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MATERIAL SAFETY DATA SHEET



English

❖ SECTION 1. PRODUCT IDENTIFICATION

Products : CTI 003-100 i-Tracker anti-Infliximab

❖ SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous components:

Name	Components
<div style="border: 1px solid black; display: inline-block; padding: 2px;">MP</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div>	<ul style="list-style-type: none"> - Infliximab coupled microparticles - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1)
<div style="border: 1px solid black; display: inline-block; padding: 2px;">CALA</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div> <div style="border: 1px solid black; display: inline-block; padding: 2px;">CALB</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div>	<ul style="list-style-type: none"> - Vials of « anti-Infliximab » Calibrators - Use of a green dye : Fast Green (CAS : 2353-45-9 ; N°-CE : 219-091-5) - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1)
<div style="border: 1px solid black; display: inline-block; padding: 2px;">CTL1</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div>	<ul style="list-style-type: none"> - Vials « anti-Infliximab » positive control - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1)
<div style="border: 1px solid black; display: inline-block; padding: 2px;">IC</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div>  SGH07	<ul style="list-style-type: none"> - Vial of ester acridinium immunoconjugate - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1)
<div style="border: 1px solid black; display: inline-block; padding: 2px;">BUF</div> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-left: 10px;">AINF</div>  SGH07	<ul style="list-style-type: none"> - Vial of PBS-Tween buffer - Preserved with ProClin 300 (CAS : 55965-84-9)

❖ SECTION 3. HAZARDS IDENTIFICATION

Primary health hazards:

Components	Hazards
Sodium azide (NaN ₃)	Contains less than 0,1 % total weight of sodium azide as a preservative. CAS : 26628-22-8 ; N°-CE : 247-852-1
Fast Green	Contains less than 0,1 % total weight of Fast Green as dying agent. CAS : 2353-45-9 ; N°-CE : 219-091-5
ProClin 300	Contains less than 0,06 % total weight of ProClin 300 as preservative. CAS : 55965-84-9

Human source material: treat as potentially infectious

Human serums used in the preparation of this product have been tested and found non-reactive for the presence of Hepatitis B surface antigen (HBsAg), antibody anti-HIV 1 and 2, and anti-HCV. No known test method can offer complete assurance that Hepatitis B virus, HIV, HCV, or other infectious agents are absent. Handle all biological materials as through capable of transmitting infection.

❖ SECTION 4. FIRST-AID MEASURES

Contact with eyes:

Immediately flush with water during at least 20 minutes, separating the eyelid.

Contact with skin:

Wash off thoroughly with plenty of clean running water. Remove and wash contaminated clothing.

Ingestion:

Obtain medical attention

Inhalation:

Go away from exposure. In case of breath difficulty, obtain medical attention if necessary.

IN CASE OF ACCIDENT OR IF YOU DO NOT FEEL WELL, OBTAIN IMMEDIATELY MEDICAL ATTENTION.

❖ SECTION 5. FIRE-FIGHTING MEASURES

Flammability:

Not combustible.

Suitable extinguishing agents:

Water, CO₂, polymer foam or dry chemical.

Firefighting instructions:

Wear approved self-contained breathing apparatus pressure and full protective gear to prevent contact with skin and eyes

❖ SECTION 6. ACCIDENTAL RELEASE

Personal protection:

Wear individual protective clothing, gloves, safety glasses/goggles, laboratory coat, to prevent exposure.

Dumping:

Wipe up spills with inert absorbent materials and place in a suitable container.

❖ SECTION 7. HANDLING AND STORAGE

Handling:

Normal precautions for handling chemicals must be observed.

Storage:

Keep containers tightly closed when not in use. Store in a dry, well ventilated storage area (between +2°C and +8°C). Protect from physical damage.

