

SAFETY DATA SHEET

DCA Systems HbA1c Controls

SDS no.:

5068A

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

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

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

Identified uses	Reconstitution Fluid	Diagnostic agents.
	Hemoglobin A1c Normal Control	Diagnostic agents.
	Hemoglobin A1c Abnormal Control	Diagnostic agents.
Restrictions on use	For professional users only.	

Supplier : Siemens Healthcare Diagnostics Limited
 Park View,
 Watchmoor Park,
 Camberley,
 Surrey,
 GU15 3YL
 United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition	Reconstitution Fluid	Mixture
	Hemoglobin A1c Normal Control	Mixture
	Hemoglobin A1c Abnormal Control	Mixture

Classification according to UK CLP/GHS

Hemoglobin A1c Normal Control

Carc. 1B, H350

Hemoglobin A1c Abnormal Control

Carc. 1B, H350

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms

:



Signal word

:	Reconstitution Fluid	No signal word.
	Hemoglobin A1c Normal Control	Danger
	Hemoglobin A1c Abnormal Control	Danger

SECTION 2: Hazards identification

Hazard statements	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	No known significant effects or critical hazards. H350 - May cause cancer. H350 - May cause cancer.
<u>Precautionary statements</u>		
Prevention	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. P201 - Obtain special instructions before use. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P201 - Obtain special instructions before use. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Response	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. P308 + P313 - IF exposed or concerned: Get medical advice or attention. P308 + P313 - IF exposed or concerned: Get medical advice or attention.
Storage	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. Not applicable. Not applicable.
Disposal	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations. P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. Not applicable. Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. Restricted to professional users. Restricted to professional users.
2.3 Other hazards		
Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
Other hazards which do not result in classification	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	None known. None known. None known.
Additional information	: Potentially biohazardous material. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.	

SECTION 3: Composition/information on ingredients

3.1 Substances : Reconstitution Fluid Mixture
 Hemoglobin A1c Normal Control Mixture
 Hemoglobin A1c Abnormal Control Mixture

Product/ingredient name	Identifiers	%	Classification	Type
Hemoglobin A1c Normal Control chloramphenicol	EC: 200-287-4 CAS: 56-75-7	≤1	Carc. 1B, H350	[1]
salts of hydrogen cyanide	EC: 205-792-3 CAS: 151-50-8 Index: 006-007-00-5	<0.1	Acute Tox. 1, H300 Acute Tox. 1, H310 Acute Tox. 2, H330 Skin Corr. 1, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH032	[1] [2]
Hemoglobin A1c Abnormal Control chloramphenicol	EC: 200-287-4 CAS: 56-75-7	≤1	Carc. 1B, H350	[1]
salts of hydrogen cyanide	EC: 205-792-3 CAS: 151-50-8 Index: 006-007-00-5	<0.1	Acute Tox. 1, H300 Acute Tox. 1, H310 Acute Tox. 2, H330 Skin Corr. 1, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH032 See Section 16 for the full text of the H statements declared above.	[1] [2]

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact	: Reconstitution Fluid	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.
	Hemoglobin A1c Normal Control	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.
	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. Continue to rinse for at least 10 minutes. Get medical attention.

SECTION 4: First aid measures

Inhalation	: Reconstitution Fluid	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
	Hemoglobin A1c Normal Control	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-to-mouth 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.
	Hemoglobin A1c Abnormal Control	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-to-mouth 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.
Skin contact	: Reconstitution Fluid	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	Hemoglobin A1c Normal Control	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.
	Hemoglobin A1c Abnormal Control	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.
Ingestion	: Reconstitution Fluid	Wash out mouth with water. 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.
	Hemoglobin A1c Normal Control	Wash out mouth with water. Remove dentures if any. 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.

SECTION 4: First aid measures

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. 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.

Hemoglobin A1c Abnormal Control

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

Protection of first-aiders : Reconstitution Fluid

Hemoglobin A1c Normal Control

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.

Hemoglobin A1c Abnormal Control

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

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

SECTION 4: First aid measures

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

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	: Reconstitution Fluid	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
	Hemoglobin A1c Normal Control	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
	Hemoglobin A1c Abnormal Control	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	: Reconstitution Fluid	No specific treatment.
	Hemoglobin A1c Normal Control	No specific treatment.
	Hemoglobin A1c Abnormal Control	No specific treatment.
	Reconstitution Fluid	Not available.
	Hemoglobin A1c Normal Control	Not available.
	Hemoglobin A1c Abnormal Control	Not available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	: In a fire or if heated, a pressure increase will occur and the container may burst.
Hazardous combustion products	: No specific data.

