



SAFETY DATA SHEET
Banyan UCH-L1 Kit

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Trade name: Banyan UCH-L1 Kit

Product number: BC-1208

ver. 040518

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name: Banyan UCH-L1 Kit

Catalog Number: BC-1208

Kit Components:

1. UCH-L1 Assay Plate
2. UCH-L1 Calibrator
3. UCH-L1 Calibrator Diluent
4. UCH-L1 Control 1
5. UCH-L1 Control 2
6. UCH-L1 Detection Ab
7. UCH-L1 Detection Ab Diluent
8. UCH-L1 Assay Diluent
9. Wash Tablet
10. Substrate A
11. Substrate B
12. Plate Seal

1.2. Relevant identified uses of the substance or mixture and uses advised against

Components of an *in-vitro* diagnostic device

1.3. Details of the supplier of the safety data sheet

Banyan Biomarkers, Inc.
16470 West Bernardo Drive, Suite 100, San Diego, CA 92127
www.banyanbio.com
Phone: +1 760-710-0460 Fax: +1 760-710-0460
E-mail: info@banyanbio.com

1.4. Emergency telephone number

For queries please contact telephone number +1 760-710-0460 (Business hours 8:30 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910.1200 (OSHA HCS).

1. UCH-L1 Assay Plate	Not classified
2. UCH-L1 Calibrator	Not classified
3. UCH-L1 Calibrator Diluent	Skin sensitization (Category 1), H317
4. UCH-L1 Control 1	Not classified
5. UCH-L1 Control 2	Not classified
6. UCH-L1 Detection Ab	Not classified
7. UCH-L1 Detection Ab Diluent	Not classified
8. UCH-L1 Assay Diluent	Not classified
9. Wash Tablet	Not classified
10. Substrate A	Not classified
11. Substrate B	Not classified
12. Plate Seal	Not classified



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2.2 Health Hazards

1. UCH-L1 Assay Plate	Not applicable
2. UCH-L1 Calibrator	Not applicable
3. UCH-L1 Calibrator Diluent	May cause allergic skin reaction
4. UCH-L1 Control 1	Not applicable
5. UCH-L1 Control 2	Not applicable
6. UCH-L1 Detection Ab	Not applicable
7. UCH-L1 Detection Ab Diluent	Not applicable
8. UCH-L1 Assay Diluent	Not applicable
9. Wash Tablet	Not applicable
10. Substrate A	Not applicable
11. Substrate B	Not applicable
12. Plate Seal	Not applicable

2.3 Label elements

Some components above contain ProClin 300:



Pictogram:

Signal Word: Warning

Hazard statement: H317: May cause an allergic skin reaction

Precautionary Statement - Prevention:

P261: Avoid breathing mist

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

P280: Wear protective gloves/protective clothing

Precautionary Statement - Response:

P302+P352: If on skin: Wash with plenty of soap and water.

P333+P313: If skin irritation or rash occurs: get medical attention.

P363: Wash contaminated clothing before reuse.

2.4 Other hazards

No other hazardous components above 1% or carcinogens above 0.1% known or anticipated by NTP, IARC, or OSHA.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances / Component:

1. UCH-L1 Assay Plate	Not applicable
2. UCH-L1 Calibrator	Not applicable
3. UCH-L1 Calibrator Diluent	Mixture, 0.5% ProClin 300
4. UCH-L1 Control 1	Not applicable
5. UCH-L1 Control 2	Not applicable
6. UCH-L1 Detection Ab	Not applicable
7. UCH-L1 Detection Ab Diluent	Not applicable
8. UCH-L1 Assay Diluent	Not applicable
9. Wash Tablet	Not applicable
10. Substrate A	Not applicable
11. Substrate B	Not applicable
12. Plate Seal	Not applicable

Hazardous Substance:

Chemical name	CAS No. (EC No.) [Index No.]	Amount (%) in the mixture	Classification according Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)	
			Hazard class/ Hazard categories	Hazard- statement
ProClin 300* - modified alkyl carboxylate		0.5%	Aquatic Chronic 4	H413
Mixture of: 5-chloro-2-methyl-4- isothiazolin-3-one [EC no. 247-500- 7] and 2-methyl-4 isothiazolin-3- one [EC no. 220-239-6] (3:1)	55965-84-9 --- 613-167-00-5	0.015%	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H314 H317 H400 H410
*ProClin 300 is used as preservative in the listed reagents.				

