

CONFIRM anti-CD15 (MMA) PAB, IVD

Version 1.2

Revision Date 11-18-2013

Print Date 03-28-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : CONFIRM anti-CD15 (MMA) PAB, IVD

Mat.-No./ Genisys-No. : 05266904001

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

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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 yellow
Odour	none

GHS Classification

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

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

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ACGIH

human carcinogen by IARC.

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 : 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.
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.

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

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| Specific hazards during firefighting | : | No information available. |
| Further information | : | The product itself does not burn.

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

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| 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

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| 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. |
| 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. |
| Materials to avoid | : | |

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

Contains no substances with occupational exposure limit values.

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Personal protective equipment

Hand protection	
Material	: Latex 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
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	: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: light yellow
Odour	: none
pH	: 7.7, (22 °C)
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	: 1.005 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.

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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	: Exposure to light.
Incompatible materials	: no data available
Hazardous decomposition products	: Hazardous decomposition products formed under fire conditions.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute inhalation toxicity	: Acute toxicity estimate : 30.06 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method
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Skin corrosion/irritation**Product:**

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation**Product:**

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Respiratory or skin sensitisation**Product:**

Remarks: Causes sensitisation.

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

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no data available

STOT - single exposure**Product:**

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.

Aspiration toxicity

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**

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| 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

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| Remarks | : | Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR |
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SECTION 15. REGULATORY INFORMATION

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| OSHA Hazards | : | No OSHA Hazards |
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| WHMIS Classification | : | Not Rated |
|----------------------|---|-----------|

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

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

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**

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

Pennsylvania Right To Know

water	7732-18-5 90 - 100 %
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New Jersey Right To Know

water	7732-18-5 90 - 100 %
Albumins, blood serum	9048-46-8 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)

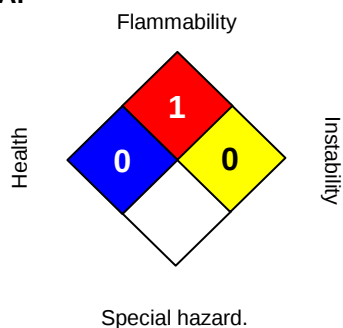
SECTION 16. OTHER INFORMATION

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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.