Reaction Buffer Concentrate (10X)

Version 1.0 Revision Date 01/07/2014 Print Date 03/28/2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Reaction Buffer Concentrate (10X)

Mat.-No./ Genisys-No. : 05353955001

Manufacturer or supplier's details

Company	:	Roche Diagnostics Limited Charles Avenue
Address	:	Burgess Hill RH15 9RY West Sussex
Telephone	:	+44 1444 256000
Telefax	:	+44 1444 256239
Emergency telephone number	:	+49(0)621-759-2012 oder +49(0)621-759-4848 oder +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: (Roche Diagnostics Ltd.)	:	Health, Safety & Environment - Product Safety / Vigilance -	+44 1444 256500 or +44 7802 260498 +44 1444 256561 or +44 7710 391653
Toxicology 24Hr help-line: Health Advice 24Hr help-line:	:	NPIS: NHS Direct: NHS 24:	+44 844 892 0111 +44 845 4647 +44 8454 242424

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Physical state	liquid
Colour	blue
Odour	slight, vinegar-like

GHS Classification

Skin irritation : Category 2
Serious eye damage : Category 1

GHS Label element

Hazard pictograms :

Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
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.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Potential Health Effects

Carcinogenicity:

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Preparation

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
acetic acid	64-19-7	>= 1 - < 5
Brij 35	9002-92-0	>= 1 - < 5

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.

In case of skin contact	:	If skin irritation persists, call a physician. 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	:	Clean mouth with water and drink afterwards plenty of water. 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.
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 fire fighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.
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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : 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.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL
		ST	15 ppm 37 mg/m3	NIOSH REL
		TWA	10 ppm 25 mg/m3	OSHA Z-1
		TWA	10 ppm 25 mg/m3	OSHA P0

Personal protective equipment

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.
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	:	impervious clothing 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

Appearance	:	liquid
Colour	:	blue
Odour	:	slight, vinegar-like
pH	:	7.6
Melting point/range	:	no data available
Boiling point/boiling range	:	no data available
Flash point	:	does not flash
Flammability (solid, gas)	:	The product is not flammable.
Upper explosion limit	:	no data available
Lower explosion limit	:	no data available
Solubility(ies)		
Water solubility	:	completely miscible
Auto-ignition temperature	:	no data available
Thermal decomposition	:	Hazardous decomposition products formed under fire conditions.
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.
Possibility of hazardous reactions	:	Reacts with the following substances: Oxidizing agents No decomposition if stored and applied as directed.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: nitrogen oxides (NOx) Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate : 36.86 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method

Components:

acetic acid:

Acute oral toxicity	:	LD50 Oral rat: 3,310 mg/kg
Acute dermal toxicity	:	LD50 Dermal rabbit: 1016 µl/kg

Brij 35:

Acute oral toxicity	:	LD50 Oral rat: 1,000 mg/kg

Skin corrosion/irritation

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:

acetic acid:

Result: Causes severe burns.
Remarks: Extremely corrosive and destructive to tissue.

Brij 35:
Result: Irritating to skin.

Serious eye damage/eye irritation

Product:

Remarks: May cause irreversible eye damage.

Components:

acetic acid:
Remarks: May cause irreversible eye damage.

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

Respiratory or skin sensitisation

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Components:

acetic acid:

Genotoxicity in vitro	:	Type: Chromosome aberration test in vitro Method: Mutagenicity (in vitro mammalian cytogenetic test) Remarks: In vitro tests did not show mutagenic effects
Germ cell mutagenicity-Assessment	:	Not mutagenic in Ames Test.

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure

Components:

acetic acid:
Remarks: no data available

Brij 35:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

acetic acid:
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

Components:
acetic acid:
no data available

Brij 35:
no data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Components:
acetic acid :

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): 410 mg/l Exposure time: 48 h NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

Ecotoxicology Assessment

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

Persistence and degradability

Components:
acetic acid :

Biodegradability	:	Biodegradation: 71 % Exposure time: 5 d Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Bioaccumulative potential

Components:
acetic acid :

Partition coefficient: n-octanol/water	:	log Pow: -0.31

Brij 35 :

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

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

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

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

OSHA Hazards : Harmful by ingestion., Corrosive to skin, Severe eye irritant

WHMIS Classification : D2B: Toxic Material Causing Other Toxic Effects
Corrosive Material

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Acetic acid	64-19-7	5000	

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

SARA 313 : 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).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

acetic acid	64-19-7	4.89 %

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

acetic acid	64-19-7	4.89 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	4.89 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

acetic acid	64-19-7	1 - 5 %

Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
trometamol	77-86-1	10 - 20 %
acetic acid	64-19-7	1 - 5 %

New Jersey Right To Know

water	7732-18-5	70 - 90 %
trometamol	77-86-1	10 - 20 %
acetic acid	64-19-7	1 - 5 %
Brij 35	9002-92-0	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.

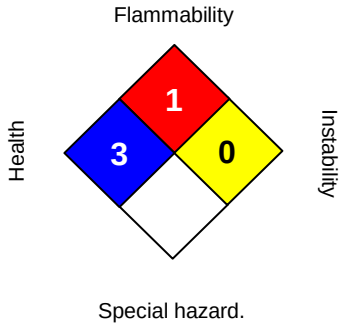
Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

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.