# SAFETY DATA SHEET



DCA Systems HbA1c Controls SDS#: 5068A

### **Section 1. Identification**

Product identifier : DCA Systems HbA1c Controls
Product code : 5068A, 03714363, 10311161

Product type : Liquid.

Relevant identified uses of the substance or mixture and uses advised against

Not applicable.

Manufactured/supplied : Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue

Tarrytown, NY 10591-5097 USA

1-877-229-3711

(800) 424-9300 (CHEMTREC) (24/365)

### Section 2. Hazards identification

OSHA/HCS status : Reconstitution Fluid While this material is not considered hazardous by the OSHA Hazard

Communication Standard (29 CFR 1910. 1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Hemoglobin A1c Normal Control This material is considered hazardous by

the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hemoglobin A1c Abnormal Control This material is considered hazardous by

the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the : Reconstitution Fluid Not classified.

Hemoglobin A1c Normal Control CARCINOGENICITY - Category 1B
Hemoglobin A1c Abnormal Control CARCINOGENICITY - Category 1B

**Additional information**: Potentially biohazardous material.

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

azides.

**GHS label elements** 

substance or mixture

Hazard pictograms :



Signal word : Reconstitution Fluid No signal word.

Hemoglobin A1c Normal Control Danger Hemoglobin A1c Abnormal Control Danger

**Hazard statements** : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control H350 - May cause cancer. Hemoglobin A1c Abnormal Control H350 - May cause cancer.

**Precautionary statements** 

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 1/17

### Section 2. Hazards identification

| Prevention : Reconstitution Fluid | Not applicable. |
|-----------------------------------|-----------------|
|-----------------------------------|-----------------|

Hemoglobin A1c Normal Control P201 - Obtain special instructions before

use.

P202 - Do not handle until all safety precautions have been read and

understood.

P280 - Wear protective gloves. Wear eye

or face protection. Wear protective

clothing.

Hemoglobin A1c Abnormal Control P201 - Obtain special instructions before

ıse.

P202 - Do not handle until all safety precautions have been read and

understood.

P280 - Wear protective gloves. Wear eye or face protection. Wear protective

clothing.

Response : Reconstitution Fluid Not applicable.

Hemoglobin A1c Normal Control P308 + P313 - IF exposed or concerned:

Get medical attention.

Hemoglobin A1c Abnormal Control P308 + P313 - IF exposed or concerned:

Get medical attention.

Storage : Reconstitution Fluid Not applicable.

Hemoglobin A1c Normal Control P405 - Store locked up. Hemoglobin A1c Abnormal Control P405 - Store locked up.

Disposal : Reconstitution Fluid

Hemoglobin A1c Normal Control P501 - Dispose of contents and container

in accordance with all local, regional, and

national regulations.

Not applicable.

Hemoglobin A1c Abnormal Control P501 - Dispose of contents and container

in accordance with all local, regional, and

national regulations.

Supplemental label

elements

: Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control None known.

None known.

Hazards not otherwise

classified

Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control None known. None known. None known.

# Section 3. Composition/information on ingredients

Substance/mixture : Reconstitution Fluid Mixture
Hemoglobin A1c Normal Control Mixture
Hemoglobin A1c Abnormal Control Mixture

| Ingredient name                                 | %    | CAS number |
|---|------|------------|
| Reconstitution Fluid sodium azide               | 0.09 | 26628-22-8 |
| Hemoglobin A1c Normal Control chloramphenicol   | 0.6  | 56-75-7    |
| Hemoglobin A1c Abnormal Control chloramphenicol | 0.6  | 56-75-7    |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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.

Occupational exposure limits, if available, are listed in Section 8.

### Section 4. First aid measures

#### Description of necessary first aid measures

: Reconstitution Fluid **Eye contact** 

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

Inhalation : Reconstitution Fluid

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

**Skin contact** : Reconstitution Fluid

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention. Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-tomouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a

collar, tie, belt or waistband.

