SAFETY DATA SHEET

Clean-Cell M 2x2l

Version	Revision Date:	Date of last issue: 04-14-2015
1.6	04-25-2015	Date of first issue: 05-21-2012

SECTION 1. IDENTIFICATION

Product name : Clean-Cell M 2x2l

Mat.-No./ Genisys-No. : 04880293190

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 : H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

Precautionary statements : **Prevention:**
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): 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 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P390 Absorb spillage to prevent material damage.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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GHS Classification

Corrosive to metals Category 1	H290: May be corrosive to metals.
Skin corrosion Category 1	H314: Causes severe skin burns and eye damage.
Serious eye damage Category 1	H318: Causes serious eye damage.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
potassium hydroxide	1310-58-3	>= 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.

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 : 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.
Rinse mouth with water.

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.
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.
Local authorities should be advised if significant spillages cannot be contained.

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 protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : 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.
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.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Components	CAS-No.
potassium hydroxide	1310-58-3

Engineering measures : No data available

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

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Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	ca. 13
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	:	1.008 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Explosive properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	No decomposition if stored and applied as directed.

tions

Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

potassium hydroxide:

Acute oral toxicity : LD50 (Rat): 273 mg/kg

Skin corrosion/irritation

Causes severe burns.

Product:

Remarks: Extremely corrosive and destructive to tissue.

Components:

potassium hydroxide:

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:

potassium hydroxide:

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

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

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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.
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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

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Ecotoxicity

Product:

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

Components:

potassium hydroxide:

Toxicity to fish	:	LC50 (Fish): > 10 mg/l Exposure time: 96 h LC50 (Fish): < 100 mg/l Exposure time: 96 h LC50 (Gambusia affinis (Mosquito fish)): 80 mg/l Exposure time: 24 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 270 mg/l Exposure time: 24 h
Ecotoxicology Assessment Toxicity Data on Soil	:	Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : 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).

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.
Can be disposed as waste water, when in compliance with local regulations.

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

UN/ID No.	:	UN 1814
Proper shipping name	:	Potassium hydroxide solution
Class	:	8
Packing group	:	III
Labels	:	Corrosives
Packing instruction (cargo aircraft)	:	856
Packing instruction (passenger aircraft)	:	852

IMDG-Code

UN number	:	UN 1814
Proper shipping name	:	Potassium hydroxide solution
Class	:	8
Packing group	:	III
Labels	:	8
EmS Code	:	F-A, S-B
Marine pollutant	:	no

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

Not applicable

National Regulations

49 CFR

UN/ID/NA number	:	UN 1814
Proper shipping name	:	Potassium hydroxide, solution
Class	:	8
Packing group	:	III
Labels	:	Class 8 - Corrosive
ERG Code	:	154
Marine pollutant	:	no

SECTION 15. REGULATORY INFORMATION

R1

TSCA list : Not relevant

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

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Potassium hydroxide	1310-58-3	1000	*

*: 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 311/312 Hazards : No SARA Hazards

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 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).
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 SOCMI 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:

potassium hydroxide	1310-58-3	0.988 %

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

potassium hydroxide	1310-58-3	0.988 %

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

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
potassium hydroxide	1310-58-3	0.1 - 1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %

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.

The components of this product are reported in the following inventories:

REACH	:	Not in compliance with the inventory
	:	Dodecyl alcohol, ethoxylated
	:	potassium hydroxide
CH INV	:	On the inventory, or in compliance with the inventory
TSCA	:	On TSCA Inventory
DSL	:	All components of this product are on the Canadian DSL.
AICS	:	On the inventory, or in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
	:	water
ISHL	:	Not in compliance with the inventory

: water

KECI : On the inventory, or in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

Inventories

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

R1

GHS Label element

Hazard pictograms :

Signal word : Danger

Hazard statements : H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.

Precautionary statements : **Prevention:**
P234 Keep only in original container.
P264 Wash skin thoroughly after handling.
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 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P363 Wash contaminated clothing before reuse.
P390 Absorb spillage to prevent material damage.
Storage:
P405 Store locked up.
P406 Store in corrosive resistant stainless steel container with a resistant inner liner.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION

Further information

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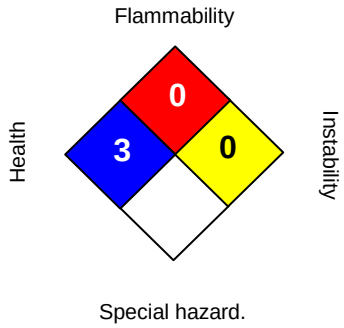
NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

Revision Date : 04-25-2015

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.

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