling.

**Environmental Precautions:**

No information available.

**Methods and Materials for Containment and Clean-Up:**

Do not dry sweep powder. Use HEPA-filtered vacuum, if available, otherwise wet mop to clean up a powder spill. Very slippery when wet. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.



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#### 7. HANDLING AND STORAGE

**Handling:**

Follow universal/standard precautions when handling this material. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

**Storage:**

Store at 2 - 8°C (36 - 46°F). Do not store with incompatible substances; see Section 10.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Guidelines:**

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

**Engineering Controls:**

Preparation and handling of this preparation should be performed in accordance with universal/standard precautions. Facilities storing or using this preparation should be equipped with an eyewash fountain.

**Personal Protective Equipment (PPE):**

<b>Respiratory</b>	A respirator is not required under normal conditions of use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety glasses or goggles.
<b>Skin</b>	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves. Change gloves regularly or immediately if they are contaminated, torn or punctured.
<b>General</b>	Follow company-specific safety procedures.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Off-white lyophilized powder	<b>pH:</b>	7.5 - 7.7 (in aqueous solution)
<b>Odor:</b>	Slight odor	<b>Solubility:</b>	Water-miscible
<b>Specific Gravity:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Boiling Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Melting Point:</b>	Not available	<b>Vapor Density:</b>	Not applicable
<b>Freezing Point:</b>	Not applicable		
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not applicable		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not applicable		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not applicable		



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### 10. STABILITY AND REACTIVITY

**Chemical Stability:**

Unknown.

**Conditions to Avoid:**

Unknown.

**Incompatible Materials:**

Unknown.

**Hazardous Decomposition Products:**

Thermal decomposition may lead to release of irritating gases and vapors.

**Possibility of Hazardous Reactions:**

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

**Acute Effects:**

**Toxicology Data - Selected LD50s and LC50s**

D-glucose	50-99-7	Oral LD50 Rat: 25800 mg/kg
Lactic acid	79-33-4	Oral LD50 Rat: 3730 mg/kg
Magnesium chloride hexahydrate	7791-18-6	Oral LD50 Rat: 8100 mg/kg
Potassium chloride	7447-40-7	Oral LD50 Rat: 2600 mg/kg
Salicylic acid	69-72-7	Inhalation LC50 Rat: >0.9 mg/L/1H; Oral LD50 Rat: 891 mg/kg; Dermal LD50 Rat: >2 g/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m <sup>3</sup> /1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg
Urea	57-13-6	Oral LD50 Rat: 8471 mg/kg; Dermal LD50 Rat: 8200 mg/kg
Valproic acid	1069-66-5	Oral LD50 Rat: 670 mg/kg

**Local Effects:**

No data available.

**Chronic Effects:**

Unknown.

**Carcinogenicity:**

No data available.

**Mutagenicity:**

No data available.

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.

**Sensitization:**

No data available.

### 12. ECOLOGICAL INFORMATION



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#### Ecotoxicity:

##### Ecotoxicity - Freshwater Algae Data

Lactic acid	79-33-4	70 Hr EC50 Selenastrum capricornutum: 3.5 mg/L
Potassium chloride	7447-40-7	72 Hr EC50 Scenedesmus subspicatus: 2500 mg/L

##### Ecotoxicity - Freshwater Fish Species Data

Lactic acid	79-33-4	96 Hr LC50 Brachydanio rerio: 320 mg/L [semi-static]
Potassium chloride	7447-40-7	96 Hr LC50 Lepomis macrochirus: 2010 mg/L [static]
Salicylic acid	69-72-7	48 Hr LC50 Leuciscus idus: 90 mg/L
Sodium chloride	7647-14-5	96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]
Urea	57-13-6	96 Hr LC50 Leuciscus idus: >3810 mg/L

##### Ecotoxicity - Microtox Data

Salicylic acid	69-72-7	5 min EC50 Photobacterium phosphoreum: 214 mg/L; 1 Hr EC50 Bacillus subtilis: 138 mg/L; 1 Hr EC50 Escherichia coli: 552 mg/L; 210 min EC50 Saccharomyces cerevisiae: 78 mg/L
Urea	57-13-6	5 min EC50 Photobacterium phosphoreum: 23914 mg/L

##### Ecotoxicity - Water Flea Data

Lactic acid	79-33-4	48 Hr EC50 Daphnia magna: 240 mg/L
Potassium chloride	7447-40-7	48 Hr EC50 Daphnia magna: 825 mg/L
Salicylic acid	69-72-7	24 Hr EC50 Daphnia magna: 105 mg/L
Sodium chloride	7647-14-5	48 Hr EC50 Daphnia magna: 1000 mg/L
Urea	57-13-6	24 Hr EC50 Daphnia magna straus: >10000 mg/L

#### Persistence and Degradability:

No data available.

