

MATERIAL SAFETY DATA SHEET
According to Regulation (EC) No. 1907/2006 (REACH)
and Regulation (EC) No. 453/2010 Issued on 28/05/2015 - Rev. n. 2 of 28.05.2015

1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier	
Trade Name:	Tuberculosis Rapid Test
Catalog Number:	C-106
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Rapid Test kit for In vitro Diagnostic	
1.3 Details of the supplier of the safety data sheet	
Manufacturer:	Intermedical S.r.l.
Address:	Via A. Genovesi, 13 Villaricca (NA)-italy
Phone number:	00390813302705
Fax number:	00390813302705
E-Mail Contact Person:	mail@intermedical.it
1.4 Emergency Telephone Number	
Contact the regional poison Control Center	

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	
Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable	
Chemical Ingredient Chemical Data / Information	
Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable	
2.2 Label elements	
Labelling according to regulation (EC) No. 1272/2008	
The product does not need to be labelled in accordance with EC directives or respective national laws.	
Hazard pictograms and Signal word:	
No	
Hazardous components for labeling: No	
Hazard statements: No	
Precautionary statements: No	
2.3 Other hazards	
At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].	

3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances					
This product is a mixture					
3.2 Mixtures					
Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0,001 %
Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1					
Lowest specific concentration limits according to Table 3.1 Annex VI:					
Skin Corr. 1B; H314 C ≥ 0.6 %					
Skin Irrit. 2; H315: $0,06$ % $\leq C < 0.6$ %					
Eye Irrit. 2; H319: $0,06$ % $\leq C < 0.6$ %					
Skin Sens. 1; H317: C ≥ 0.015 %					

4 FIRST-AID MEASURES

4.1 Description of first aid measures	
<i>After inhalation</i>	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
<i>After skin contact</i>	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
<i>After eye contact</i>	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
<i>After Ingestion</i>	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
4.2 Most important symptoms and effects, both acute and delayed	
Not applicable.	
4.3 Indication of any immediate medical attention and special treatment needed	
No data available.	

5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media	
<i>Suitable extinguishing media:</i>	The common fire extinguish media can be used
<i>Unsuitable extinguishing media:</i>	Not investigate
5.2 Special hazards arising from the substance or mixture	
Not find yet	
5.3 Advice for fire-fighters	
dry-chemical fire extinguisher	

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.	
6.2 Environmental precautions	
Avoid release to the environment.	
6.3 Methods and material for containment and cleaning up	
Clean up with broom.	
6.4 Reference to other sections	
Collect material and dispose of waste according to section 13.	

7 HANDLING AND STORAGE

7.1 Precautions for safe handling	
General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must remove before entering eating areas.	
7.2 Conditions for safe storage, including any incompatibilities	
Information about storage conditions: Note the storage conditions on product packaging.	
Requirements for storage rooms and containers: Store in a cool dry place.	
7.3 Specific end uses	
Rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens..	

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.	
8.2 Exposure controls	
8.2.1 Appropriate engineering controls	
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.	
8.2.2 Personal protective equipment	
<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.

<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat
8.2.3 Environmental exposure controls	
There are no special precautions and measures. See section 6 and 7!	

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
<i>Physical State:</i>	Solid
<i>Colour:</i>	White appearance and some content of the test strip is purple
<i>Odour:</i>	tasteness
<i>Odour threshold:</i>	Not established
<i>Flash point:</i>	Not established
<i>Self-igniting:</i>	Product is not known to be self-igniting
<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure:</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product almost could not solute in the water
9.2 Other safety information:	
No	

10 STABILITY AND REACTIVITY

10.1 Reactivity	
The product is stable in accordance with the recommended storage conditions.	
10.2 Chemical stability	
All the chemicals in the test kits are stable.	
10.3 Possibility of hazardous reactions	
Almost impossible	
10.4 Conditions to avoid	
High humidity and the temperature out of 2-30°C	
10.5 Incompatible materials	
No	
10.6 Hazardous decomposition products	
No	

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Mixture)	
<i>Acute toxicity:</i>	Quantitative data on the toxic effects of this product is not available.
<i>Irritation:</i>	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
<i>Corrosivity:</i>	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
<i>Sensitisation:</i>	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
<i>Repeated dose toxicity:</i>	Not yet investigate
<i>Carcinogenicity:</i>	Not yet investigate
<i>Mutagenicity:</i>	Not yet investigate
<i>Toxicity for reproduction:</i>	No reproductive toxic effect known.

