

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : ASSY, CONFIRM Anti-EGFR (3C6), IVD

Mat.-No./ Genisys-No. : 05278341001

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	yellow
Odour	none

GHS Classification

Acute toxicity (Inhalation) : Category 4

GHS Label element

Hazard pictograms :



Signal word : Warning

Hazard statements : H332 Harmful if inhaled.

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P271 Use only outdoors or in a well-ventilated area.
Response:
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.

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

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : 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 on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
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.

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

Rinse mouth with water.

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.

Specific hazards during firefighting : No information available.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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 : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

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

Contains no substances with occupational exposure limit values.

Personal protective equipment

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

Respiratory protection	: No personal respiratory protective equipment normally required.
Hand protection 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	: Safety glasses
Skin and body protection	: Protective suit
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: yellow
Odour	: none
pH	: 7.5
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	: 1.016 g/cm ³
Auto-ignition temperature	: no data available
Thermal decomposition	: 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 reactions	: Reacts with the following substances: Oxidizing agents

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

Stable under recommended storage conditions.

Stable under recommended storage conditions.
No hazards to be specially mentioned.

Conditions to avoid : no data available

Incompatible materials : no data available

Hazardous decomposition products : Carbon oxides
nitrogen oxides (NO_x)
Hydrogen chloride gas
Sodium oxides

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate : 15.1 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method**Skin corrosion/irritation**

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure

no data available

STOT - repeated exposure

no data available

Aspiration toxicity

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

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

Persistence and degradability

no data available

Bioaccumulative potential

no data available

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
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).

Remarks

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : The product has to be disposed of as laboratory chemical in accordance with local regulations.

Contaminated packaging : 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

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

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 : no data available

SECTION 15. REGULATORY INFORMATION**OSHA Hazards** : No OSHA Hazards**WHMIS Classification** : Not Rated**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	
sodium azide	26628-22-8	1000	

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

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.

ASSY, CONFIRM Anti-EGFR (3C6), IVD

Version 1.1

Revision Date 11-19-2013

Print Date 03-28-2014

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**

sodium azide 26628-22-8 0 - 0.1 %

Pennsylvania Right To Know

Caseins 9000-71-9 90 - 100 %
 water 7732-18-5 90 - 100 %
 sodium azide 26628-22-8 0 - 0.1 %

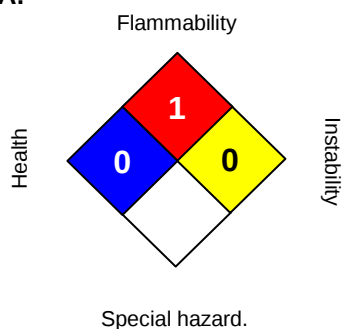
New Jersey Right To Know

Caseins 9000-71-9 90 - 100 %
 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.

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.