

## MATERIAL SAFETY DATA SHEET

<b>Date of Issue:</b>	<b>02-Feb-09</b>
<b>Replaced Version:</b>	<b>05-May-08</b>

### 1. Product and Company Identification

Product Name:	FLUOROGNOST HIV-1 IFA FG-25 (Article No.: 400142) FLUOROGNOST HIV-1 IFA FG-50 (Article No.: 400143)
Intended Use:	In vitro diagnostic assay
Manufacturer:	Sanochemia Pharmazeutika A-2491 Neufeld/Leitha Landegger Straße 7 Phone: +43-2624-52342-510 Fax: +43-2624-52342-601
Manufactured for:	Sanochemia Corporation US One Stamford Plaza 263 Tresser Blvd. Stamford, CT 06901 Phone: +1-203-564-1580
Emergency Telephone Numbers	Austria: +43-2624-52342-510 USA: +1-203-564-1580

### 2. Hazards Identification

Human Serum (component of controls)	The specimens were heat inactivated but should be handled as potentially infectious according to the Centers for Disease / National Institute of Health guidelines and OSHA regulations. Each donor unit used in the preparation of these reagents was tested by an approved method for the presence of the antibody to Hepatitis C (Anti – HCV) as well as for Hepatitis surface antigen (HbsAG) and was found negative.
Human Cell Line (component of coated slides)	IFA cell substrate slides have HIV-1 infected and non infected cells in their wells. The slides have been solvent fixed and are not considered to be infectious or carcinogenic.
Rabbit antihuman IgG (component of FITC conjugate)	Potentially infectious material if skin is penetrated and /or mucous membranes are exposed. Handle in accordance with

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	local, state and federal regulations.
Sodium azide (component of controls)	CAS: 26628-22-8 Sodium azide may react with lead and copper plumbing to form explosive metal azides. On disposal, flush with a large volume of water to prevent azide build up. Sodium azide is a highly poisonous agent. It may cause eye, skin and tissue irritation if splashed, spilled, or ingested. It can be fatal if ingested or injected in quantities above those found in the kit. LD 50 (rat oral): 27mg/kg.
Thimerosal (component of FITC Conjugate)	CAS: 54-64-8 Very toxic by inhalation, in contact with skin and if swallowed. May cause sensitization by inhalation and skin contact. After contact with skin, wash immediately with plenty of water and seek medical advice. Concentration found in the kit poses no danger to humans or animals. LD 50 (mouse per oral): 75mg/kg.
BSA (component of FITC Conjugate)	The BSA (Bovine Serum Albumin) originates from USA where BSE has not been reported.
Glycerol (component of Mounting Media)	Redness and irritation of the eyes and skin can occur with acute exposure.
Misc. Inorganic Salts (components of Mounting Media and liquid buffer)	May cause temporary minor eye, skin and upper respiratory tract irritation.
Fluorescein Isothiocyanate (component of FITC Conjugate)	May cause eye, skin, or tissue irritation if splashed on the body or ingested.

### 3. Composition, Information on Ingredients

Negative Control Serum (>25µl, Article No.: 300001)	Human Serum, Sodium azide (0.1%)
Positive Control Serum (>25µl, Article No.: 300002)	Human Serum, Sodium azide (0.1%)
FITC – Conjugate (>300µl, Article No.:	Fluorescein Isothiocyanate conjugated to

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300003)	rabbit antihuman IgG, BSA, PBS, thimerosal (0.01%)
Mounting Media (3ml, Article No.: 300006)	Glycerol, PBS
PBS Buffer Concentrate (2 x 30ml, Article No.: 300004)	NaCl (CAS: 7647-14-5) KCl (CAS: 7447-40-7) Na <sub>2</sub> HPO <sub>4</sub> (CAS: 7558-79-4) KH <sub>2</sub> PO <sub>4</sub> (CAS: 7778-77-0)
Coated Slides (5 or 10 pcs., Article No.: 300897)	Coated with HIV-1 infected and uninfected human cells
Glass Cover Slips (1 or 2 packages, Article No.: 300008)	Glass Cover Slips
Package Insert and IFA Evaluation Sheet	Paper

**4. First Aid Measures**

Eye Contact	Immediately rinse eyes with running water and seek medical advice.
Skin Contact	Remove contaminated clothing. Wash affected area with soap and water. May cause dermatitis.
Swallowing	If swallowed wash mouth with plenty of water. Take patient to physician (factory medical center) or call for ambulance. Change contaminated clothes immediately. Rinse, and wash as usual.
Inhalation	Remove from exposure to fresh air.

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### 5. Fire Fighting Measures

Flash Point	Not tested.
Combustion Products	Principally carbon, nitrogen and sulfur oxides. Not flammable (except for packaging materials).
Extinguishing Media	Water, CO <sub>2</sub> , dry chemicals or alcohol foam
Fire fighting	Use protective clothing and breathing apparatus.

### 6. Accidental Release Measure

Personal Precautions	Wear appropriate protective clothing.
Cleaning Measures	Cleaning of working area and devices with appropriate disinfectant and water.

### 7. Handling and Storage

Handling	For in vitro diagnostic use only. Avoid contact with eyes, skin and clothing. Standard laboratory guidelines for handling infectious agents and all chemical reagents supplied with the kit should be observed throughout all procedures.
Storage	Storage temperature of the kit should be controlled to between 2 and 8 °C.

### 8. Exposure Controls, Personal Protection

MAK – Value	Not applicable.
Inhalation protection	None.
Hand protection	Use disposable vinyl gloves.
Eye protection	Use protective goggles.

### 9. Physical and Chemical Properties

Appearance	Controls: clear to light brown liquid FITC Conjugate: yellow liquid Slides: clear glass (solid) Cover Slips: clear glass (solid) Mounting Media: viscous clear liquid PBS Buffer: clear liquid
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Solubility	All reagents except slides and cover slips are soluble in water.
pH – Value of PBS Buffer	6.2 ± 0.1 (20°C)
pH – Value of Mounting Media	7.0 ± 0.2 (20°C)
pH – Value of other ingredients	Not applicable.

### 10. Stability and Reactivity

Stability	Stable under standard conditions. Do not mix components from different lots. Do not use after stated expiry date.
Hazardous reactions	Not applicable.

### 11. Toxicological Information

Acute Effects	No data available.
Local Effects	No data available.
Chronic Effects	No data available.
Carcinogenicity	No data available.
Mutagenicity	No data available.
Teratogenicity	No data available.
Reproductive Effects	No data available.
Sensitization	No data available.

### 12. Ecological Information

Ecotoxicity	No data available.
Persistence and Degradability	No data available.
Bioaccumulative Potential	No data available.
Mobility in Environmental Media	No data available.

### 13. Disposal Considerations

Disposal considerations	According to disposal guidelines for biological material.
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### 14. Transport Information

UN number	Not classified.
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### 15. Regulatory Information

Licensed by	FDA (BL 103288_0/1631/FC)
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### 16. Other Information

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Since the use this information and the conditions of use of the product are not within the control of Sanochemia Pharmazeutika AG, it is the user's obligation to determine the suitability of the information for the intended application and use appropriate safety procedures.

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Current Version: 02-Feb-2009

#### Amendment History:

Adaptation of Material Safety Data Sheet in accordance with EG 1907/2006 (REACH).