

1. Product and Company Identification

Material name	DC-TROL Level I
Version #	01
Issue date	04-18-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Product code	SM-052
Product use	For in vitro diagnostic use in quality control.
Synonym(s)	DC-Trol Multi-Analyte Control
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042
Emergency Telephone Numbers	Americas 1-760-476-3962 Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazards Identification

Physical state	Solid.
Appearance	Off-white lyophilized powder.
Emergency overview	CAUTION May cause skin and eye irritation. 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.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	Inhalation may cause systemic effects.
Ingestion	May cause discomfort if swallowed.
Target organs	Eyes. Skin.
Chronic effects	No data available.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.
Potential environmental effects	The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Cholesterol	57-88-5	< 2
Chloramphenicol	56-75-7	0.01 - 0.1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists.

Notes to physician Provide general supportive measures and treat symptomatically.

General advice Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties Material may burn when exposed to sufficient heat.

Extinguishing media

Suitable extinguishing media Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Protection of firefighters

Specific hazards arising from the chemical Fire will generate toxic and irritating gases.

Protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products No data available.

6. Accidental Release Measures

Personal precautions Avoid dust formation. Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Do not allow to enter drains, sewers or watercourses.

Methods for containment Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes. Wash thoroughly after handling. Observe good industrial hygiene practices.

Storage Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Exposure guidelines Follow standard monitoring procedures.

Engineering controls Observe occupational exposure limits and minimize the risk of inhalation of dust and fumes.

Personal protective equipment

Eye / face protection Wear approved safety glasses or goggles.

Skin protection Remove contaminated clothing promptly.

Respiratory protection In case of inadequate ventilation or risk of inhalation of dust, use a suitable NIOSH approved respirator with an appropriate particulate filter.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Off-white lyophilized powder.
Physical state	Solid.
Form	Lyophilized powder.
Color	Off-white.
Odor	Slight.
Odor threshold	Not available.
pH	7.5 - 7.7
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Miscible in water.
Specific gravity	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	No data available.
Hazardous decomposition products	Thermal decomposition may lead to release of irritating gases and vapors.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	Not classified.
Acute effects	May cause discomfort if swallowed.
Local effects	May cause skin and eye irritation.
Chronic effects	No data available.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Chloramphenicol (CAS 56-75-7)	2A Probably carcinogenic to humans.
Cholesterol (CAS 57-88-5)	3 Not classifiable as to carcinogenicity to humans.

US NTP Report on Carcinogens: Anticipated carcinogen

Chloramphenicol (CAS 56-75-7)	Reasonably Anticipated to be a Human Carcinogen.
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Epidemiology	No epidemiological data is available for this product.
Mutagenicity	Not classified.
Reproductive effects	Not classified.
Symptoms and target organs	Direct contact with skin and eyes may cause irritation.
Further information	No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicological data

Components	Species	Test Results
Chloramphenicol (CAS 56-75-7)		
Aquatic		
Crustacea	EC50 Shrimp (<i>Penaeus stylirostris</i>)	0.0537 mg/l, 48 hours
Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.	
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulation / Accumulation	Not available.	
Mobility in environmental media	No data available.	

13. Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) No

SARA 311/312 Hazardous chemical No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
Canadian regulations	This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.
WHMIS status	Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

State regulations WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Chloramphenicol (CAS 56-75-7) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Chloramphenicol (CAS 56-75-7) Listed.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Chloramphenicol (CAS 56-75-7) Listed: October 1, 1989 Carcinogenic.

US - Pennsylvania RTK - Hazardous Substances: Special hazard

Chloramphenicol (CAS 56-75-7) Special hazard.

US. Massachusetts RTK - Substance List

Chloramphenicol (CAS 56-75-7) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Chloramphenicol (CAS 56-75-7) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
 Health: 1
 Flammability: 0
 Physical hazard: 0

NFPA ratings
 Health: 1
 Flammability: 0
 Instability: 0

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