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-tomouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a

collar, tie, belt or waistband.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if

symptoms occur.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes

thoroughly before reuse.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes

thoroughly before reuse.

Date of issue/Date of revision : 6/19/2019 Version: 1.08 3/17 : 11/7/2019 Date of previous issue

### Section 4. First aid measures

Ingestion

: Reconstitution Fluid

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention

if symptoms occur.

Wash out mouth with water. Remove dentures if any. Remove victim to fresh

air and keep at rest in a position

comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or

waistband.

Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or

# Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : F

: Reconstitution Fluid

No known significant effects or critical

hazards.

waistband.

Hemoglobin A1c Normal Control

No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control

No known significant effects or critical

hazards.

Inhalation : Reconstitution Fluid

No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control

No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control

No known significant effects or critical

hazards.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 4/17

### Section 4. First aid measures

Skin contact : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

Ingestion : Reconstitution Fluid No known significant effects or critical

hazards

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

Over-exposure signs/symptoms

Inhalation

Skin contact

Eye contact : Reconstitution Fluid No specific data.

> Hemoglobin A1c Normal Control No specific data. Hemoglobin A1c Abnormal Control No specific data.

: Reconstitution Fluid No specific data.

Hemoglobin A1c Normal Control No specific data. Hemoglobin A1c Abnormal Control No specific data. : Reconstitution Fluid No specific data.

Hemoglobin A1c Normal Control No specific data. Hemoglobin A1c Abnormal Control No specific data.

Reconstitution Fluid Ingestion No specific data.

Hemoglobin A1c Normal Control No specific data. Hemoglobin A1c Abnormal Control No specific data.

#### Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

**Specific treatments** : No specific treatment.

**Protection of first-aiders** No action shall be taken involving any personal risk or without suitable training. If it is

suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water

before removing it, or wear gloves.

#### See toxicological information (Section 11)

# Section 5. Fire-fighting measures

#### **Extinguishing media**

Suitable extinguishing media

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

Unsuitable extinguishing

media

: None known.

Specific hazards arising from the chemical

**Hazardous thermal** decomposition products : In a fire or if heated, a pressure increase will occur and the container may burst.

: No specific data.

Special protective actions for fire-fighters

: 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

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.

Date of issue/Date of revision 5/17 : 11/7/2019 Date of previous issue : 6/19/2019 Version: 1.08

### Section 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: 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. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders:

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

**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).

#### Methods and materials for containment and cleaning up

**Small spill** 

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

Large spill

: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

### Section 7. Handling and storage

#### Precautions for safe handling

**Protective measures** 

Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

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. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

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. Store locked up. 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.

# Section 8. Exposure controls/personal protection

**Control parameters** 

Occupational exposure limits

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 6/17

## Section 8. Exposure controls/personal protection

| Ingredient name                               | Exposure limits  |
|---|--|
| Reconstitution Fluid                          |  |
| sodium azide                                  | ACGIH TLV (United States, 3/2015). Notes: as hydrazoic acid vapor C: 0.11 ppm, (as Hydrazoic acid vapor) Form: as Hydrazoic acid vapor ACGIH TLV (United States, 3/2015). C: 0.29 mg/m³, (as Sodium azide) Form: as Sodium azide NIOSH REL (United States, 10/2013). Absorbed through skin. Notes: NAN3 CEIL: 0.3 mg/m³, (NAN3) NIOSH REL (United States, 10/2013). Absorbed through skin. Notes: as HN3 CEIL: 0.1 ppm, (as HN3) OSHA PEL 1989 (United States, 3/1989). Absorbed through skin. Notes: as HN3 CEIL: 0.1 ppm, (as HN3) OSHA PEL 1989 (United States, 3/1989). Absorbed through skin. Notes: as NaN3 CEIL: 0.3 mg/m³, (as NaN3) |
| Hemoglobin A1c Normal Control chloramphenicol | AlHA WEEL (United States, 10/2011). TWA: 0.5 mg/m³ 8 hours.  |
| Hemoglobin A1c Abnormal Control               |  |
| chloramphenicol                               | AIHA WEEL (United States, 10/2011).<br>TWA: 0.5 mg/m³ 8 hours.   |

# Appropriate engineering controls

: If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

# 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.

#### **Individual protection measures**

**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.

Eye/face protection

: 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, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.