#### Bioaccumulative Potential:

No data available.

#### Mobility in Environmental Media:

No data available.

### 13. DISPOSAL CONSIDERATIONS

#### Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

### 14. TRANSPORT INFORMATION

#### Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.



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**15. REGULATORY INFORMATION**

**US Federal Regulations:**

This preparation is a component of an FDA-regulated in vitro diagnostic device.

**Inventory - United States - Section 8(b) Inventory (TSCA)**

Cholesterol, bovine-source	57-88-5	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Lactic acid	79-33-4	Present
Magnesium chloride hexahydrate	7791-18-6	XU
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

**US State Regulations:**

**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Magnesium chloride hexahydrate	7791-18-6	[present]
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### International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

### **Canada - WHMIS - Classifications of Substances**

Calcium chloride dihydrate	10035-04-8	D2B
D-glucose	50-99-7	Uncontrolled product according to WHMIS classification criteria
Magnesium chloride hexahydrate	7791-18-6	Uncontrolled product according to WHMIS classification criteria
Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria (including 23.8%)
Salicylic acid	69-72-7	D2A
Sodium acetate trihydrate	6131-90-4	Uncontrolled product according to WHMIS classification criteria
Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
Urea	57-13-6	Uncontrolled product according to WHMIS classification criteria

### **Canada - WHMIS - Ingredient Disclosure List**

Salicylic acid	69-72-7	0.1 %
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### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Magnesium chloride hexahydrate	7791-18-6	F; R-15 R-17
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### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Magnesium chloride hexahydrate	7791-18-6	S-2 S-7/8 S-43
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### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Potassium chloride	7447-40-7	ID Number 230, hazard class 1 - low hazard to waters
Salicylic acid	69-72-7	ID Number 281, hazard class 1 - low hazard to waters
Sodium acetate trihydrate	6131-90-4	ID Number 367, hazard class 1 - low hazard to waters
Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters
Urea	57-13-6	ID Number 118, hazard class 1 - low hazard to waters

### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Alpha lactose	5989-81-1	Present
Calcium chloride dihydrate	10035-04-8	Present
Cholesterol, bovine-source	57-88-5	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Lactic acid	79-33-4	Present
Magnesium chloride hexahydrate	7791-18-6	Present
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium acetate trihydrate	6131-90-4	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present
Valproic acid	1069-66-5	Present

### **Inventory - Canada - Domestic Substances List (DSL)**

Cholesterol, bovine-source	57-88-5	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Lactic acid	79-33-4	Present
Magnesium chloride hexahydrate	7791-18-6	Mg
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

### **Inventory - China**

Alpha lactose	5989-81-1	Present
Calcium chloride dihydrate	10035-04-8	Present



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### DC-TROL Level 1

#### Inventory - China

Cholesterol, bovine-source	57-88-5	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Lactic acid	79-33-4	Present
Magnesium chloride hexahydrate	7791-18-6	Present
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium acetate trihydrate	6131-90-4	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

#### Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Cholesterol, bovine-source	57-88-5	200-353-2
D-glucose	50-99-7	200-075-1
HEPES, Free Acid	7365-45-9	230-907-9
Lactic acid	79-33-4	201-196-2
Magnesium chloride hexahydrate	7791-18-6	231-104-6; Mg
Potassium chloride	7447-40-7	231-211-8
Salicylic acid	69-72-7	200-712-3
Sodium chloride	7647-14-5	231-598-3
Urea	57-13-6	200-315-5
Valproic acid	1069-66-5	213-961-8

#### Inventory - Japan Existing and New Chemical Substances (ENCS)

Calcium chloride dihydrate	10035-04-8	1-176
Cholesterol, bovine-source	57-88-5	4-1301
D-glucose	50-99-7	8-46
Lactic acid	79-33-4	2-1369
Magnesium chloride hexahydrate	7791-18-6	1-233
Potassium chloride	7447-40-7	1-228
Salicylic acid	69-72-7	3-1640
Sodium acetate trihydrate	6131-90-4	2-692
Sodium chloride	7647-14-5	1-236
Urea	57-13-6	2-1732
Valproic acid	1069-66-5	2-611

