Material Safety Data Sheet



DCA Systems HbA1c Controls

MSDS no. 5068A

Product and company identification 1.

Product name DCA Systems HbA1c Controls

Code 5068A, 03714363 Diagnostic agents. **Material uses**

Product type : Liquid.

Siemens Healthcare Diagnostics Inc. Manufactured/supplied

1717 Deerfield Road Deerfield, IL 60015-0778

1-847-267-5300

Siemens Healthcare Diagnostics Ltd. 1200 Courtneypark Drive East Mississauga, Ontario, Canada

L5T-1P2 (905) 564-7333 (800) 264-0083

In case of emergency Transportation: (800) 424-9300 (CHEMTREC)

Medical: (800) 228-5635 ext. 284 (Prosar)

2. Hazards identification

Physical state Reconstitution Fluid Liquid. Solid.

Hemoglobin A1c Normal

Control

Hemoglobin A1c Solid.

Abnormal Control

OSHA/HCS status This material is not considered hazardous by the OSHA Hazard Communication

Standard (29 CFR 1910.1200).

: NOT EXPECTED TO PRODUCE SIGNIFICANT ADVERSE HEALTH EFFECTS WHEN **Emergency overview**

THE RECOMMENDED INSTRUCTIONS FOR USE ARE FOLLOWED.

No known significant effects or critical hazards. Avoid prolonged contact with eyes, skin

and clothing.

Potentially biohazardous material.

Potential acute health effects

Inhalation : No known significant effects or critical hazards. Ingestion No known significant effects or critical hazards. Skin No known significant effects or critical hazards. No known significant effects or critical hazards. **Eyes**

Potential chronic health effects

Chronic effects : No known significant effects or critical hazards. Carcinogenicity No known significant effects or critical hazards. No known significant effects or critical hazards. Mutagenicity **Teratogenicity** No known significant effects or critical hazards. **Developmental effects** No known significant effects or critical hazards. **Fertility effects** No known significant effects or critical hazards. **Target organs** Not available.

Reconstitution Fluid

Hemoglobin A1c Normal

Not available.

Control Hemoglobin A1c

Not available.

Abnormal Control

Over-exposure signs/symptoms

5/12/2010. 1/12 DCA Systems HbA1c Controls

2. Hazards identification

Inhalation: No specific data.Ingestion: No specific data.Skin: No specific data.Eyes: No specific data.

See toxicological information (section 11)

3. Composition/information on ingredients

United States

Name CAS number %

Reconstitution Fluid

sodium azide 26628-22-8 0.09

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. First aid measures

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical

attention if symptoms occur.

Skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean

shoes thoroughly before reuse. Get medical attention if symptoms occur.

Inhalation : Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if

symptoms occur.

Ingestion : Wash out mouth with water. Do not induce vomiting unless directed to do so by medical

personnel. Never give anything by mouth to an unconscious person. Get medical

attention if symptoms occur.

5. Fire-fighting measures

Flammability of the product : In a fire or if heated, a pressure increase will occur and the container may burst.

Extinguishing media

In case of fire, use water spray (fog), foam or dry chemical.

Not suitable

: None known.

Special exposure hazards

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable

training.

Hazardous combustion products

: No specific data.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions : No action shall be taken involving any personal risk or without suitable training.

Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal

protective equipment (see section 8).

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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6. Accidental release measures

Small spill

Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

7. Handling and storage

Handling

: Put on appropriate personal protective equipment (see section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

Storage

: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

Product nameUnited States

Reconstitution Fluid

sodium azide

Exposure limits

ACGIH TLV (United States, 1/2009).

C: 0.29 mg/m³, (as hydrazoic acid vapor) Form: as Sodium azide NIOSH REL (United States, 6/2009). Absorbed through skin. Notes: NAN3

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.