# Skin protection Hand protection

: 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

### **Body protection**

 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.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 7/17

### Section 8. Exposure controls/personal protection

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection** 

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

### Section 9. Physical and chemical properties

**Physical state** : Reconstitution Fluid Liquid. Hemoglobin A1c Normal Control Solid. Hemoglobin A1c Abnormal Control Solid. Color : Reconstitution Fluid Colorless. Hemoglobin A1c Normal Control Brownish-red. Hemoglobin A1c Abnormal Control Brownish-red. Odor : Reconstitution Fluid Odorless. Hemoglobin A1c Normal Control Bland.

Hemoglobin A1c Abnormal Control Bland. : Reconstitution Fluid Not applicable. pН Hemoglobin A1c Normal Control Not applicable.

Hemoglobin A1c Abnormal Control Not applicable. Flash point : Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Not available. Hemoglobin A1c Abnormal Control : Reconstitution Fluid

Flammability (solid, gas) Not relevant/applicable due to nature of the product.

Not relevant/applicable due to nature of Hemoglobin A1c Normal Control

the product. Hemoglobin A1c Abnormal Control Not relevant/applicable due to nature of

the product.

Relative density Reconstitution Fluid

Not relevant/applicable due to nature of Hemoglobin A1c Normal Control

the product.

Not relevant/applicable due to nature of Hemoglobin A1c Abnormal Control

the product.

Not available.

Not applicable.

Solubility in water : Reconstitution Fluid Not relevant/applicable due to nature of the product.

Hemoglobin A1c Normal Control Not relevant/applicable due to nature of

the product.

Hemoglobin A1c Abnormal Control Not relevant/applicable due to nature of

the product.

Partition coefficient: n-: Reconstitution Fluid

**Auto-ignition temperature** 

octanol/water

Not available. Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control : Reconstitution Fluid Not available. Not available. Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control Not available. Not available. : Reconstitution Fluid **Viscosity** 

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

**Aerosol product** 

: Reconstitution Fluid Not applicable. Type of aerosol Hemoglobin A1c Normal Control Not applicable. Hemoglobin A1c Abnormal Control

Date of issue/Date of revision 8/17 : 6/19/2019 Version: 1.08 : 11/7/2019 Date of previous issue

### Section 10. Stability and reactivity

Reactivity : Reconstitution Fluid

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

No specific test data related to reactivity available for this product or its ingredients. No specific test data related to reactivity available for this product or its ingredients. No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control The product is stable. The product is stable. The product is stable.

Possibility of hazardous

reactions

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

Conditions to avoid : Reconstitution Fluid

Reconstitution Fluid
Hemoglobin A1c Normal Control
Hemoglobin A1c Abnormal Control
No specific data.
No specific data.

Incompatible materials : Reconstitution Fluid

Hemoglobin A1c Normal Control No specific data.
Hemoglobin A1c Abnormal Control No specific data.

Hazardous decomposition

products

: Reconstitution Fluid

Under normal conditions of storage and

use, hazardous decomposition products

should not be produced.

No specific data.

Hemoglobin A1c Normal Control

Under normal conditions of storage and use, hazardous decomposition products

should not be produced.

Hemoglobin A1c Abnormal Control

Under normal conditions of storage and use, hazardous decomposition products

should not be produced.