♣ **ProClin 300 contains active ingredients:** mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4 isothiazolin-3-one [EC no. 220-239-6] (3:1). The Classification of this mixture at the contained concentration of 0.015% ($0.0015\% \leq C \leq 0.06\%$) is Skin Sensitization (Category 1), H317.

Full text of H- phases: see section 16.



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4. FIRST AID MEASURES

4.1 Description of first aid measure

General information	No special measures required
If inhaled	Supply fresh air. If not breathing, give artificial respiration. In case of severe disturbance, consult a physician.
Following skin contact	Rinse skin with plenty of water. Remove contaminated clothing and protective gloves. Wash clothes thoroughly before reuse. Clean shoes. In case of severe disturbance, consult a physician
Following eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
If swallowed	Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Appropriate extinguishing media include: Alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides, Sodium oxides, Phosphor oxides, Hydrogen chloride gas.

5.3 Advice for firefighters

Advice for firefighters Wear self-contained breathing apparatus for firefighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Dilute with plenty of water. Do not let product enter drains.



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6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Refer to section 8 for information on personal protection equipment.

Refer to section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid direct contact with skin and eyes. Avoid inhalation of vapour or mist. Use all reagents in accordance with the relevant package insert.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents at 2-8°C as instructed in the relevant package insert.

7.3 Specific end use

For professional in vitro diagnostic use 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 at the workplace.

8.2 Exposure controls

The usual precautionary measures for handling chemicals should be followed.

Keep away from food, beverages and feed.

Wash hands before breaks and at the end of work.

Personal protective equipment:

Eye/face protection Wear tightly fitting safety goggles with side shields.

Respiratory protection Not required

Hand protection Wear protective gloves, vinyl or rubber gloves are recommended.
Dispose of contaminated gloves after use in accordance with good laboratory practices.

Wash and dry hands.

Skin and body protection Wear lab coat. Immediately remove all contaminated clothing and wash before reuse.



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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General Information

Component	Physical State	Color	Odor
1. UCH-L1 Assay Plate	Plastic plate	White	None
2. UCH-L1 Calibrator	Lyophilized	Green colored	None
3. UCH-L1 Calibrator Diluent	Liquid	Clear, colorless to amber-colored	None
4. UCH-L1 Control 1	Lyophilized	Yellow colored	None
5. UCH-L1 Control 2	Lyophilized	Yellow colored	None
6. UCH-L1 Detection Ab	Liquid	Amber-colored	None
7. UCH-L1 Detection Ab Diluent	Liquid	Red-colored	None
8. UCH-L1 Assay Diluent	Liquid	Clear, colorless	None
9. Wash Tablet	Lyophilized buffer tablet	White	None
10. Substrate A	Liquid	Clear, colorless	None
11. Substrate B	Liquid	Clear, colorless	None
12. Plate Seal	Plastic adhesive seal	Clear	None

9.2 Chemical Properties:

pH	1. UCH-L1 Assay Plate	Not applicable
	2. UCH-L1 Calibrator (upon reconstitution)	7 - 8
	3. UCH-L1 Calibrator Diluent	7 - 8
	4. UCH-L1 Control 1 (upon reconstitution)	7 - 8
	5. UCH-L1 Control 2 (upon reconstitution)	7 - 8
	6. UCH-L1 Detection Ab	6 - 7
	7. UCH-L1 Detection Ab Diluent	6 - 7
	8. UCH-L1 Assay Diluent	7 - 8
	9. Wash (in solution)	7 - 8
	10. Substrate A	8.4 – 9.2
	11. Substrate B	8.4 – 9.2
	12. Plate Seal	Not applicable
Boiling Point	1. UCH-L1 Assay Plate	Not applicable
	2. UCH-L1 Calibrator (upon reconstitution)	Lowest known value (water): 100°C/212°F
	3. UCH-L1 Calibrator Diluent	
	4. UCH-L1 Control 1 (upon reconstitution)	
	5. UCH-L1 Control 2 (upon reconstitution)	
	6. UCH-L1 Detection Ab	
	7. UCH-L1 Detection Ab Diluent	
	8. UCH-L1 Assay Diluent	
	9. Wash (in solution)	
	10. Substrate A	
	11. Substrate B	
	12. Plate Seal	Not applicable



