

1. Identification

Product identifier	Sorbitol Dehydrogenase Control Level 2
Other means of identification	
Product code	SM-741
Synonyms	SDH Control Level 2 * SDH Low Level Control * Sorbitol Dehydrogenase (SDH) Control Materials
Recommended use	For in vitro diagnostic use in quality control procedures to monitor the accuracy and precision of quantitative sorbitol dehydrogenase assays.
Recommended restrictions	Use in accordance with supplier's recommendations.
Manufacturer/Importer/Supplier/Distributor information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Skin corrosion/irritation Category 2 Serious eye damage/eye irritation Category 2 Specific target organ toxicity, single exposure Category 3 respiratory tract irritation
OSHA defined hazards	Not classified.
Label elements	



Signal word	Warning
Hazard statement	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.
Precautionary statement	
Prevention	Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling. Avoid breathing dust.
Response	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
2-Amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride	1185-53-1	90-100
Sodium azide	26628-22-8	<0.1

Lyophilized powder mixture containing salt, animal-source material and trace amounts of enzyme (protein) and preservative.

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

Inhalation	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
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.
Ingestion	If material is ingested, immediately contact a poison control center.
Most important symptoms/effects, acute and delayed	Ingestion may cause irritation and malaise.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Fire will generate toxic and irritating gases.
Special 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.
General fire hazards	The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and 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.
Environmental precautions	Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe handling	Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes. Avoid inhalation of dust and fumes. Wash thoroughly after handling. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	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

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m ³
		0.11 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m ³
		0.1 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Appropriate engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of dust. Provide easy access to water supply and eye wash facilities.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	pale-yellow powder.
Physical state	Solid.
Form	Powder.
Color	Pale yellow
Odor	Characteristic.
Odor threshold	Not available.
pH	7 - 8 @ 25°C
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	No data available.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Vapors may irritate throat and respiratory system and cause coughing.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics
Ingestion may cause irritation and malaise.

Information on toxicological effects

Acute toxicity
May cause discomfort if swallowed.

Components	Species	Test Results
Sodium azide (CAS 26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not classified.	
Skin sensitization	Not classified.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Not classified.	
Specific target organ toxicity - single exposure	May cause respiratory irritation.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Chronic effects	No data available.	
Further information	No other specific acute or chronic health impact noted.	

12. Ecological information

Ecotoxicity

Components	Species		Test Results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Algae	EC50	Pseudokirchnerella subcapitata	0.35 mg/l, 96 hours
Fish	LC50	Fish	5.7 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential	Not available.		
Mobility in soil	Not available.		
Mobility in general	The product is soluble in water.		
Other adverse effects	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.		

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.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company and/or appropriate testing.
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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is hazardous according to OSHA 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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

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

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

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

*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).

16. Other information, including date of preparation or last revision

Issue date 24-November-2014

Revision date -

Version # 01

NFPA ratings



List of abbreviations

LD50: Lethal Dose, 50%.

References

ACGIH

EPA: AQUIRE database

IARC Monographs. Overall Evaluation of Carcinogenicity

HSDB® - Hazardous Substances Data Bank

National Toxicology Program (NTP) Report on Carcinogens

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