# Section 11. Toxicological information

### Information on toxicological effects

#### **Acute toxicity**

| Product/ingredient name                             | Result                                  | Species              | Dose                             | Exposure |
|---|---|----------------------|----------------------------------|----------|
| Reconstitution Fluid sodium azide                   | LD50 Dermal<br>LD50 Dermal<br>LD50 Oral | Rabbit<br>Rat<br>Rat | 20 mg/kg<br>50 mg/kg<br>27 mg/kg | -        |
| Hemoglobin A1c Normal<br>Control<br>chloramphenicol | LD50 Oral                               | Rat                  | 2500 mg/kg                       | -        |
| Hemoglobin A1c Abnormal Control chloramphenicol     | LD50 Oral                               | Rat                  | 2500 mg/kg                       | -        |

Conclusion/Summary : Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control Not available. Not available. Not available.

**Irritation/Corrosion** 

Not available.

**Conclusion/Summary** 

Skin : Reconstitution Fluid Not available.
Hemoglobin A1c Normal Control Not available.
Hemoglobin A1c Abnormal Control Not available.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 9/17

### **Section 11. Toxicological information**

Eyes : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available. Reconstitution Fluid Not available.

Respiratory: Reconstitution Fluid Not available.
Hemoglobin A1c Normal Control Not available.
Hemoglobin A1c Abnormal Control Not available.

**Sensitization** 

Not available.

**Conclusion/Summary** 

Skin : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Respiratory: Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Mutagenicity
Not available.

Conclusion/Summary: Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Carcinogenicity

Not available.

Conclusion/Summary: Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Classification

| Product/ingredient name                               | OSHA | IARC | NTP  |
|---|------|------|--|
| Hemoglobin A1c Normal<br>Control<br>chloramphenicol   | -    | 2A   | Reasonably anticipated to be a human carcinogen. |
| Hemoglobin A1c Abnormal<br>Control<br>chloramphenicol | _    | 2A   | Reasonably anticipated to be a human carcinogen. |

#### **Reproductive toxicity**

Not available.

Conclusion/Summary : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

**Teratogenicity** 

Not available.

Conclusion/Summary: Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Abnormal Control Not available.

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

**Aspiration hazard** 

Not available.

Information on the likely

routes of exposure

Hemoglobin A1c Normal Control

Hemoglobin A1c Abnormal Control

: Reconstitution Fluid

Not available. Not available. Not available.

Potential acute health effects

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 10/17

### Section 11. Toxicological information

Eye contact : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

Inhalation : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

Skin contact : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

Ingestion : Reconstitution Fluid No known significant effects or critical

hazards.

Hemoglobin A1c Normal Control No known significant effects or critical

hazards.

Hemoglobin A1c Abnormal Control No known significant effects or critical

hazards.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : Reconstitution Fluid No specific data.

Hemoglobin A1c Normal Control No specific data. Hemoglobin A1c Abnormal Control No specific data.

Inhalation: Reconstitution FluidNo specific data.Hemoglobin A1c Normal ControlNo specific data.

Hemoglobin A1c Normal Control
Hemoglobin A1c Abnormal Control
Reconstitution Fluid
Hemoglobin A1c Normal Control
No specific data.
No specific data.
No specific data.
No specific data.

Hemoglobin A1c Abnormal Control

No specific data.

Ingestion: Reconstitution FluidNo specific data.Hemoglobin A1c Normal ControlNo specific data.

Hemoglobin A1c Normal Control No specific data.

Hemoglobin A1c Abnormal Control No specific data.

#### Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

**Skin contact** 

Potential immediate: Reconstitution FluidNot available.effectsHemoglobin A1c Normal ControlNot available.

Hemoglobin A1c Normal Control Not available.
Hemoglobin A1c Abnormal Control Not available.

Potential delayed effects : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Long term exposure

Potential immediate : Reconstitution Fluid Not available.

effectsHemoglobin A1c Normal ControlNot available.Hemoglobin A1c Abnormal ControlNot available.

Potential delayed effects : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Not available. Reconstitution Fluid

Not available. Hemoglobin A1c Normal Control Not available. Hemoglobin A1c Abnormal Control

General : No known significant effects or critical hazards.

