SAFETY DATA SHEET

CONFIRM anti-CD45 (LCA) (RP2/18) PAB

SECTION 1. IDENTIFICATION

Product name : CONFIRM anti-CD45 (LCA) (RP2/18) PAB
Mat.-No./ Genisys-No. : 05266912001

Manufacturer or supplier’s details
Company name of supplier : Roche Diagnostics
Address : 9115 Hague Road
46250 Indianapolis IN
Telephone : 1-800-428-5074
Emergency telephone:
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
Not a hazardous substance or mixture.

GHS Label element
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Substance name : Confirm (TM) Primary Antibodies (Diluent 95119)

Hazardous ingredients
No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material 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
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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.
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.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed: None known.

Notes to physician: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING 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 fire fighting: No information available.

Hazardous combustion products: No hazardous combustion products are known

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 fire-fighters: 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 vapors/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 sensitization 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.

Technical measures/Precautions: See label, package insert or internal guidelines

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters
Contains no substances with occupational exposure limit values.

Engineering measures: No data available

Personal protective equipment

Hand protection

Material: Latex gloves
Remarks: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

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 con-
Hygiene measures: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: liquid
- **Color**: light yellow
- **Odor**: none
- **Odor Threshold**: No data available
- **pH**: 7.7, (22 °C)
- **Melting point/range**: No data available
- **Boiling point/boiling range**: No data available
- **Flash point**: does not flash
- **Evaporation rate**: No data available
- **Upper explosion limit**: No data available
- **Lower explosion limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: 1.005 g/cm³
- **Solubility(ies)**
  - **Water solubility**: completely miscible
  - **Solubility in other solvents**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Autoignition temperature**: No data available
- **Decomposition temperature**: Hazardous decomposition products formed under fire conditions.
- **Viscosity**
  - **Viscosity, dynamic**: No data available
  - **Viscosity, kinematic**: No data available
- **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: Exposure to light.

Incompatible materials: No data available

Hazardous decomposition products: Hazardous decomposition products formed under fire conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Skin corrosion/irritation
Not classified based on available information.

Product:
Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation
Not classified based on available information.

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

Respiratory or skin sensitization
Skin sensitization: Not classified based on available information.
Respiratory sensitization: Not classified based on available information.

Product:
Remarks: Causes sensitization.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

IARC
No ingredient 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 ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by OSHA.
equal to 0.1% is identified as a carcinogen or potential carcino- 
gen by OSHA.

**NTP**
No ingredient 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.

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

**STOT-repeated exposure**
Not classified based on available information.

**Product**:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeat- 
ed exposure.

**Aspiration toxicity**
Not classified based on available information.

**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**

**Product**:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro- 
tection of Stratospheric Ozone - CAA Section 602 Class I 
Substances

Remarks: This product neither contains, nor was manufactu-
red 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
UNRTDG Not regulated as a dangerous good
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.

Domestic regulation
49 CFR Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards: Acute Health Hazard

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
- 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
- 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 %

New Jersey Right To Know
- Water 7732-18-5 90 - 100 %
- Bovine Serum Albumin Fraction V 90604-29-8 1 - 5 %
- Animal serum /-plasma - different species Not Assigned 1 - 5 %

California Prop. 65
- This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

CH INV
- Not in compliance with the inventory
  - Animal serum /-plasma - different species
  - Glycols
  - Modified alkyl carboxylate
  - Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

TSCA
- Not On TSCA Inventory
  - Bovine Serum Albumin Fraction V
  - Animal serum /-plasma - different species
  - Glycols
  - Modified alkyl carboxylate
  - Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

DSL
- This product contains the following components that are not
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on the Canadian DSL nor NDSL.
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Glycols
Modified alkyl carboxylate

AICS: Not in compliance with the inventory
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Glycols
Modified alkyl carboxylate
Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

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

ENCS: Not in compliance with the inventory
Water
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Tris hydrochloride
Glycols
Modified alkyl carboxylate

ISHL: Not in compliance with the inventory
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Tris hydrochloride
Glycols
Modified alkyl carboxylate

KECI: Not in compliance with the inventory
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Glycols
Modified alkyl carboxylate

PICCS: Not in compliance with the inventory
Bovine Serum Albumin Fraction V
Animal serum /-plasma - different species
Glycols
Modified alkyl carboxylate

IECSC: Not in compliance with the inventory
Animal serum /-plasma - different species
Glycols
Modified alkyl carboxylate

TSCA list
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECSC - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RQ - Reportable Quantity; SARA - Superfund Amendments and Reauthorization Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice; ERG - Emergency Response Guide; NTP - National Toxicology Program; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods

Further information

NFPA:

Health

0

Flammability

0

Aggregation

0

Special hazard.

HMIS III:

Health

0

Flammability

0

Physical Hazard

0

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

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The information provided in this Material 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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