



MATERIAL SAFETY DATA SHEET

(Based on Directive 91/155/EEC et seq.)

Art. Code: See 1.1

Product Name: LIFECODES LifeScreen Deluxe

1. INFORMATION OF THE SUBSTANCE PREPARATION AND COMPANY

Product name LIFECODES LifeScreen Deluxe (LMX)

Intended Use Bead-based immunoassay used to qualitatively detect IgG antibodies to HLA Class I and Class II antigens.

Catalog Numbers 628215 - LIFECODES LifeScreen Deluxe

Kit components

Kit	Beads	Conjugate Concentrate	Wash Buffer	Positive Control Serum	Negative Control Serum
628215 - LIFECODES LifeScreen Deluxe	LifeScreen Deluxe Beads 480µL	550µL	150mL	80µL	80µL

1.1. Company Gen-Probe Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902 USA
(203) 328-9500 or 1-888-329-0255
technicalsupport@gen-probe.com

1.2. In emergencies Call your local emergency center

2. HAZARDS IDENTIFICATION

LifeScreen Deluxe Beads

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.

Animal proteins are potentially infectious.

Conjugate Concentrate

Harmful if swallowed.

Goat and bovine proteins are potentially infectious.

Wash Buffer

Harmful if swallowed.

Bovine proteins are potentially infectious.

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.

3. COMPONENTS AND HAZARDOUS INGREDIENTS

Kit Components	Hazardous Ingredients	Classification Substance	EINECS NR.
LifeScreen Deluxe Beads	0.05 % ProClin Contains material from human origin Contains bovine proteins	T, N, R23/24/25-34-43-50/53	(*)
Conjugate Concentrate	0.1 % Sodium Azide (NaN ₃) Contains goat proteins Contains bovine proteins	T+, N, R28-32-50/53	247-852-1
Wash Buffer	0.1 % Sodium Azide (NaN ₃) Contains bovine proteins	T+, N, R28-32-50/53	247-852-1
Positive Control Serum	0.1% Sodium Azide (NaN ₃) Contains material from human origin	T+, N, R28-32-50/53	247-852-1
Negative Control Serum	0.1% Sodium Azide (NaN ₃) Contains material from human origin	T+, N, R28-32-50/53	247-852-1

(*) ProClin 300 contains a dangerous ingredient : mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one at a concentration between 2.8 and 3.8%.

In the column classification substance, the classification of this ingredient is mentioned.

4. FIRST AID MEASURES
All Kit Components

- Eye contact:* -Rinse immediately with water for 15 minutes
-Do not apply neutralizing agents
- Skin contact:* -Consult a doctor/medical service if irritation persists
-Rinse with water
-Remove clothing before washing
- After inhalation:* -Consult a doctor/medical service if irritation persists
-Remove the victim into fresh air
-Unconscious: maintain adequate airway and respiration
-Consult a doctor/medical service if breathing problems develop
- After ingestion:* -Never give water to an unconscious person
-Give nothing (little) to drink
-Consult a doctor/medical service if you feel unwell

5. FIRE FIGHTING MEASURES
All Kit Components

- Suitable extinguishing media:* - All non combustible extinguishing media allowed
- Unsuitable extinguishing media:* - No data available
- Special exposure hazards:* - On heating, burning: formation of small quantities of nitrous vapors, carbon monoxide, carbon dioxide
- Instructions:* - Take account of toxic fire fighting water
- Use fire fighting water moderately and contain it

Special protective equipment for firefighters:

- Heat/fire exposure: compressed air/oxygen apparatus
- Heat/fire exposure: gas-tight suit

6. ACCIDENTAL RELEASE MEASURES**All Kit Components***Personal protection:* see 8*Environmental precautions:*

- Prevent soil and water pollution
- Discharge according to local regulations

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

7. HANDLING AND STORAGE**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, and metals
- Storage temperature: see component label

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Exposure Limits**

Chemical/Component	TLV/NIOSH REL	OSHA PEL
Sodium azide (as NaN_3)	0.3 mg/m^3 ACGIH TLV-CL	Not listed
Sodium azide (as HN_3)	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

9. PHYSICAL AND CHEMICAL PROPERTIES**All Kit Components**

Liquid

LifeScreen Deluxe Beads

Light blue

Conjugate Concentrate

Pink

Wash Buffer

Clear and slightly yellow

Positive Control Serum, Negative Control Serum

Clear and slightly yellow to amber

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 rat	: 20 mg/kg
	LD50 dermal rat	: > 10,000 mg/kg

Chronic toxicity:

<i>Sodium azide:</i>	Carcinogenicity (TLV)	: A4
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Routes of exposure

Ingestion, inhalation, eyes and skin

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

Acute effects/symptoms*Negative Control Serum, Positive Control Serum, Conjugate Concentrate, Wash Buffer, LifeScreen Deluxe Beads:*

-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**

<i>Sodium azide:</i>	-LC50 (96h):	0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
	-LC50 (96h):	0.7 mg/l (LEPOMIS MACROCHIRUS)
	-LC50 (96h):	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 waster water 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:

- Patient samples, Negative Control Serum, Positive Control Serum, LifeScreen Deluxe Beads, Conjugate Concentrate and Wash Buffer solution are potentially infectious. 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

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

Conjugate Concentrate, Wash Buffer, Positive Control Serum, Negative Control Serum

Contains: Sodium azide



Harmful

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

16. OTHER INFORMATION

This product is designed for use by professionals.

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.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long term effects in the aquatic environment

The human blood components included in this kit have been tested by European approved and/or 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.

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 a 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.

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