12 ECOLOGICAL INFORMATION

12.1 Toxicity
No data available
12.2 Persistence and degradability
No data available
12.3 Bioaccumulative potential
No data available
12.4 Mobility in soil
No data available
12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
12.6 Other adverse effects
No data available

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

14 TRANSPORT INFORMATION

14.1 UN proper shipping name
ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods
14.2 Transport hazard class
ADR/RID: - IMDG: - IATA: -
14.3 Packing group
ADR/RID: - IMDG: - IATA: -
14.4 Environmental hazards
ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: <input type="checkbox"/> yes / <input checked="" type="checkbox"/> no
Marine Pollutant: <input type="checkbox"/> yes / <input checked="" type="checkbox"/> no
14.5 Special precautions for user
See sections 6-8
14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Delivery will only be taken in suitable and regulatory approved packaging

15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
<i>EU regulations:</i>	This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.
15.2 Chemical Safety Assessment	
The mixture was not subjected to security assessment	

16 OTHER INFORMATION

General information
The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501]. The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier	
Trade Name:	Tuberculosis buffer
Catalog Number:	N/A
1.2 Relevant identified uses of the substance or mixture and uses advised against	
Dilution the Whole Blood, Serum or Plasma specimen only.	
1.3 Details of the supplier of the safety data sheet	
Manufacturer:	Intermedical S.r.l.
Address:	Via A. Genovesi, 13 Villaricca (NA)-italy
Phone number:	00390813302705
Fax number:	00390813302705
E-Mail Contact Person:	mail@intermedical.it
1.4 Emergency Telephone Number	
Contact the regional poison Control Center	

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	
Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable	
Chemical Ingredient Chemical Data / Information	
Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable	
2.2 Label elements	
Labelling according to regulation (EC) No. 1272/2008	
The product does not need to be labelled in accordance with EC directives or respective national laws.	
Hazard pictograms and Signal word:	
No	
Hazardous components for labeling: No	
Hazard statements: No	
Precautionary statements: No	
2.3 Other hazards	
No	

3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances					
This product is a mixture					
3.2 Mixtures					
Component	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0,001 %
Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1					
Lowest specific concentration limits according to Table 3.1 Annex VI:					
Skin Corr. 1B; H314 C ≥ 0.6 %					
Skin Irrit. 2; H315: $0,06$ % $\leq C < 0.6$ %					
Eye Irrit. 2; H319: $0,06$ % $\leq C < 0.6$ %					
Skin Sens. 1; H317: C ≥ 0.015 %					

4 FIRST-AID MEASURES

4.1 Description of first aid measures	
After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.

<i>After skin contact</i>	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
<i>After eye contact</i>	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
<i>After Ingestion</i>	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
4.2 Most important symptoms and effects, both acute and delayed	
Not applicable.	
4.3 Indication of any immediate medical attention and special treatment needed	
No data available.	

5 FIRE-FIGHTING MEASURES

5.1 Extinguishing media	
<i>Suitable extinguishing media:</i>	The common fire extinguish media can be used
<i>Unsuitable extinguishing media:</i>	Not investigate
5.2 Special hazards arising from the substance or mixture	
Not find yet	
5.3 Advice for fire-fighters	
dry-chemical fire extinguisher	

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.	
6.2 Environmental precautions	
Avoid release to the environment.	
6.3 Methods and material for containment and cleaning up	
Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.	
6.4 Reference to other sections	
Collect material and dispose of waste according to section 13.	

7 HANDLING AND STORAGE

7.1 Precautions for safe handling	
General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must remove before entering eating areas.	
7.2 Conditions for safe storage, including any incompatibilities	
Information about storage conditions: Note the storage conditions on product packaging. Requirements for storage rooms and containers: Store in a cool dry place.	
7.3 Specific end uses	
Dilution the Whole Blood, Serum or Plasma specimen only.	

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.	
8.2 Exposure controls	
8.2.1 Appropriate engineering controls	
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.	
8.2.2 Personal protective equipment	
<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

8.2.3 Environmental exposure controls
There are no special precautions and measures. See section 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
<i>Physical State:</i>	Liquid
<i>Colour:</i>	Colorless
<i>Odour:</i>	Odourless
<i>Odour threshold:</i>	Not established
<i>Flash point:</i>	Not established
<i>Self-igniting:</i>	Product is not known to be self-igniting
<i>Danger of explosion:</i>	There is no substances in the kit could lead to the danger of explosion
<i>Melting point:</i>	Not established
<i>Boiling point:</i>	Not established
<i>Vapour pressure:</i>	Not established
<i>Density (20°C):</i>	Not established
<i>pH-value at 20°C:</i>	Not established
<i>Solubility in water:</i>	The product could solute in water easily
9.2 Other safety information:	
No	

10 STABILITY AND REACTIVITY

10.1 Reactivity	
The product is stable in accordance with the recommended storage conditions.	
10.2 Chemical stability	
All the chemicals in the test kits are stable.	
10.3 Possibility of hazardous reactions	
Almost impossible	
10.4 Conditions to avoid	
Temperature out of 2-30°C	
10.5 Incompatible materials	
No	
10.6 Hazardous decomposition products	
No	

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects (Mixture)	
<i>Acute toxicity:</i>	Quantitative data on the toxic effects of this product is not available.
<i>Irritation:</i>	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
<i>Corrosivity:</i>	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
<i>Sensitisation:</i>	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
<i>Repeated dose toxicity:</i>	Not yet investigate
<i>Carcinogenicity:</i>	Not yet investigate
<i>Mutagenicity:</i>	Not yet investigate
<i>Toxicity for reproduction:</i>	No reproductive toxic effect known.

12 ECOLOGICAL INFORMATION

12.1 Toxicity	
No data available	
12.2 Persistence and degradability	
No data available	
12.3 Bioaccumulative potential	