#### Inventory - Korea - Existing and Evaluated Chemical Substances

Cholesterol, bovine-source	57-88-5	KE-05945
D-glucose	50-99-7	KE-17727
Lactic acid	79-33-4	KE-21803
Magnesium chloride hexahydrate	7791-18-6	KE-22673
Potassium chloride	7447-40-7	KE-29086
Salicylic acid	69-72-7	KE-20367
Sodium chloride	7647-14-5	KE-31387
Urea	57-13-6	KE-35144

#### Canadian Hazardous Products:

WHMIS Status Exempt

#### European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

### 16. OTHER INFORMATION



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### DC-TROL Level 1

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**Further Information:**

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

**MSDS Origination Date:** September 09, 2008

**Version #:** 3

**Revision Date:** October 29, 2008

**Disclaimer:**

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.



# MATERIAL SAFETY DATA SHEET

## DC-TROL Level 2

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** DC-TROL Level 2

**Product Number:** SM-056

**Synonym(s):** DC-Trol Multi-Analyte Control

**Product Use:** For in vitro diagnostic use in quality control.

**Description:** Lyophilized powder mixture containing human serum, salts, buffers, and trace amounts of antibiotics, drugs, hormones and enzymes.

**Corporate Headquarters**

**Genzyme Corporation**

500 Kendall Street  
Cambridge, MA 02142  
USA

**Phone:** 617-252-7500

**Distributor**

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**Phone:** 800-332-1042

**Distributor**

**Genzyme Diagnostics**

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Framingham, MA 01701-9322  
USA

**Phone:** 800-332-1042

**Emergency Telephone Numbers**

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 800-424-9300  
**CHEMTREC (Outside U.S.):** 703-527-3887

### 2. HAZARDS IDENTIFICATION

**Precautionary Statements:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May cause irritation to skin, eyes and respiratory tract. May be harmful if inhaled, absorbed or swallowed. Avoid contact with eyes and skin. Do not ingest or inhale. The human serum in this preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1 & 2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions. Preparation appearance: off-white lyophilized powder.

**Routes of Exposure:**

Occupational exposure routes may include eye contact, skin contact, skin absorption and inhalation.

**Potential Health Effects:**

<b>Inhalation</b>	No data available. Inhalation may cause respiratory tract irritation and may result in systemic effects.
<b>Eye</b>	No data available. Eye exposure may cause irritation, redness and watering.
<b>Skin</b>	No data available. Skin contact may be irritating. Possible systemic effects from skin absorption are unknown.
<b>Ingestion</b>	No data available.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	Unknown.



## MATERIAL SAFETY DATA SHEET

### DC-TROL Level 2

#### Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

#### Potential Environmental Effects:

No data available.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Human serum EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	35 - 50
Alpha lactose EC R-Phrases: None	5989-81-1 EC Hazard Class: None	Not Assigned	20 - 30
HEPES, Free Acid EC R-Phrases: None	7365-45-9 EC Hazard Class: None	230-907-9	2.5 - 5
Sodium chloride EC R-Phrases: None	7647-14-5 EC Hazard Class: None	231-598-3	2.5 - 5
D-glucose EC R-Phrases: None	50-99-7 EC Hazard Class: None	200-075-1	1 - 2.5
Urea EC R-Phrases: None	57-13-6 EC Hazard Class: None	200-315-5	< 1
Potassium chloride EC R-Phrases: R36	7447-40-7 EC Hazard Class: Xi	231-211-8	< 1
Calcium chloride dihydrate EC R-Phrases: None	10035-04-8 EC Hazard Class: None	233-140-8	< 1
Magnesium chloride hexahydrate EC R-Phrases: None	7791-18-6 EC Hazard Class: None	Not Assigned	< 1
Salicylic acid EC R-Phrases: R22, R36/38	69-72-7 EC Hazard Class: Xn	200-712-3	< 1
Valproic acid EC R-Phrases: None	1069-66-5 EC Hazard Class: None	213-961-8	< 1

### 4. FIRST AID MEASURES

#### General Advice:

In the event of occupational exposure, follow company-specific bloodborne pathogen post-exposure requirements.

#### Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.



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#### Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

#### Skin Contact:

In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

#### Ingestion:

In case of ingestion, contact a poison control center and seek immediate medical attention.

### 5. FIRE FIGHTING MEASURES

#### Flammable Properties:

Material may burn when exposed to sufficient heat.

#### Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

#### Unsuitable Extinguishing Media:

Unknown.

#### Specific Hazards Arising from the Chemical:

Irritating or highly toxic gases may be generated by combustion.

#### Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid generating or inhaling dust. Ensure adequate ventilation. Wash hands thoroughly after handling.

#### Environmental Precautions:

No information available.

#### Methods and Materials for Containment and Clean-Up:

Do not dry sweep powder. Use HEPA-filtered vacuum, if available, otherwise wet mop to clean up a powder spill. Very slippery when wet. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

### 7. HANDLING AND STORAGE

#### Handling:

Follow universal/standard precautions when handling this material. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

#### Storage:

Store at 2 - 8°C (36 - 46°F). Do not store with incompatible substances; see Section 10.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).



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#### Engineering Controls:

Preparation and handling of this preparation should be performed in accordance with universal/standard precautions. Facilities storing or using this preparation should be equipped with an eyewash fountain.

#### Personal Protective Equipment (PPE):

<b>Respiratory</b>	A respirator is not required under normal conditions of use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety glasses or goggles.
<b>Skin</b>	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves. Change gloves regularly or immediately if they are contaminated, torn or punctured.
<b>General</b>	Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Off-white lyophilized powder	<b>pH:</b>	7.5 - 7.7 (in aqueous solution)
<b>Odor:</b>	Slight odor	<b>Solubility:</b>	Water-miscible
<b>Specific Gravity:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Boiling Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Melting Point:</b>	Not available	<b>Vapor Density:</b>	Not applicable
<b>Freezing Point:</b>	Not applicable		
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not applicable		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not applicable		
<b>Auto-Ignition Temperature:</b>	Not available		
<b>Flash Point:</b>	Not applicable		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

Unknown.

#### Conditions to Avoid:

Unknown.

#### Incompatible Materials:

Unknown.

#### Hazardous Decomposition Products:

Thermal decomposition may lead to release of irritating gases and vapors.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION



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#### Acute Effects:

##### Toxicology Data - Selected LD50s and LC50s

D-glucose	50-99-7	Oral LD50 Rat: 25800 mg/kg
Magnesium chloride hexahydrate	7791-18-6	Oral LD50 Rat: 8100 mg/kg
Potassium chloride	7447-40-7	Oral LD50 Rat: 2600 mg/kg
Salicylic acid	69-72-7	Inhalation LC50 Rat: >0.9 mg/L/1H; Oral LD50 Rat: 891 mg/kg; Dermal LD50 Rat: >2 g/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m <sup>3</sup> /1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg
Urea	57-13-6	Oral LD50 Rat: 8471 mg/kg; Dermal LD50 Rat: 8200 mg/kg
Valproic acid	1069-66-5	Oral LD50 Rat: 670 mg/kg

#### Local Effects:

No data available.

#### Chronic Effects:

Unknown.

#### Carcinogenicity:

No data available.

#### Mutagenicity:

No data available.

#### Teratogenicity:

No data available.

#### Reproductive Effects:

No data available.

#### Sensitization:

No data available.

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity:

##### Ecotoxicity - Freshwater Algae Data

Potassium chloride 7447-40-7 72 Hr EC50 *Scenedesmus subspicatus*: 2500 mg/L

##### Ecotoxicity - Freshwater Fish Species Data

Potassium chloride 7447-40-7 96 Hr LC50 *Lepomis macrochirus*: 2010 mg/L [static]  
Salicylic acid 69-72-7 48 Hr LC50 *Leuciscus idus*: 90 mg/L  
Sodium chloride 7647-14-5 96 Hr LC50 *Lepomis macrochirus*: 9675 mg/L [flow-through];  
96 Hr LC50 *Lepomis macrochirus*: 12946 mg/L [static]; 96 Hr  
LC50 *Pimephales promelas*: 7650 mg/L [static]  
Urea 57-13-6 96 Hr LC50 *Leuciscus idus*: >3810 mg/L

##### Ecotoxicity - Microtox Data

Salicylic acid 69-72-7 5 min EC50 *Photobacterium phosphoreum*: 214 mg/L; 1 Hr  
EC50 *Bacillus subtilis*: 138 mg/L; 1 Hr EC50 *Escherichia coli*:  
552 mg/L; 210 min EC50 *Saccharomyces cerevisiae*: 78 mg/L  
Urea 57-13-6 5 min EC50 *Photobacterium phosphoreum*: 23914 mg/L

##### Ecotoxicity - Water Flea Data

Potassium chloride 7447-40-7 48 Hr EC50 *Daphnia magna*: 825 mg/L  
Salicylic acid 69-72-7 24 Hr EC50 *Daphnia magna*: 105 mg/L  
Sodium chloride 7647-14-5 48 Hr EC50 *Daphnia magna*: 1000 mg/L  
Urea 57-13-6 24 Hr EC50 *Daphnia magna straus*: >10000 mg/L

#### Persistence and Degradability:

No data available.