**Carcinogenicity** : May cause cancer. Risk of cancer depends on duration and level of exposure.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 11/17

## **Section 11. Toxicological information**

Mutagenicity: No known significant effects or critical hazards.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.

# Numerical measures of toxicity Acute toxicity estimates

Not available.

Interactive effects : Reconstitution Fluid

Reconstitution Fluid
Hemoglobin A1c Normal Control
Hemoglobin A1c Abnormal Control
Not available.
Not available.

Other information : Reconstitution Fluid

Reconstitution Fluid
Hemoglobin A1c Normal Control
Hemoglobin A1c Abnormal Control
Not available.
Not available.

# Section 12. Ecological information

#### **Toxicity**

| Product/ingredient name          | Result                                 | Species  | Exposure |
|----------------------------------|--|--|----------|
| Reconstitution Fluid             |  |  |          |
| sodium azide                     | Acute EC50 0.348 mg/l Fresh water      | Algae - Pseudokirchneriella subcapitata                    | 96 hours |
|                                  | Acute EC50 4.2 to 6.2 mg/l Fresh water | Daphnia - Daphnia pulex - Larvae                           | 48 hours |
|                                  | Acute LC50 9000 μg/l Fresh water       | Crustaceans - Gammarus lacustris                           | 48 hours |
|                                  | Acute LC50 0.68 mg/l Fresh water       | Fish - Lepomis macrochirus                                 | 96 hours |
|                                  | Chronic NOEC 5600 µg/l Marine water    | Algae - Macrocystis pyrifera                               | 96 hours |
| Hemoglobin A1c Normal<br>Control |  |  |          |
| chloramphenicol                  | Acute EC50 53.7 ug/ml Marine water     | Crustaceans - Penaeus stylirostris                         | 48 hours |
|                                  | Acute EC50 345000 µg/l                 | Daphnia - Daphnia magna                                    | 48 hours |
|                                  | Acute IC50 0.1 mg/l Fresh water        | Algae - Scenedesmus intermedius - Exponential growth phase | 72 hours |
|                                  | Chronic NOEC 10 mg/l Marine water      | Algae - Tetraselmis suecica -<br>Exponential growth phase  | 96 hours |
| Hemoglobin A1c Abnormal Control  |  |  |          |
| chloramphenicol                  | Acute EC50 53.7 ug/ml Marine water     | Crustaceans - Penaeus stylirostris                         | 48 hours |
|                                  | Acute EC50 345000 µg/l                 | Daphnia - Daphnia magna                                    | 48 hours |
|                                  | Acute IC50 0.1 mg/l Fresh water        | Algae - Scenedesmus intermedius - Exponential growth phase | 72 hours |
|                                  | Chronic NOEC 10 mg/l Marine water      | Algae - Tetraselmis suecica -<br>Exponential growth phase  | 96 hours |

**Conclusion/Summary** 

: Reconstitution Fluid Not available. Hemoglobin A1c Normal Control Not available.

Hemoglobin A1c Abnormal Control

Persistence and degradability

Conclusion/Summary : Reconstitution Fluid Not available.

Hemoglobin A1c Normal Control Not available.
Hemoglobin A1c Abnormal Control Not available.

Not available.

**Bioaccumulative potential** 

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 12/17

### Section 12. Ecological information

| Product/ingredient name                               | LogPow | BCF | Potential |
|---|--------|-----|-----------|
| Hemoglobin A1c Normal<br>Control<br>chloramphenicol   | 1.14   | -   | low       |
| Hemoglobin A1c Abnormal<br>Control<br>chloramphenicol | 1.14   | -   | low       |

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

Hemoglobin A1c Abnormal Control

Not available. Not available. Not available.

Mobility

: Reconstitution Fluid Hemoglobin A1c Normal Control Not available. Not available. Not available.

Other adverse effects

: No known significant effects or critical hazards.

# Section 13. Disposal considerations

**Disposal methods** 

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. 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.