❖ SECTION 8. EXPOSURE CONTROL / PERSONAL PROTECTION

Components	CAS	Value	Control parameters	Basis
Sodium azide (NaN ₃)	26628-22-8	TWA	0,1 mg/m ³	EU ELV
		STEL	0,3 mg/m ³	EU ELV
		VME	0,1 mg/m ³	INRS (FR)
		VLCT	0,3 mg/m ³	INRS (FR)
Fast Green	2353-45-9	Contains no substances with occupational exposure limit values.		
ProClin 300	55965-84-9	Contains no substances with occupational exposure limit values.		

Respiratory protection: good local ventilation.

Eyes protection: safety glasses/goggles.

Skin protection: laboratory coat.

Hands protection: One-way gloves.

❖ SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

- Microparticles: colorless liquid phase + brown film of sedimentation of the microbeads (separate phases) otherwise brown liquid (mixed phases)
- Calibrators: blue liquids
- Positive control: colorless liquid
- Ester acridinium immunoconjugate: opalescent liquid
- PBS-Tween buffer : blue liquid

Odor: solutions are odorless

Boiling point: no data available

Melting point: no data available

Flash point: no data available

Explosion limit: no data available

Vapor pressure (mm Hg): no data available

Density: no data available

Viscosity: no data available

Solubility in water: solutions are soluble.

❖ SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary condition of storage and use.

Hazardous polymerization: no data available

Conditions and materials to avoid: no data available

Hazardous conditions: no data available

Hazardous decomposition products: no data available

❖ SECTION 11. TOXICOLOGICAL INFORMATION

Components	Toxicity
Sodium azide (NaN ₃)	DL50 (oral, rat) = 27 mg/kg DL50 (dermis, rabbit) = 20 mg/kg
Fast Green	DL50 (oral, rat) > 2000 mg/kg
ProClin 300	DL50 (oral, rat) = 862 mg/kg DL50 (dermis, rabbit) = 2800 mg/kg

❖ SECTION 12. ECOLOGICAL INFORMATION

Components	Toxicity
Sodium azide (NaN ₃)	CL50 (Oncorhynchus mykiss) = 2,96 mg/L – 96h CE50r (Pseudokirchneriella subcapitata) = 0,348 mg/L - 96h EC10 (activated sludge) = 0,687 mg/L – 3h
Fast Green	No data available
ProClin 300	No data available

❖ SECTION 13. DISPOSAL CONSIDERATION

Observe all Governmental environmental regulations for waste disposal. Chemical waste generators must determine if a discarded chemical is classified as a hazardous waste. Contact a licensed professional waste disposal service for disposal of unused product.

All Human sources and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.

❖ SECTION 14. TRANSPORT INFORMATION

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

Sea transport notes (IMDG): not classified

Air transport notes (IATA): not classified

Road or rail transports notes (ADR/RID): not classified

UN number: not applicable

UN proper shipping name: not applicable

Transport hazard class(es): not applicable

Packing group: not applicable

Environmental hazards: not applicable

Special precautions for user: not applicable




Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: not applicable

❖ SECTION 15. REGULATORY INFORMATION

The products are classified and identified in accordance with European regulation (EC) n ° 1272/2008 on dangerous substances and mixtures.

❖ SECTION 16. OTHER INFORMATIONS

i-Tracker kits contain Sodium Azide as a preservative. Sodium Azide has been reported to form lead or Copper Azide in laboratory plumbing which may explode on percussion. Use proper disposal procedures.

 provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by properly trained personnel using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.  makes no representations or warranties, either express or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with the respect to the information set forth herein or the product to which the information refers. Accordingly,  will not be liable for any claims, losses or damages resulting from use of or reliance upon this information.

Risk phrase(s):

H317: May cause an allergic skin reaction

Precautionary statements:

Prevention:

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P261: Avoid breathing dust/fume/gas/mist/vapors/spray.

P272: Contaminated work clothing should not be allowed out of the workplace.

Intervention:

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P321: Specific treatment (see section 4 on this material safety data sheet)

P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364: Take off contaminated clothing and wash it before reuse.

Elimination:

P501: Dispose of contents/container to appropriate containers in accordance with the local/regional/international regulations.