5.3 Advice for firefighters

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 training.
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.

SECTION 6: Accidental release measures

6.1 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 spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	: If specialised 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".

SECTION 6: Accidental release measures

6.2 Environmental precautions : Avoid dispersal of spilt 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).

6.3 Methods and material 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 the 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 spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 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 vapour 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.

7.2 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Hemoglobin A1c Normal Control salts of hydrogen cyanide	EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin. STEL: 5 mg/m ³ , (as CN) 15 minutes. TWA: 1 mg/m ³ , (as CN) 8 hours.
Hemoglobin A1c Abnormal Control salts of hydrogen cyanide	EH40/2005 WELs (United Kingdom (UK), 1/2020). Absorbed through skin. STEL: 5 mg/m ³ , (as CN) 15 minutes. TWA: 1 mg/m ³ , (as CN) 8 hours.

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. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
Hemoglobin A1c Normal Control salts of hydrogen cyanide	DNEL	Long term Dermal	0.14 mg/ kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.94 mg/m ³	Workers	Systemic
	DNEL	Short term Dermal	4.03 mg/ kg bw/day	Workers	Systemic
	DNEL	Short term Inhalation	12.5 mg/m ³	Workers	Systemic
Hemoglobin A1c Abnormal Control salts of hydrogen cyanide	DNEL	Long term Dermal	0.14 mg/ kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	0.94 mg/m ³	Workers	Systemic
	DNEL	Short term Dermal	4.03 mg/ kg bw/day	Workers	Systemic
	DNEL	Short term Inhalation	12.5 mg/m ³	Workers	Systemic

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : If user operations generate dust, fumes, gas, vapour 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.

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.

SECTION 8: Exposure controls/personal protection

- 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 side-shields.
- 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.
- 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.
- 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.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

Appearance

Physical state	: Reconstitution Fluid	Liquid.
	Hemoglobin A1c Normal Control	Solid.
	Hemoglobin A1c Abnormal Control	Solid.
Colour	: Reconstitution Fluid	Colourless.
	Hemoglobin A1c Normal Control	Brownish-red.
	Hemoglobin A1c Abnormal Control	Brownish-red.
Odour	: Reconstitution Fluid	Odourless.
	Hemoglobin A1c Normal Control	Bland.
	Hemoglobin A1c Abnormal Control	Bland.
Odour threshold	: Not relevant/applicable due to nature of the product.	
Melting point/freezing point	: Not relevant/applicable due to nature of the product.	
Softening point	: Not relevant/applicable due to nature of the product.	
Sublimation temperature	: Not relevant/applicable due to nature of the product.	
Initial boiling point and boiling range	: Reconstitution Fluid	Not available.
	Hemoglobin A1c Normal Control	Not available.
	Hemoglobin A1c Abnormal Control	Not available.
Flammability (solid, gas)	: 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.

SECTION 9: Physical and chemical properties

Upper/lower flammability or explosive limits	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not applicable. Not applicable.
Flash point	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	[Product does not sustain combustion.] [Product does not sustain combustion.] [Product does not sustain combustion.]

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Reconstitution Fluid sodium azide	309	588.2	EU A.16

Decomposition temperature : Not relevant/applicable due to nature of the product.

pH	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not applicable. Not applicable. Not applicable.
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Viscosity	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not applicable. Not applicable.
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Solubility(ies) :
Not available.

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

Miscible with water : Not relevant/applicable due to nature of the product.

Partition coefficient: n-octanol/ water : Not relevant/applicable due to nature of the product.

Vapour pressure :

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Reconstitution Fluid water	23.8	3.2				

Evaporation rate : Not relevant/applicable due to nature of the product.

Relative density	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	1 Not available. Not available.
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Density	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
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Vapour density	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not applicable. Not applicable.
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Explosive properties	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
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Oxidising properties	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
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Particle characteristics

Median particle size : Not applicable.

9.2 Other information

Fire point	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
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Burning time : Not relevant/applicable due to nature of the product.

Fundamental burning velocity : Not relevant/applicable due to nature of the product.

