

SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: TM bil-eXact® L-1 & L-2
Application: Quality control material for clinical chemical work (for in vitro diagnostic use)
Supplier: Pfaff medical GmbH
Dr.-Karl-Lexer-Weg 299
86633 Neuburg an der Donau
GERMANY
Telephone: +49 (0) 8431 41669
Fax: +49 (0) 8431 45912

2. COMPOSITION; INFORMATION ON INGREDIENTS

Composition:	<u>Main ingredients:</u>	<u>CAS No.:</u>	<u>Content:</u>	<u>Hazard:</u>
Classification:	human serum	none	100 %	none

3. HAZARDS IDENTIFICATION

Emergency overview: Freeze dried serum to be reconstituted with water. Presents little hazard if spilled or in fire.
Human serum, from which this product has derived, is from thoroughly controlled voluntary unpaid donors of Blood Centres. Each unit is tested negative for Hbs antigen, HCV - HIV-I – HIV-II antibodies by approved tests. No test method can offer complete assurance that products containing human source material will be absent of these and other infectious agents. Precautions should be taken as for any potentially infectious material.

Health Hazard: Regarded as having very low health hazard.

4. FIRST-AID MEASURES

General: Miscible with water. Precautions as for human serum.
Eyes: Flush eyes with water. If persistent irritation occurs, seek medical advice.
Skin contact: Wash with soap and water.
Ingestion: Drink water to dilute the swallowed solution and contact physician for medical advice.
Inhalation: Not applicable.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use extinguishing media appropriate for surrounding fire.
Flammable properties: Not flammable. This product does not present any fire or explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear gloves, other protection is not necessary. Should be handled as an ordinary patient sample.
Cleanup procedures: Clean up, contaminated area should be washed with soap and water.

7.	HANDLING AND STORAGE
Handling precautions:	The product should be handled as if it was potentially infectious.
Storage precautions:	Store in original container according to temperature stated on container. Avoid high temperature and direct sun light.
8.	EXPOSURE CONTROLS, PERSONAL PROTECTION
Ventilation:	No particular ventilation requirements.
Protective gloves:	Hand protection is recommended.
Eye protection:	Eye protection not normally required.
Protective clothing:	Protective clothing is not necessary.
9.	PHYSICAL AND CHEMICAL PROPPERTIES
Appearance:	Freeze dried, to be reconstituted with water.
Colour:	Yellow
Solubility:	Readily miscible with water.
Specific gravity:	Not Applicable.
pH-value:	6 - 10
10.	STABILITY AND REACTIVITY
Stability:	Stable and non-reactive.
11.	TOXICOLOGICAL INFORMATION
Acute Effects:	Not known.
Skin Effects:	Not a skin irritant.
Eye Effects:	Not an eye irritant.
12.	ECOLOGICAL INFORMATION
Summary:	This preparation is readily miscible with water and rated not toxic. It has no potential for bioaccumulation.
13.	DISPOSAL CONSIDERATION
General information:	Disposal should be made in accordance with existing disposal practices employed for patient serum samples or infectious waste.
14.	TRANSPORT INFORMATION
General information:	Transportation of the product is not regulated by ADR. Fragile containers, handle with care. Protect from high temperatures. Transport temperature according to data stated on temperature label on container,-cool storage 2 – 8 °C.
15.	REGULATORY INFORMATION
	EU regulations: Not regulated under the European Community Directive 93/21/EEC.
16.	OTHER INFORMATION
Revision Date:	June 2004
Replaces:	None

This Safety Data Sheet conforms to the European Community Directive 93/112/EEC amended 91/155/EEC.

Note: The above-mentioned data are based on our present knowledge of this product.