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

1.1 Product identifier

Commercial Product Name	:	C.f.a.s. HbA1c
Mat.-No./ Genisys-No.	:	04528417190

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

Recommended restrictions on use	:	For professional users only.

1.3 Details of the supplier of the safety data sheet

Company	:	Roche Diagnostics Deutschland GmbH - Sandhoferstrasse 116 68305 Mannheim
E-mail address	:	mannheim.umweltschutz@roche.com
Telephone	:	+496217590
Telefax	:	+496217592890
Responsible Department	:	+49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies:	:	Central Works Security Roche Diagnostics GmbH	+49(0)621-759-2203
Centre for detoxification:	:	Mainz Munich	+49(0)6131-19240 +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word	:	Danger	
Hazard statements	:	H314	Causes severe skin burns and eye damage.
Precautionary statements	:	**Prevention:**	
		P260	Do not breathe dust or mist.
		P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Response:	

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional Labelling:

EUH208 Contains 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3. May produce an allergic reaction.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1

Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1B — H314: Causes severe skin burns and eye damage.

Classification (67/548/EEC, 1999/45/EC)

Irritant — R36/38: Irritating to eyes and skin.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
tetradonium bromide	1119-97-7 214-291-9	C; C; R34	Skin Corr. 1B; H314 Eye Dam. 1; H318	>= 5 - < 10
Edetic acid disodium salt dihydrate (EDTA-2Na-2H2O)	6381-92-6	Xn; Xn; R20	Acute Tox. 4; H332	>= 1 - < 10
Brij 35	9002-92-0 500-002-6	Xn; R22 Xi; R41	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 1 - < 3
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3 247-499-3	Xn; R42/43 C; C; R34	Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1; H317	>= 0,1 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapours/dust.
Avoid exposure - obtain special instructions before use.
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.
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Storage class (TRGS 510)	:	8B, Non-combustible, corrosive hazardous materials
Other data	:	No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s)	:	Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.

Hand protection

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

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1

Appearance	:	solid
Colour	:	red brown
Odour	:	none
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	completely soluble
Partition coefficient: n-octanol/water	:	No data available
Ignition temperature	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

R1

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1

Acute toxicity

Not classified based on available information.

Components:

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

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.

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.

Components:

Brij 35:
Result: Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

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.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:

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:

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:

Brij 35:
No data available

Further information

Components:

tetradonium bromide:
Remarks: Other dangerous properties can not be excluded.

SECTION 12: Ecological information

12.1 Toxicity

R1

Components:

tetradonium bromide:
Ecotoxicology Assessment

Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

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 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.

12.2 Persistence and degradability

R1

Components:

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

Biodegradability	:	Biodegradation: 3 % 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

12.3 Bioaccumulative potential

R1

Components:

tetradonium bromide:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	:	log Pow: 2,2

Brij 35:

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Exposure time: 72 h Bioconcentration factor (BCF): 220

12.4 Mobility in soil

R1

No data available

12.5 Results of PBT and vPvB assessment

R1

Not relevant

12.6 Other adverse effects

R1

Components:

Brij 35:

Additional ecological information	:	Remarks: No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

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

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water contaminating class (Germany) : WGK 3 highly water endangering

R1

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

Precautionary statements : **Prevention:**

P260 Do not breathe dust or mist.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Hazardous components which must be listed on the label:

1119-97-7 tetradonium bromide

Additional Labelling:

EUH208 Contains 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3. May produce an allergic reaction.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

R20	:	Harmful by inhalation.
R22	:	Harmful if swallowed.
R34	:	Causes burns.
R41	:	Risk of serious damage to eyes.
R42/43	:	May cause sensitisation by inhalation and skin contact.

Full text of H-Statements

H302	:	Harmful if swallowed.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H332	:	Harmful if inhaled.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Eye Dam.	:	Serious eye damage
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation

Further information

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.

DE / EN