SECTION 9: Physical and chemical properties

Burning rate	: Not relevant/applicable due to nature of the product.
SADT	: Not relevant/applicable due to nature of the product.
SAPT	: Not relevant/applicable due to nature of the product.
Heat of reaction	: Not relevant/applicable due to nature of the product.
Heat of combustion	: Not relevant/applicable due to nature of the product.
Flow time (ISO 2431)	: Not relevant/applicable due to nature of the product.
Molecular weight	: Not relevant/applicable due to nature of the product.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
10.5 Incompatible materials	: No specific data.
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Hemoglobin A1c Normal Control chloramphenicol salts of hydrogen cyanide	LD50 Oral	Rat	2500 mg/kg	-
	LD50 Oral	Rat	5 mg/kg	-
Hemoglobin A1c Abnormal Control chloramphenicol salts of hydrogen cyanide	LD50 Oral	Rat	2500 mg/kg	-
	LD50 Oral	Rat	5 mg/kg	-

Conclusion/Summary	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
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Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Hemoglobin A1c Normal Control chloramphenicol salts of hydrogen cyanide	2500 5	N/A 5	N/A N/A	N/A N/A	N/A 0.05
Hemoglobin A1c Abnormal Control chloramphenicol salts of hydrogen cyanide	2500 5	N/A 5	N/A N/A	N/A N/A	N/A 0.05

Irritation/Corrosion

Conclusion/Summary

SECTION 11: Toxicological information

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

Sensitisation

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 Abnormal Control	Not available.

Mutagenicity

Conclusion/Summary

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

Carcinogenicity

Conclusion/Summary

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

Reproductive toxicity

Conclusion/Summary

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

Teratogenicity

Conclusion/Summary

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

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure

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

Potential acute health effects

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.

SECTION 11: Toxicological information

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

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects	: Reconstitution Fluid	Not 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 effects	: Reconstitution Fluid	Not 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.

Potential chronic health effects

Not available.

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

SECTION 11: Toxicological information

General	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Carcinogenicity	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	No known significant effects or critical hazards. May cause cancer. Risk of cancer depends on duration and level of exposure. May cause cancer. Risk of cancer depends on duration and level of exposure.
Mutagenicity	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Reproductive toxicity	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Interactive effects	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
Toxicokinetics		
Absorption	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
Distribution	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
Metabolism	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
Elimination	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.
Other information	: Reconstitution Fluid Hemoglobin A1c Normal Control Hemoglobin A1c Abnormal Control	Not available. Not available. Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Hemoglobin A1c Normal Control chloramphenicol	Acute EC50 53.7 ug/ml Marine water	Crustaceans - Shrimp - Penaeus stylirostris	48 hours
	Acute EC50 345000 µg/l Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
	Acute IC50 0.1 mg/l Fresh water	Algae - Green algae - Scenedesmus intermedius - Exponential growth phase	72 hours

SECTION 12: Ecological information

salts of hydrogen cyanide	Chronic NOEC 10 mg/l Marine water	Algae - Prasinophyte - Tetraselmis suecica - Exponential growth phase	96 hours	
	Acute EC50 0.331 mg/l Fresh water	Algae - Green algae - Chlamydomonas reinhardtii - Exponential growth phase	72 hours	
	Acute LC50 64.4 µg/l Marine water	Crustaceans - Rock crab - Cancer irroratus - Zoea	48 hours	
	Acute LC50 1 µg/l Fresh water	Daphnia - Water flea - Daphnia pulex	48 hours	
	Acute LC50 0.03 mg/l Marine water	Fish - Cobia - Rachycentron canadum - Young	96 hours	
	Chronic EC10 0.158 mg/l Fresh water	Algae - Green algae - Chlamydomonas reinhardtii - Exponential growth phase	72 hours	
	Chronic NOEC 0.05 mg/l Fresh water	Fish - Zambezi barbel - Clarias gariepinus - Adult	4 weeks	
	Hemoglobin A1c Abnormal Control chloramphenicol	Acute EC50 53.7 µg/ml Marine water	Crustaceans - Shrimp - Penaeus stylirostris	48 hours
		Acute EC50 345000 µg/l Fresh water	Daphnia - Water flea - Daphnia magna	48 hours
		Acute IC50 0.1 mg/l Fresh water	Algae - Green algae - Scenedesmus intermedius - Exponential growth phase	72 hours
		Chronic NOEC 10 mg/l Marine water	Algae - Prasinophyte - Tetraselmis suecica - Exponential growth phase	96 hours
	salts of hydrogen cyanide	Acute EC50 0.331 mg/l Fresh water	Algae - Green algae - Chlamydomonas reinhardtii - Exponential growth phase	72 hours
		Acute LC50 64.4 µg/l Marine water	Crustaceans - Rock crab - Cancer irroratus - Zoea	48 hours
		Acute LC50 1 µg/l Fresh water	Daphnia - Water flea - Daphnia pulex	48 hours
Acute LC50 0.03 mg/l Marine water		Fish - Cobia - Rachycentron canadum - Young	96 hours	
Chronic EC10 0.158 mg/l Fresh water		Algae - Green algae - Chlamydomonas reinhardtii - Exponential growth phase	72 hours	
Chronic NOEC 0.05 mg/l Fresh water		Fish - Zambezi barbel - Clarias gariepinus - Adult	4 weeks	