# **Section 14. Transport information**

#### **DOT Classification**

UN number Reconstitution Fluid Hemoglobin A1c Normal Control

Not regulated. Not regulated. Not regulated.

UN proper shipping name

Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control

Hemoglobin A1c Abnormal Control

-

Transport hazard class(es)

Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control --

Packing group

Reconstitution Fluid

Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Environmental hazards

information

Reconstitution Fluid Hemoglobin A1c Normal Control

No. No.

Additional

Hemoglobin A1c Abnormal Control Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control No. -

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 13/17

### **Section 14. Transport information**

**TDG Classification** 

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

Hemoglobin A1c Abnormal Control Not regulated.

Not regulated.

UN proper Reconstitution Fluid - shipping name Hemoglobin A1c Normal Control -

Hemoglobin A1c Abnormal Control -

Transport Reconstitution Fluid -

hazard class(es) Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control -

Hemoglobin A1c Abnormal Control -

Packing group Reconstitution Fluid -

Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Environmental<br/>hazardsReconstitution FluidNo.Hemoglobin A1c Normal ControlNo.

hazards Hemoglobin A1c Normal Control No. Hemoglobin A1c Abnormal Control No.

Additional Reconstitution Fluid information Hemoglobin A1c Normal Control -

Hemoglobin A1c Abnormal Control -

ADR/RID

UN number Reconstitution Fluid Not regulated.

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

UN proper Reconstitution Fluid -

shipping name Hemoglobin A1c Normal Control - Hemoglobin A1c Abnormal Control -

Transport Reconstitution Fluid - hazard class(es) Hemoglobin A1c Normal Control -

hazard class(es) Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Packing group Reconstitution Fluid -

Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Environmental Reconstitution Fluid No. hazards Hemoglobin A1c Normal Control No.

rds Hemoglobin A1c Normal Control No.
Hemoglobin A1c Abnormal Control No.

Additional Reconstitution Fluid Information Hemoglobin A1c Normal Control

information Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

**IMDG** 

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

Hemoglobin A1c Abnormal Control Not regulated.

Not regulated.

Not regulated.

UN proper Reconstitution Fluid

shipping name Hemoglobin A1c Normal Control - Hemoglobin A1c Abnormal Control -

Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control -

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 14/17

### **Section 14. Transport information**

Transport hazard class(es)

Packing group Reconstitution Fluid -

Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Environmental Reconstitution Fluid

hazards Hemoglobin A1c Normal Control No. Hemoglobin A1c Abnormal Control No.

Additional Reconstitution Fluid -

information Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

IATA

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

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

UN proper Reconstitution Fluid -

shipping name Hemoglobin A1c Normal Control - Hemoglobin A1c Abnormal Control -

- Temographi ATC Apriormal Control

Transport Reconstitution Fluid - hazard class(es) Hemoglobin A1c Normal Control -

Hemoglobin A1c Abnormal Control

Packing group Reconstitution Fluid -

Hemoglobin A1c Normal Control -Hemoglobin A1c Abnormal Control -

Environmental Reconstitution Fluid No.

hazards Hemoglobin A1c Normal Control No.

Hemoglobin A1c Abnormal Control No.

Additional Reconstitution Fluid Information Hemoglobin A1c Normal Control -

information Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control -

Special precautions for user : Reconstitution Fluid Transport within user's premises:

are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or

spillage.

Hemoglobin A1c Normal Control Transport within user's premises:

No.

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or

always transport in closed containers that

spillage.

