INFORM CYTOPLASMIC LAMBDA MRNA PROBE

Version 1.1 Revision Date 11-18-2013 Print Date 01-15-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : INFORM CYTOPLASMIC LAMBDA MRNA PROBE

Mat.-No./ Genisys-No. : 05278686001

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 - +44 1444 256500 or +44 7802 260498 Product Safety / Vigilance - +44 1444 256561 or +44 7710 391653
Toxicology 24Hr help-line: Health Advice 24Hr help-line:	:	NPIS: +44 844 892 0111 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.

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.

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.

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/m3	NIOSH REL
		TWA	20 ppm 30 mg/m3	OSHA P0
		STEL	30 ppm 45 mg/m3	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.

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/cm3
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

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

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:

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).

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.

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):

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.

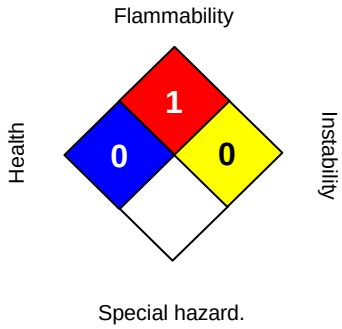
Inventories

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

SECTION 16. OTHER INFORMATION

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.