Notes: as NaN3

NIOSH REL (United States, 6/2009). Absorbed through skin. Notes:

NAN3

CEIL: 0.3 mg/m³, (NAN3)

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.

Notes: as NaN3

NIOSH REL (United States, 6/2009). Absorbed through skin. Notes:

NAN3

CEIL: 0.1 ppm, (as HN3)

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.

Notes: as NaN3

CEIL: 0.1 ppm, (as HN3)

NIOSH REL (United States, 6/2009). Absorbed through skin. Notes:

NAN3

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.

Notes: as NaN3

CEIL: 0.3 mg/m³, (as NaN3)

NIOSH REL (United States, 6/2009). Absorbed through skin. Notes:

NAN3

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin.

Notes: as NaN3

ACGIH TLV (United States, 1/2009). Notes: as hydrazoic acid vapor C: 0.11 ppm, (as hydrazoic acid vapor) Form: as Hydrazoic acid vapor

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8. Exposure controls/personal protection

Consult local authorities for acceptable exposure limits.

Recommended monitoring procedures

: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

Engineering measures

: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protection

Respiratory

: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Hands

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Eyes

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

Skin

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. Physical and chemical properties

_	-	-
Physical state	Reconstitution Flu Hemoglobin A1c N Control Hemoglobin A1c Abnormal Control	Normal Solid. Solid.
Flash point	Reconstitution Flu Hemoglobin A1c N Control Hemoglobin A1c Abnormal Control	Normal Not available. Not available.
Auto-ignition temperature	Reconstitution Flu Hemoglobin A1c N Control Hemoglobin A1c Abnormal Control	Normal Not available. Not available.

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9. Physical and chemical properties

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Flammable limits	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Color	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Colorless. Reddish-brown
		Hemoglobin A1c Abnormal Control	Reddish-brown
Molecular weight	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not applicable. Not applicable.
		Hemoglobin A1c Abnormal Control	Not applicable.
Molecular formula	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not applicable. Not applicable.
		Hemoglobin A1c Abnormal Control	Not applicable.
pH	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not applicable. Not applicable.
		Hemoglobin A1c Abnormal Control	Not applicable.
Boiling/condensation point	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Melting/freezing point	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Relative density	:	Reconstitution Fluid Hemoglobin A1c Normal Control	1 Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Vapor pressure	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Volatility	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.
Evaporation rate	:	Reconstitution Fluid Hemoglobin A1c Normal Control	Not available. Not available.
		Hemoglobin A1c Abnormal Control	Not available.

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Physical and chemical properties 9.

Reconstitution Fluid **Viscosity**

Hemoglobin A1c Normal

Control

Hemoglobin A1c **Abnormal Control**

Not available. Not available.

Not available.

10. Stability and reactivity

Stability : The product is stable.

Conditions to avoid : No specific data. Materials to avoid : No specific data.

Not available.

Hazardous decomposition

products

: Under normal conditions of storage and use, hazardous decomposition products should

3 mg/kg

30 mg/kg

not be produced.

Hazardous polymerization : Under normal conditions of storage and use, hazardous polymerization will not occur.

11. Toxicological information

United States

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure	
sodium azide	LD50 Dermal	Rat	50 mg/kg	-	
	LD50 Dermal	Rabbit	20 mg/kg	-	
	LD50	Rat	47.5 mg/kg	-	
	Intratracheal				
	LD50	Rat	47500 ug/kg	-	
	Intratracheal				
	LD50 Oral	Rat	27 mg/kg	-	
	LD50	Rat	45100 ug/kg	-	
	Subcutaneous				
	LD50	Rat	45 mg/kg	-	
	Subcutaneous				

Intraperitoneal

LDLo

LDLo Intraperitoneal

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	ACGIH	IARC	EPA	NIOSH	NTP	OSHA
Reconstitution Fluid						
sodium azide	A4	-	-	None.	-	-

Rat

Rat

Mutagenicity

Not available.

Teratogenicity

Not available.