Hemoglobin A1c Abnormal Control Transport within user's premises:

always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or

spillage.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 15/17

## **Section 14. Transport information**

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

### **Section 15. Regulatory information**

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

Commerce control list precursor: potassium cyanide
United States inventory (TSCA 8b): Not determined.
Clean Water Act (CWA) 307: potassium cyanide
Clean Water Act (CWA) 311: potassium cyanide

Clean Air Act Section 112

(b) Hazardous Air Pollutants (HAPs)

Clean Air Act Section 602 : Not listed

**Class I Substances** 

Clean Air Act Section 602 : Not listed

Class II Substances

DEA List I Chemicals

: Not listed

: Listed

(Precursor Chemicals)

Precursor Chemicals)

DEA List II Chemicals
(Facential Chemicals)

(Essential Chemicals)

: Not listed

#### **SARA 302/304**

### **Composition/information on ingredients**

|   |      |      | SARA 302 TPQ |           | SARA 304 RQ |           |
|---|------|------|--------------|-----------|-------------|-----------|
| Name  | %    | EHS  | (lbs)        | (gallons) | (lbs)       | (gallons) |
| Reconstitution Fluid  |      |      |              |           |             |           |
| sodium azide  | 0.09 | Yes. | 500          | -         | 1000        | -         |
| Hemoglobin A1c Normal Control<br>hydrogen cyanide, salts of with the exception<br>of complex cyanides such as ferrocyanides,<br>ferricyanides and mercuric oxycyanide and<br>those specified elsewhere in this database | 0.03 | Yes. | 100          | -         | 10          | -         |
| Hemoglobin A1c Abnormal Control hydrogen cyanide, salts of with the exception of complex cyanides such as ferrocyanides, ferricyanides and mercuric oxycyanide and those specified elsewhere in this database           | 0.03 | Yes. | 100          | -         | 10          | -         |

**SARA 304 RQ** : 50000 lbs / 22700 kg

**SARA 311/312** 

Classification : Delayed (chronic) health hazard

#### Composition/information on ingredients

| Name  | %    | Fire<br>hazard | Sudden<br>release of<br>pressure | Reactive | Immediate<br>(acute)<br>health<br>hazard | Delayed<br>(chronic)<br>health<br>hazard |
|---|------|----------------|----------------------------------|----------|--|--|
| Reconstitution Fluid sodium azide               | 0.09 | No.            | No.                              | No.      | Yes.                                     | No.                                      |
| Hemoglobin A1c Normal Control chloramphenicol   | 0.6  | No.            | No.                              | No.      | No.                                      | Yes.                                     |
| Hemoglobin A1c Abnormal Control chloramphenicol | 0.6  | No.            | No.                              | No.      | No.                                      | Yes.                                     |

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 16/17

### Section 15. Regulatory information

#### State regulations

Massachusetts : None of the components are listed.

New York : The following components are listed: Chloramphenicol

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: ACETAMIDE, 2,2-DICHLORO-N-[2-HYDROXY-1-

(HYDROXYMETHYL)-2-(4-NITROPHENYL)ETHYL], [R-(R\*,R\*)]-

#### California Prop. 65

**WARNING:** This product contains less than 1% of a chemical known to the State of California to cause birth defects or other reproductive harm.

| Ingredient name                                   | Cancer | Reproductive | No significant risk level | Maximum<br>acceptable dosage<br>level |
|---|--------|--------------|---------------------------|---------------------------------------|
| Femoglobin A1c Normal Control potassium cyanide   | No.    | Yes.         | No.                       | 25 μg/day (ingestion)                 |
| Hemoglobin A1c Abnormal Control potassium cyanide | No.    | Yes.         | No.                       | 25 μg/day (ingestion)                 |

#### **International regulations**

Chemical Weapons
Convention List Schedule

**I Chemicals** 

**Chemical Weapons Convention List Schedule** 

II Chemicals

Chemical Weapons
Convention List Schedule
III Chemicals

: Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control : Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control : Reconstitution Fluid

Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control Not listed Not listed Not listed

Not listed Not listed Not listed

Not listed Not listed Not listed

### Section 16. Other information

#### **History**

Date of issue/Date of

revision

: 11/7/2019

Version : 1.08

Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

Indicates information that has changed from previously issued version.

Date of issue/Date of revision : 11/7/2019 Date of previous issue : 6/19/2019 Version : 1.08 17/17