

14 rue Ambroise Croizat
CS 90136 CROISSY BEAUBOURG
77435 MARNE LA VALLEE CX2
France
Tél : 01 64 62 10 12
Fax : 01 64 62 09 66
E-mail : support@theradiag.com
Internet : www.theradiag.com



MATERIAL SAFETY DATA SHEET

❖ SECTION 1. PRODUCT IDENTIFICATION

Products : LTR 002 LISA-TRACKER Rituximab
LTR 003 LISA-TRACKER anti-Rituximab
LTR 005 LISA-TRACKER Duo Rituximab

❖ SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous components:

Name	Components
Strips	<ul style="list-style-type: none"> - Strips of individual breakaway: <ul style="list-style-type: none"> ▪ Blue wells coated with anti-Rituximab antibody ▪ Yellow wells coated with Rituximab - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1) for anti-Rituximab - Only preserved with sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1) for Rituximab
Calibrators	<ul style="list-style-type: none"> - Vials of « Rituximab » Standards and « anti-Rituximab » Standards - 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)
Positive controls	<ul style="list-style-type: none"> - Vials « Rituximab » and « anti-Rituximab » positive controls - Preserved with ProClin 300 (CAS : 55965-84-9) and sodium azide (CAS : 26628-22-8 ; N°-CE : 247-852-1)
Biotinylated solutions	<ul style="list-style-type: none"> - Biotinylated antibody vial - Preserved with ProClin 300 (CAS : 55965-84-9)
 SGH07	<ul style="list-style-type: none"> - Vial of HRP labelled Streptavidin. - Preserved with ProClin 300 (CAS : 55965-84-9)
 SGH07	<ul style="list-style-type: none"> - Vial of Phosphate-Tween Buffer pH 7,2 (10x) - Use of a green dye : Fast Green (CAS : 2353-45-9 ; N°-CE : 219-091-5) - Preserved with ProClin 300 (CAS : 55965-84-9)
Substrate	<ul style="list-style-type: none"> - Substrate vial TMB (CAS : 54827-17-7 ; N°-CE : 259-364-6) - In solution with Peroxide hydrogen (CAS : 7722-84-1 ; N°-CE : 231-765-0)
Stop solution	<ul style="list-style-type: none"> - Stop solution H₂SO₄ (CAS : 7664-93-9 ; N°-CE : 231-639-5)

❖ 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
Sulfuric acid (H ₂ SO ₄)	Contains less than 5% total weight of sulfuric acid as stop solution. CAS : 7664-93-9 ; N°-CE : 231-639-5
Fast Green	Contains less than 0,1 % total weight of Fast Green as dyeing agent. CAS : 2353-45-9 ; N°-CE : 219-091-5
ProClin 300	Contains less than 0,6 % total weight of ProClin 300 as preservative. CAS : 55965-84-9
TMB	Contains less than 1% total weight of TMB as a substrate. CAS : 54827-17-7 ; N°-CE : 259-364-6
Hydrogen Peroxide (H ₂ O ₂)	Contains less than 0.03% total weight of Hydrogen Peroxide for the substrate solution. CAS : 7722-84-1 ; N°-CE : 231-765-0

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 though 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	ECTLV
		STEL	0,3 mg/m ³	ECTLV
		VME	0,1 mg/m ³	FVL
		VLCT	0,3 mg/m ³	FVL
Sulfuric acid (H ₂ SO ₄)	7664-93-9	TWA	0,05 mg/m ³	European Commission
Fast Green	2353-45-9	N/A	N/A	N/A
ProClin 300	55965-84-9	N/A	N/A	N/A
TMB	54827-17-7	N/A	N/A	N/A
Hydrogen Peroxide (H ₂ O ₂)	7722-84-1	VME	1.5 mg/m ³	INRS

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:

- Strips: solid polystyrene plastic
- Calibrators: blue liquids
- Positive controls: colourless liquids
- Biotinylated solutions: colourless liquid to slightly yellow liquid
- Conjugated solution : colourless liquid to slightly yellow liquid
- Washing buffer : blue liquid
- Substrate : colourless liquid

Odor: solutions are odorless

Boiling point: N/A

Melting point: N/A

Flash point: N/A

Explosion limit: N/A

Vapor pressure (mm Hg): N/A

Density: N/A

Viscosity: N/A

Solubility in water: solutions are soluble.

❖ SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary condition of storage and use.

Hazardous polymerization: N/A

Conditions and materials to avoid: N/A

Hazardous conditions: N/A

Hazardous decomposition products: N/A

❖ SECTION 11. TOXICOLOGICAL INFORMATION

Components	Toxicity
Sodium azide (NaN ₃)	DL50 (oral, rat) = 27 mg/kg DL50 (dermis, rabbit) = 20 mg/kg
Sulfuric acide (H ₂ SO ₄)	N/A
Fast Green	DL50 (oral, rat) = 2000 mg/kg
ProClin 300	DL50 (oral, rat) = 862 mg/kg DL50 (dermis, rabbit) = 2800 mg/kg
TMB	DL50 (oral, rat) = 268 mg/kg DL50 (dermis, rabbit) = 5390 mg/kg
Hydrogen Peroxide (H ₂ O ₂)	DL50 (oral, rat) = 2000 mg/kg DL50 (derme, rabbit) = 7500 mg/kg

❖ SECTION 12. ECOLOGICAL INFORMATION

Components	Toxicity
Sodium azide (NaN ₃)	CL50 (Lepomis macrochirus) = 0,7 mg/L – 96h CE50 (Daphnia pulex) = 4,2 mg/L - 48h IC50 (culture mixte d'algues vertes) = 272 mg/L CE50 (Photobacterium phosphoreum) = 38,5 mg/mL
Sulfuric acide (H ₂ SO ₄)	N/A
Fast Green	N/A
ProClin 300	N/A
TMB	N/A
Hydrogen Peroxide (H ₂ O ₂)	CL50 (C.carpio) = 42 ppm - 48h CL50 (Chlorella vulgaris) = 2,5 ppm - 72h CL50 (Daphnia magna) = 7,7 ppm - 24h

❖ 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

Products are classified and identified according the European Communities regulation number 1272/2008 on dangerous substances.

❖ SECTION 16. OTHER INFORMATIONS

LISA-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):

H315: Causes skin irritation

H317: May cause an allergic skin reaction

H319: Causes serious eye irritation

Precautionary statements:

Prevention:

P264: Wash your hand thoroughly after handling.

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)

P362: Take off contaminated clothing and wash before reuse.

P363: Wash contaminated clothing before reuse.

P332 + P313: If skin irritation occurs: Get medical advice/attention.

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

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Elimination:

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