Reproductive toxicity

Not available.

Canada

Acute toxicity

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11. Toxicological information

Not available.

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name ACGIH IARC EPA NIOSH NTP OSHA Reconstitution Fluid

None.

sodium azide

Mutagenicity

Not available. Teratogenicity

Not available.

Reproductive toxicity

Not available.

12. Ecological information

Environmental effects: No known significant effects or critical hazards.

A4

United States

Aquatic ecotoxicity

Aquatic ecotoxicity				_
Product/ingredient name sodium azide	Test -	Result Acute EC50 6.4 to 8.9 mg/L Fresh water	Species Crustaceans - Water flea - Simocephalus serrulatus - LARVAE	48 hours
	-	Acute EC50 4.2 to 6.2 mg/L Fresh water	Daphnia - Water flea - Daphnia pulex - LARVAE	48 hours
	-	Acute LC50 0.8 mg/L Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss - 1.4 g	96 hours
	-	Acute LC50 0.68 mg/L Fresh water	Fish - Bluegill - Lepomis macrochirus - 0.6 g	96 hours
	-	Acute LC50 5460 to 5870 ug/L Fresh water	Fish - Fathead minnow - Pimephales promelas - 30 days - 18.8 mm - 0.098 g	96 hours
	-	Acute LC50 3920 ug/L Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss - 8.57 cm - 7.84 g	96 hours
	-	Acute LC50 2840 ug/L Fresh water	Fish - Rainbow trout,donaldson trout - Oncorhynchus mykiss - 7.87 cm	96 hours

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12. Ecological information

Acute LC50 2750 Fish - Rainbow ug/L Fresh water trout, donaldson

- 6.07 g trout -

96 hours

Oncorhynchus mykiss - 7.32 cm

- 4.76 g

Biodegradability

Not available.

Canada

Aquatic ecotoxicity

Not available.

Biodegradability

Not available.

13. Disposal considerations

Waste disposal

: The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

14. Transport information

International transport regulations

DOT Classification

UN number Reconstitution Fluid Not regulated. Hemoglobin A1c Normal Control Not regulated. Hemoglobin A1c Abnormal Control Not regulated.

Proper shipping Reconstitution Fluid

name Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

Classes Reconstitution Fluid

> Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

PG* Reconstitution Fluid

> Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

Label

Reconstitution Fluid **Additional**

information Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

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14. Transport information

TDG Classification UN number

Label

		Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not regulated. Not regulated.
	Proper shipping	Reconstitution Fluid	<u>-</u>
	name	Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	Classes	Reconstitution Fluid	-
		Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	PG*	Reconstitution Fluid	-
		Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	Label		
	Additional	Reconstitution Fluid	-
	information	Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	<u>exico</u>		
Cl	<u>assification</u>		
	UN number	Reconstitution Fluid	Not regulated.
		Hemoglobin A1c Normal Control	Not regulated.
		Hemoglobin A1c Abnormal Control	Not regulated.
	Proper shipping	Reconstitution Fluid	-
	name	Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	Classes	Reconstitution Fluid	-
		Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
	PG*	Reconstitution Fluid	-
		Hemoglobin A1c Normal Control	-
	Label	Hemoglobin A1c Abnormal Control	-
	Additional	Reconstitution Fluid	-
	information	Hemoglobin A1c Normal Control	-
		Hemoglobin A1c Abnormal Control	-
IM	DG Class		
	UN number	Reconstitution Fluid	Not regulated.
	ON Humber	Hemoglobin A1c Normal Control	Not regulated.
		Hemoglobin A1c Abnormal Control	Not regulated.
	Proper shipping	Reconstitution Fluid	-
	name	Hemoglobin A1c Normal Control	-
	Hamo	Hemoglobin A1c Abnormal Control	_
	Classes	Reconstitution Fluid	_
	V143353	Hemoglobin A1c Normal Control	_
		Hemoglobin A1c Abnormal Control	-
	PG*	Reconstitution Fluid	
	FG	Reconstitution Fluid	-

Reconstitution Fluid

Not regulated.

