



# MATERIAL SAFETY DATA SHEET

(Based on Directive 2001/58/EC)

Publication Date : 2006-09-13

Product Name: LIFECODES Donor Specific Antibody

## 1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- 1.1 Product name LIFECODES Donor Specific Antibody
- Catalog # 628230 – LIFECODES DSA
- Kit components Capture Beads  
Conjugate Concentrate (LMD)  
SA-PE Concentrate  
Lymphocyte Lysis Buffer  
Specimen Diluent  
Lysate Control Reagent  
Wash Buffer  
Positive Control Serum  
Negative Control Serum  
Dried Lymphocyte Control pellet
- 1.2 Intended Use Donor Specific Antibody (DSA) is a bead-based immunoassay using the Luminex for the qualitative detection of IgG antibodies to donor-specific Class I and Class II Human Leukocyte Antigens.
- 1.3 Company **Gen-Probe Transplant Diagnostics, Inc.**  
550 West Avenue  
Stamford, CT 06902 USA  
Tel: (203) 328-9500  
Toll Free Tel: (888) 329-0255  
Fax: (203) 328-9599  
[lifecodes@gen-probe.com](mailto:lifecodes@gen-probe.com)  
[WWW.GEN-PROBE.COM](http://WWW.GEN-PROBE.COM)
- 1.4 In emergencies Call your local emergency center

## 2. HAZARDS IDENTIFICATION

### Positive Control Serum, Negative Control Serum

Harmful if swallowed

Contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

### Lymphocyte Lysis Buffer

Harmful if swallowed

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Irritating to skin and eyes.

### Conjugate Concentrate (LMD), Wash Buffer, Specimen Diluent

Harmful if swallowed

Animal proteins are potentially infectious.



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## Dried Lymphocyte Control pellet

Contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

Animal proteins are potentially infectious.

## Capture Beads

May cause sensitization by skin contact.

Contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

Animal proteins are potentially infectious.

## SA-PE Concentrate, Lysate Control Reagent

May cause sensitization by skin contact.

Animal proteins are potentially infectious.

### 3. COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Components	Hazardous Ingredients	Classification Substance	EINECS NR.
Capture Beads	0.05% ProClin 300 (*) Contains material from human origin Contains bovine proteins Contains murine proteins	T, N, R23/24/25-34-43-50/53	(*)
Conjugate Concentrate (LMD)	0.1 % Sodium azide (NaN <sub>3</sub> ) Contains bovine and caprine proteins	T+, N, R28-32-50/53	247-852-1
SA-PE Concentrate	0.05% ProClin 300 (*) Contains bovine proteins	T, N, R23/24/25-34-43-50/53	(*)
Lymphocyte Lysis Buffer	0.5 % Sodium azide (NaN <sub>3</sub> )	T+, N, R28-32-50/53	247-852-1
Specimen Diluent	0.09 % Sodium azide (NaN <sub>3</sub> ) Contains bovine and murine proteins	T+, N, R28-32-50/53	247-852-1
Lysate Control Reagent	0.05% ProClin 300 (*) Contains bovine proteins Contains murine proteins	T, N, R23/24/25-34-43-50/53	(*)
Wash Buffer	0.1 % Sodium azide (NaN <sub>3</sub> ) Contains bovine proteins	T+, N, R28-32-50/53	247-852-1
Positive Control Serum	0.1 % Sodium azide (NaN <sub>3</sub> ) Contains material from human origin	T+, N, R28-32-50/53	247-852-1
Negative Control Serum	0.1 % Sodium azide (NaN <sub>3</sub> ) Contains material from human origin	T+, N, R28-32-50/53	247-852-1



*Clean-up:*

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

<b>7. HANDLING AND STORAGE</b>
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**All Kit Components**
*Handling:*

- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

*Storage:*

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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**8.1 Exposure Limits**

Chemical/Component	TLV/NIOSH REL	OSHA PEL
Sodium azide (as NaN <sub>3</sub> )	0.3 mg/m <sup>3</sup> ACGIH TLV-CL	Not listed
Sodium azide (as HN <sub>3</sub> )	0.1 ppm	Not listed

Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2003.

**8.2 Control of Exposure**
**All Kit Components**

*Eye protection:* - Safety glasses or face shield

*Hand protection:* - Protective Gloves

*Skin protection:* - Protective clothing

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**All Kit Components**

Liquid (except Dried Lymphocyte Control pellet)

**Specimen Diluent, Lysate Control Reagent, Capture Beads**

Light blue

**Positive Control Serum, Negative Control Serum, Wash Buffer**

Clear and slightly yellow to amber

**Lymphocyte Lysis Buffer**

Dark blue

**Conjugate Concentrate (LMD), SA-PE Concentrate**

Pink

**10. STABILITY AND REACTIVITY****All Kit Components***Stability:* All components are stable until expiry date if stored in specified conditions (see label)*Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities*Conditions/Materials to avoid:* Keep away from metals and acids (Azide containing components)**11. TOXICOLOGICAL INFORMATION**

See "2. Composition/Information on ingredients" to identify the kit components that contain the substances mentioned in this section