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**Bioaccumulative Potential:**

No data available.

**Mobility in Environmental Media:**

No data available.

**13. DISPOSAL CONSIDERATIONS**

**Methods of Disposal:**

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

**14. TRANSPORT INFORMATION**

**Basic Shipping Description:**

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

**15. REGULATORY INFORMATION**

**US Federal Regulations:**

This preparation is a component of an FDA-regulated in vitro diagnostic device.

**Inventory - United States - Section 8(b) Inventory (TSCA)**

D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Magnesium chloride hexahydrate	7791-18-6	XU
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

**US State Regulations:**

**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Magnesium chloride hexahydrate                      7791-18-6                      [present]



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### International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

#### **Canada - WHMIS - Classifications of Substances**

Calcium chloride dihydrate	10035-04-8	D2B
D-glucose	50-99-7	Uncontrolled product according to WHMIS classification criteria
Magnesium chloride hexahydrate	7791-18-6	Uncontrolled product according to WHMIS classification criteria
Potassium chloride	7447-40-7	Uncontrolled product according to WHMIS classification criteria (including 23.8%)
Salicylic acid	69-72-7	D2A
Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
Urea	57-13-6	Uncontrolled product according to WHMIS classification criteria

#### **Canada - WHMIS - Ingredient Disclosure List**

Salicylic acid	69-72-7	0.1 %
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#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Magnesium chloride hexahydrate	7791-18-6	F; R-15 R-17
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#### **EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Magnesium chloride hexahydrate	7791-18-6	S-2 S-7/8 S-43
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#### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Potassium chloride	7447-40-7	ID Number 230, hazard class 1 - low hazard to waters
Salicylic acid	69-72-7	ID Number 281, hazard class 1 - low hazard to waters
Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters
Urea	57-13-6	ID Number 118, hazard class 1 - low hazard to waters

#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Alpha lactose	5989-81-1	Present
Calcium chloride dihydrate	10035-04-8	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Magnesium chloride hexahydrate	7791-18-6	Present
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present
Valproic acid	1069-66-5	Present

#### **Inventory - Canada - Domestic Substances List (DSL)**

D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Magnesium chloride hexahydrate	7791-18-6	Mg
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present

#### **Inventory - China**

Alpha lactose	5989-81-1	Present
Calcium chloride dihydrate	10035-04-8	Present
D-glucose	50-99-7	Present
HEPES, Free Acid	7365-45-9	Present
Magnesium chloride hexahydrate	7791-18-6	Present
Potassium chloride	7447-40-7	Present
Salicylic acid	69-72-7	Present
Sodium chloride	7647-14-5	Present
Urea	57-13-6	Present



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#### Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

D-glucose	50-99-7	200-075-1
HEPES, Free Acid	7365-45-9	230-907-9
Magnesium chloride hexahydrate	7791-18-6	231-104-6; Mg
Potassium chloride	7447-40-7	231-211-8
Salicylic acid	69-72-7	200-712-3
Sodium chloride	7647-14-5	231-598-3
Urea	57-13-6	200-315-5
Valproic acid	1069-66-5	213-961-8

#### Inventory - Japan Existing and New Chemical Substances (ENCS)

Calcium chloride dihydrate	10035-04-8	1-176
D-glucose	50-99-7	8-46
Magnesium chloride hexahydrate	7791-18-6	1-233
Potassium chloride	7447-40-7	1-228
Salicylic acid	69-72-7	3-1640
Sodium chloride	7647-14-5	1-236
Urea	57-13-6	2-1732
Valproic acid	1069-66-5	2-611

#### Inventory - Korea - Existing and Evaluated Chemical Substances

D-glucose	50-99-7	KE-17727
Magnesium chloride hexahydrate	7791-18-6	KE-22673
Potassium chloride	7447-40-7	KE-29086
Salicylic acid	69-72-7	KE-20367
Sodium chloride	7647-14-5	KE-31387
Urea	57-13-6	KE-35144

#### Canadian Hazardous Products:

WHMIS Status Exempt

#### European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

### 16. OTHER INFORMATION

#### Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.



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**MSDS Origination Date:** September 09, 2008

**Version #:** 3

**Revision Date:** October 29, 2008

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