

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : INFORM HER2 DUAL ISH DNA PROBE CKTL US

Mat.-No./ Genisys-No. : 05586640001

Manufacturer or supplier's detailsCompany : Roche Diagnostics Limited
Charles AvenueAddress : Burgess Hill
RH15 9RY West Sussex

Telephone : +44 1444 256000

Telefax : +44 1444 256239

Emergency telephone : +49(0)621-759-2012 oder +49(0)621-759-4848 oder
number +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: : Health, Safety & +44 1444 256500 or +44 7802
(Roche Diagnostics Ltd.) Environment 260498

- +44 1444 256561 or +44 7710

Product Safety / Vigilance 391653

-

Toxicology 24Hr help-line: : NPIS: +44 844 892 0111

Health Advice 24Hr help-line: NHS Direct: +44 845 4647

NHS 24: +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	light brown
Odour	none

GHS Classification

Reproductive toxicity : Category 1B

GHS Label element

Hazard pictograms :



Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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 [%]
formamide	75-12-7	>= 50 - < 70

SECTION 4. FIRST AID MEASURES

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

If inhaled : Move to fresh air.

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

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

- | | |
|-------------------------|---|
| In case of skin contact | : If on skin, rinse well with water. |
| In case of eye contact | : Flush eyes with water as a precaution.
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 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.
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. |

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

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.
- 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.
- Materials to avoid :

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
formamide	75-12-7	TWA	10 ppm	ACGIH
		TWA	10 ppm 15 mg/m ³	NIOSH REL
		TWA	20 ppm 30 mg/m ³	OSHA P0
		STEL	30 ppm 45 mg/m ³	OSHA P0

Personal protective equipment

- Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

- Hand protection
 Material : Nitrile rubber

- 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.

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles
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	: light brown
Odour	: none
pH	: 7.4
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
Density	: 1.12 - 1.19 g/cm ³
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	: no data available
Incompatible materials	: Oxidizing agents

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

Hazardous decomposition products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Sulphur oxides
nitrogen oxides (NOx)
Hydrogen chloride gas

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 : > 40 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:**formamide:**

Acute oral toxicity : LD50 Oral rat: 5,570 mg/kg

Acute inhalation toxicity : LC50 rat: > 7.3 mg/l
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 Dermal rabbit: 17,000 mg/kg

Skin corrosion/irritation**Components:****formamide:**

Species: rabbit
Result: No skin irritation

Serious eye damage/eye irritation**Components:****formamide:**

Species: rabbit
Result: No eye irritation

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

no data available

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

Carcinogenicity

no data available

Reproductive toxicity**Components:****formamide:**Reproductive toxicity -
Assessment: May damage the unborn child., Presumed human
reproductive toxicant**STOT - single exposure****Product:**

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

Components:**formamide:**

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

STOT - repeated exposure**Product:**

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

Components:**formamide:**

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

Aspiration toxicity**Components:****formamide:**

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:

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

formamide :

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3,200 mg/l
Method: OECD Test Guideline 203
- LC100 (Oncorhynchus mykiss (rainbow trout)): 5,000 mg/l
Method: OECD Test Guideline 203
- LC0 (Oncorhynchus mykiss (rainbow trout)): 2,000 mg/l
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h
- Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
- Toxicity to bacteria : EC50 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 17 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**Components:****formamide :**

- Biodegradability : Biodegradation: > 70 %
Exposure time: 28 d
Method: OECD Test Guideline 302
Remarks: Readily biodegradable, according to appropriate OECD test.

Bioaccumulative potential**Components:****formamide :**

- Partition coefficient: n-octanol/water : log Pow: -1.51

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).

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

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**

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** : Reproductive hazard

- WHMIS Classification** : D2A: Very Toxic Material Causing Other Toxic Effects

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

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

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

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 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

formamide	75-12-7	55 %
-----------	---------	------

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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**

formamide	75-12-7	50 - 70 %
-----------	---------	-----------

Pennsylvania Right To Know

formamide	75-12-7	50 - 70 %
water	7732-18-5	10 - 20 %
Dextransulfat, Natriumsalz	9011-18-1	10 - 20 %
Sodium citrate	6132-04-3	5 - 10 %
sodium chloride	7647-14-5	5 - 10 %

New Jersey Right To Know

formamide	75-12-7	50 - 70 %
water	7732-18-5	10 - 20 %
Dextransulfat, Natriumsalz	9011-18-1	10 - 20 %
Sodium citrate	6132-04-3	5 - 10 %
sodium chloride	7647-14-5	5 - 10 %

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)

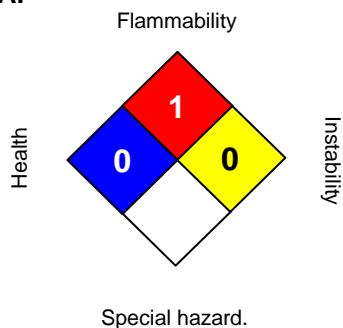
SECTION 16. OTHER INFORMATION

INFORM HER2 DUAL ISH DNA PROBE CKTL US

Version 1.1

Revision Date 11-18-2013

Print Date 02-21-2014

Further information**NFPA:****HMIS III:**

HEALTH	0*
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.