**Acute toxicity:**

<i>Sodium azide:</i>	LD50 oral rat	: 27 mg/kg
	LD50 dermal rabbit	: 20 mg/kg
<i>Tween 20:</i>	LD50 oral rat	: 36,700 µl/kg
<i>ProClin300:</i>	LD50 Oral rat, female	: 3,723 mg/kg
	LD50 Oral rat, male	: 3,600 mg/kg
	LD50 Skin Rabbit	: > 3,600 mg/kg
	LD50 Skin Rabbit	: 3,500 mg/kg

**Chronic toxicity:**

<i>Sodium azide:</i>	Carcinogenicity (TLV) : A4
	Target Organ(s): nerves, heart, brain, laboratory experiments have shown mutagenic effects
<i>Tween 20:</i>	Teratogen, Reproductive Hazard

**Irritation data:**

<i>ProClin300:</i>	Skin Rabbit 18.6 %	Remarks: Severe irritation effect
	Skin Rabbit 9.3 %	Remarks: Moderate irritation effect
	Skin Rabbit 1.8 %	Remarks: No irritation effect
	Eyes Rabbit	Remarks: Severe irritation effect
	Eyes Rabbit 9.3 %	Remarks: Moderate irritation effect
	Eyes 1.8 %	Remarks: No irritation effect
	Eyes Rabbit	Remarks: Severe irritation effect
	Skin Rabbit	Remarks: Severe irritation effect

**Routes of exposure**

Ingestion, inhalation, eyes and skin

Caution! Most components contain (a) substance(s) that are absorbed through the skin

**Acute effects/symptoms**

*Positive Control Serum, Wash Buffer, Negative Control Serum, Conjugate Concentrate (LMD), Lymphocyte Lysis Buffer, Specimen Diluent*

- Harmful if swallowed
- May cause skin irritation, eye irritation, vomiting, and diarrhea upon ingestion
- May be harmful if inhaled
- May irritate mucous membranes and upper respiratory tract
- May cause nausea, headache, vomiting. Experiments have shown animals to produce hypotensive effects, demyelination of myelinated nerve fibers in the CNS, testicular damage, blindness, attacks of rigidity, hepatic and cerebral effects

*Lymphocyte Lysis Buffer:*

- May cause skin irritation, severe eye irritation
- Harmful if swallowed
- May be harmful when inhaled

*Capture Beads, SA-PE Concentrate, Lysate Control Reagent*

- May cause allergic skin reaction. Contact with skin may cause burns. Harmful if absorbed through skin.
- Exposure may cause Dermatitis. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. Inhalation may result in spasm, inflammation and edema of the larynx and bronchi, chemical pneumonitis, and pulmonary edema. Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting.
- Contact with eyes may cause burns.
- Harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
- Harmful if swallowed.

**Chronic effects**

See also Chronic Toxicity. Other components do not contain substances with a known chronic effect (e.g. carcinogenicity, mutagenicity, toxicity to reproduction)

**12. ECOLOGICAL INFORMATION**

**Aquatic toxicity**

*Sodium azide:*

- LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
- LC50 (96 h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
- LC50 (48 h) : 9 mg/l (GAMMARUS SP.)

**Other information**

- WGK: 1 (Classification based on the components as per Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 17 May 1999)
- Effect on the ozone layer: Not dangerous for the ozone layer (1999/45/EC)
- Greenhouse effect: No data available
- Effect on wastewater purification: No data available

**13. WASTE DISPOSAL CONSIDERATIONS**

*Provisions relating to waste:* Hazardous waste (91/689/EEC)

*Packaging/container:* Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

*Disposal methods:*

- All the kit components except Lymphocyte Lysis Buffer contain human or animal source material which is potentially infectious materials. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

**14. TRANSPORT INFORMATION**

No restrictions.

**15. REGULATORY INFORMATION**

Classification according to directives 67/548/EEC and 1999/45/EC

**Lymphocyte Lysis Buffer**

Contains: Sodium azide



Harmful

- R22 : Harmful if swallowed
- R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
- S23 : Do not breathe vapour
- S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label
- S61 : Avoid release to the environment. Refer to special instructions/safety data sheets.

Product Name: LIFECODES Donor Specific Antibody

**Positive Control Serum, Negative Control Serum, Wash Buffer, Conjugate Concentrate (LMD), Specimen Diluent**

Contains: Sodium azide



Harmful

- R22 : Harmful if swallowed  
S23 : Do not breathe vapour  
S45/46 : If swallowed, in case of accident, or if you feel unwell, seek medical advice immediately and show this container or label  
S61 : Avoid release to the environment. Refer to special instructions/safety data sheets.

**Capture Beads, SA-PE Concentrate, Lysate Control Reagent**



Irritant

- R43 : May cause sensitization by skin contact  
S2 : Keep out of the reach of children  
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice  
S28 : After contact with skin, wash immediately with plenty of water  
S36/37/39 : Wear suitable protective clothing, gloves and eye/face protection  
S45 : In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

**16. OTHER INFORMATION**

Professionals design this product for use.

R and S phrases used in Section 3:

- R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.  
R28: Very toxic if swallowed.  
R32: Contact with acids liberates very toxic gas.  
R34: Causes burns.  
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

The human serum included in this kit has been tested by FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1/2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.



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All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

**MSDS established** : 02 February 2007

**Revision number** : 3