

C.f.a.s. HbA1c

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : C.f.a.s. HbA1c

Mat.-No./ Genisys-No. : 04528417190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or
Canada)
1-703-527-3887 (International)**Recommended use of the chemical and restrictions on use**

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

GHS Label element

Hazard pictograms



Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

: **Prevention:**
P260 Do not breathe dust or mist.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off

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immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/ physician.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**R1****GHS Classification**

Skin corrosion, Category 1B

H314: Causes severe skin burns and eye damage.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
sucrose	57-50-1	>= 50 - < 70
tetradonium bromide	1119-97-7	>= 5 - < 10
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	>= 5 - < 10
Brij 35	9002-92-0	>= 1 - < 5
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.

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- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during firefighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Observe label precautions.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**R1****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

Personal protective equipment

Hand protection

- Material : Protective gloves
Remarks : The selected protective gloves have to satisfy the

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specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
R1

Appearance	: solid
Colour	: red brown
Odour	: none
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	
Water solubility	: completely soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.

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Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION**R1****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	: Acute toxicity estimate : > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Components:**sucrose:**

Acute oral toxicity	: LD50 Oral (Rat): 29,700 mg/kg LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate : > 30 mg/l Method: Expert judgement
Acute dermal toxicity	: Acute toxicity estimate : > 5,001 mg/kg Method: Expert judgement

tetradonium bromide:

Acute oral toxicity	: LD50 Oral (Rat): 3,900 mg/kg
Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):	
Acute oral toxicity	: LD50 Oral (Rat): > 2,000 mg/kg Test substance: anhydrous substance LD50 Oral (Rabbit): 2,300 mg/kg
Acute inhalation toxicity	: LC50 (Rat): 1 - 5 mg/l Exposure time: 6 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Test substance: anhydrous substance

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Acute toxicity estimate : 1.5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Brij 35:

Acute oral toxicity : LD50 Oral (Rat): 1,000 mg/kg

Skin corrosion/irritation

Causes severe burns.

Product:

Remarks: Extremely corrosive and destructive to tissue.

Components:**tetradonium bromide:**

Result: Causes burns.

Brij 35:

Result: Irritating to skin.

2-methyl-2H-isothiazol-3-one hydrochloride:

Result: Causes burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:**Brij 35:**

Result: Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Assessment: May cause sensitisation by skin contact.

Germ cell mutagenicity

Not classified based on available information.

Components:**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

Genotoxicity in vitro

: Test Type: Ames test

Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity

Not classified based on available information.

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IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**sucrose:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

tetradonium bromide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

Brij 35:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:**sucrose:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

tetradonium bromide:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Brij 35:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**sucrose:**

No data available

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Brij 35:

No data available

Further information**Components:****sucrose:**

Remarks: Health injuries are not known or expected under normal use.

tetradonium bromide:

Remarks: Other dangerous properties can not be excluded.

SECTION 12. ECOLOGICAL INFORMATION**R1****Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment**Components:****sucrose:**Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 hToxicity to fish (Chronic : > 1 mg/l
toxicity)Ecotoxicology Assessment : This product has no known ecotoxicological effects.
Acute aquatic toxicity

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment**tetradonium bromide:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l
Exposure time: 96 h
Test substance: anhydrous substance

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- LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): > 100 mg/l
Exposure time: 24 h
- Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
- Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l
Exposure time: 8 h
Test substance: anhydrous substance
- Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Brij 35:

- Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 6.46 mg/l
Exposure time: 48 h
- Ecotoxicology Assessment
Acute aquatic toxicity : Toxic to aquatic life.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

2-methyl-2H-isothiazol-3-one hydrochloride:

- Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
- Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Persistence and degradability
Components:
Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

- Biodegradability : Biodegradation: 3 %
Testing period: 30 d
Method: Directive 67/548/EEC Annex V, C.4.C.
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.
- Biochemical Oxygen Demand (BOD) : 10 mg/g
Incubation time: 5 d

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Bioaccumulative potential**Components:****sucrose:**

Partition coefficient: n-octanol/water : log Pow: -3.67

tetradonium bromide:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 2.2

Brij 35:Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 220
Exposure time: 72 h**Mobility in soil**

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:**Brij 35:**

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulation**

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IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**R1****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium phosphate dibasic dihydrate	10028-24-7	2.4 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium phosphate dibasic dihydrate	10028-24-7	2.4 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

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Sodium phosphate dibasic dihydrate 10028-24-7 1 - 5 %

Pennsylvania Right To Know

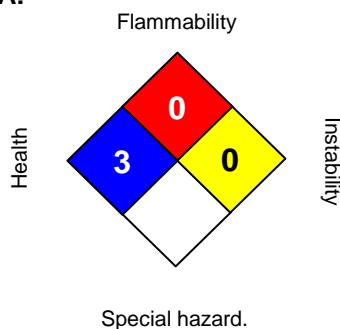
sucrose	57-50-1	50 - 70 %
Albumins, blood serum	9048-46-8	5 - 10 %
tetradonium bromide	1119-97-7	5 - 10 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	5 - 10 %
non hazardous compounds	Not Assigned	1 - 5 %
Sodium phosphate dibasic dihydrate	10028-24-7	1 - 5 %

New Jersey Right To Know

sucrose	57-50-1	50 - 70 %
Albumins, blood serum	9048-46-8	5 - 10 %
tetradonium bromide	1119-97-7	5 - 10 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	5 - 10 %
non hazardous compounds	Not Assigned	1 - 5 %
Sodium phosphate dibasic dihydrate	10028-24-7	1 - 5 %

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****R1****NFPA:****HMIS III:**

HEALTH	3
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.