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Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

14. Transport information

AdditionalReconstitution Fluid-informationHemoglobin A1c Normal Control-

Hemoglobin A1c Abnormal Control

IATA-DGR Class

UN number Reconstitution Fluid Not regulated.

Hemoglobin A1c Normal Control Not regulated. Hemoglobin A1c Abnormal Control Not regulated.

Proper shipping Reconstitution Fluid -

name Hemoglobin A1c Normal Control -

Hemoglobin A1c Abnormal Control -

Classes Reconstitution Fluid -

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control -

PG* Reconstitution Fluid -

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control -

Label

Additional Reconstitution Fluid -

information Hemoglobin A1c Normal Control - Hemoglobin A1c Abnormal Control -

PG*: Packing group

15. Regulatory information

United States

HCS Classification : Not regulated.

U.S. Federal regulations : TSCA 8(a) IUR: water

United States inventory (TSCA 8b): Not determined.

15. Regulatory information

SARA 302/304/311/312 extremely hazardous substances: No products were found. SARA 302/304 emergency planning and notification: No products were found.

SARA 302/304/311/312 hazardous chemicals: No products were found.

SARA 311/312 MSDS distribution - chemical inventory - hazard identification: No

products were found. Clean Water Act (CWA) 307: No products were found.

Clean Water Act (CWA) 311: No products were found.

Clean Air Act (CAA) 112 accidental release prevention: No products were found. Clean Air Act (CAA) 112 regulated flammable substances: No products were found.

Clean Air Act (CAA) 112 regulated toxic substances: No products were found.

State regulations

: Connecticut Carcinogen Reporting: None of the components are listed.

Connecticut Hazardous Material Survey: None of the components are listed.

Florida substances: None of the components are listed.

Illinois Chemical Safety Act: None of the components are listed.

Illinois Toxic Substances Disclosure to Employee Act: None of the components are

listed.

Louisiana Reporting: None of the components are listed. Louisiana Spill: None of the components are listed. Massachusetts Spill: None of the components are listed.

Massachusetts Substances: None of the components are listed. Michigan Critical Material: None of the components are listed.

Minnesota Hazardous Substances: None of the components are listed. New Jersey Hazardous Substances: None of the components are listed.

New Jersey Spill: None of the components are listed.

New Jersey Toxic Catastrophe Prevention Act: None of the components are listed. New York Acutely Hazardous Substances: None of the components are listed. New York Toxic Chemical Release Reporting: None of the components are listed. Pennsylvania RTK Hazardous Substances: None of the components are listed. Rhode Island Hazardous Substances: None of the components are listed.

United States inventory (TSCA 8b)

: Not determined.

Use only for medical diagnostic (R&D) purposes

Canada

WHMIS (Canada)

: Not controlled under WHMIS (Canada).

Canadian lists : **CEPA Toxic substances**: None of the components are listed.

> Canadian ARET: None of the components are listed. Canadian NPRI: None of the components are listed.

Alberta Designated Substances: None of the components are listed. Ontario Designated Substances: None of the components are listed. Quebec Designated Substances: None of the components are listed.

Canada inventory

: Not determined.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

16. Other information

EU regulations

Risk phrases

: This product is not classified according to EU legislation.

International regulations

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16. Other information

International lists : Australia inventory (AICS): Not determined.

China inventory (IECSC): Not determined. Japan inventory (ENCS): Not determined. Japan inventory (ISHL): Not determined. Korea inventory (KECI): Not determined.

New Zealand Inventory of Chemicals (NZIoC): Not determined.

Philippines inventory (PICCS): Not determined.

 Date of printing
 : 5/12/2010.

 Date of issue
 : 5/12/2010.

 Version
 : 2.01

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.