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

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

SECTION 12: Ecological information

Product/ingredient name	LogP _{ow}	BCF	Potential
Hemoglobin A1c Normal Control chloramphenicol	1.14	-	low
Hemoglobin A1c Abnormal Control chloramphenicol	1.14	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc})	: Reconstitution Fluid	Not available.
	Hemoglobin A1c Normal Control	Not available.
	Hemoglobin A1c Abnormal Control	Not available.
Mobility	: Reconstitution Fluid	Not available.
	Hemoglobin A1c Normal Control	Not available.
	Hemoglobin A1c Abnormal Control	Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Methods of disposal	: The generation of waste should be avoided or minimised 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.
Hazardous waste	: The classification of the product may meet the criteria for a hazardous waste. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
Packaging	
Methods of disposal	: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
Special precautions	: 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 spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information**ADR/RID**

14.1 UN number	Reconstitution Fluid	Not regulated.
	Hemoglobin A1c Normal Control	Not regulated.
	Hemoglobin A1c Abnormal Control	Not regulated.
14.2 UN proper shipping name	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

SECTION 14: Transport information

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

14.4 Packing group	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

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

Additional information	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

ADN

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

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

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

14.4 Packing group	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

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

Additional information	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

IMDG

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

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

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

14.4 Packing group	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-

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

SECTION 14: Transport information

Additional information	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-
IATA		
14.1 UN number	Reconstitution Fluid	Not regulated.
	Hemoglobin A1c Normal Control	Not regulated.
	Hemoglobin A1c Abnormal Control	Not regulated.
14.2 UN proper shipping name	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-
14.3 Transport hazard class(es)	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-
14.4 Packing group	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-
14.5 Environmental hazards	Reconstitution Fluid	No.
	Hemoglobin A1c Normal Control	No.
	Hemoglobin A1c Abnormal Control	No.
Additional information	Reconstitution Fluid	-
	Hemoglobin A1c Normal Control	-
	Hemoglobin A1c Abnormal Control	-
14.6 Special precautions for user	Reconstitution Fluid	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.
	Hemoglobin A1c Normal 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.
	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.
14.7 Transport in bulk according to IMO instruments	Not applicable.	

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

UK (GB) /REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

SECTION 15: Regulatory information

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: Reconstitution Fluid	Not applicable.
	Hemoglobin A1c Normal Control	Restricted to professional users.
	Hemoglobin A1c Abnormal Control	Restricted to professional users.

Seveso Directive

This product is not controlled under the Seveso Directive.

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air	: Reconstitution Fluid	Not listed
	Hemoglobin A1c Normal Control	Not listed
	Hemoglobin A1c Abnormal Control	Not listed

Industrial emissions (integrated pollution prevention and control) - Water	: Reconstitution Fluid	Not listed
	Hemoglobin A1c Normal Control	Not listed
	Hemoglobin A1c Abnormal Control	Not listed

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

15.2 Chemical safety assessment	: Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.
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SECTION 16: Other information

🔍 Indicates information that has changed from previously issued version.

Abbreviations and acronyms	: ATE = Acute Toxicity Estimate GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments DMEL = Derived Minimal Effect Level DNEL = Derived No Effect Level EUH statement = GB CLP-specific Hazard statement N/A = Not available PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number
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SECTION 16: Other information

SGG = Segregation Group
 vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
Hemoglobin A1c Normal Control Carc. 1B, H350	Calculation method
Hemoglobin A1c Abnormal Control Carc. 1B, H350	Calculation method

Full text of abbreviated H statements

Hemoglobin A1c Normal Control	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H350	May cause cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.
Hemoglobin A1c Abnormal Control	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H350	May cause cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Full text of classifications

Hemoglobin A1c Normal Control	
Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Carc. 1B	CARCINOGENICITY - Category 1B
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1	SKIN CORROSION/IRRITATION - Category 1
Hemoglobin A1c Abnormal Control	
Acute Tox. 1	ACUTE TOXICITY - Category 1
Acute Tox. 2	ACUTE TOXICITY - Category 2
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Carc. 1B	CARCINOGENICITY - Category 1B
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1	SKIN CORROSION/IRRITATION - Category 1

Date of printing : 12/13/2022

SECTION 16: Other information

Date of issue/ Date of revision : 12/13/2022

Date of previous issue : No previous validation

Version : 1

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.