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Melting Point	1. UCH-L1 Assay Plate	Not applicable
	2. UCH-L1 Calibrator (upon reconstitution)	May melt at 0°C/32°F. This specification is based on the ingredient water.
	3. UCH-L1 Calibrator Diluent	
	4. UCH-L1 Control 1 (upon reconstitution)	
	5. UCH-L1 Control 2 (upon reconstitution)	
	6. UCH-L1 Detection Ab	
	7. UCH-L1 Detection Ab Diluent	
	8. UCH-L1 Assay Diluent	
	9. Wash (in solution)	
	10. Substrate A	
	11. Substrate B	
	12. Plate Seal	Not applicable
Solubility	1. UCH-L1 Assay Plate	Not applicable
	2. UCH-L1 Calibrator (upon reconstitution)	Complete solubility in cold or hot water.
	3. UCH-L1 Calibrator Diluent	
	4. UCH-L1 Control 1 (upon reconstitution)	
	5. UCH-L1 Control 2 (upon reconstitution)	
	6. UCH-L1 Detection Ab	
	7. UCH-L1 Detection Ab Diluent	
	8. UCH-L1 Assay Diluent	
	9. Wash (in solution)	
	10. Substrate A	
	11. Substrate B	
	12. Plate Seal	Not applicable
Vapour Pressure	1. UCH-L1 Assay Plate	Not applicable
	2. UCH-L1 Calibrator (upon reconstitution)	23.4 mbar at 20°C/68°F. This specification is based on the ingredient water.
	3. UCH-L1 Calibrator Diluent	
	4. UCH-L1 Control 1 (upon reconstitution)	
	5. UCH-L1 Control 2 (upon reconstitution)	
	6. UCH-L1 Detection Ab	
	7. UCH-L1 Detection Ab Diluent	
	8. UCH-L1 Assay Diluent	
	9. Wash (in solution)	
	10. Substrate A	
	11. Substrate B	
	12. Plate Seal	Not applicable

No Available Data: To flash point, evaporation rate, explosion limits, ignition temperatures, viscosity, oxidizing properties, density, partition coefficient (n-octanol/water).

9.3 Other information

No other information available.



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10. STABILITY AND REACTIVITY

10.1 <u>Reactivity</u>	No data available
10.2 <u>Chemical stability</u>	Stable under recommended storage conditions
10.3 <u>Possibility of hazardous reactions</u>	No data available
10.4 <u>Conditions to avoid</u>	Strong oxidizing agents, reducing agents, Amines,
10.5 <u>Incompatible materials</u>	No materials known
10.6 <u>Hazardous decomposition</u>	Hazardous decomposition products formed under fire Products conditions - Carbon oxides, nitrogen oxides, Sulphur oxides, Hydrogen chloride gas.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

a) Acute toxicity:	No data available.
b) Skin corrosion/irritation	No data available.
c) Respiratory or skin sensitisation:	May cause allergic skin reaction.
d) Germ cell mutagenicity:	No data available
e) Carcinogenicity:	No data available
f) Reproductive toxicity:	No data available
g) Specific target organ toxicity-single exposure:	No data available
h) Specific target organ toxicity-repeated exposure	No data available
i) Aspiration hazard	No data available.

12. ECOLOGICAL INFORMATION

12.1 <u>Toxicity</u>	No further relevant information available
12.2 <u>Persistence and degradability</u>	No further relevant information available
12.3 <u>Bioaccumulative potential</u>	No further relevant information available
12.4 <u>Mobility in soil</u>	No further relevant information available
12.5 <u>Results of PBT and vPvB assessment</u>	Not applicable
12.6 <u>Other adverse effects</u>	No further relevant information available



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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Dispose of waste according to applicable local, state, and federal regulations.

Contaminated packaging:

Dispose of waste according to applicable local, state, and federal regulations.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

14.1 <u>UN number</u>	None
14.2 <u>UN proper shipping name</u>	None
14.3 <u>Transport hazard class(es)</u>	None
14.4 <u>Packing group</u>	None
14.5 <u>Environmental hazards</u>	None
14.6 <u>Special precautions for user</u>	Not applicable

15. REGULATORY INFORMATION

This Safety Data Sheet is according to:

29 CFR 1910.1200	Hazard Communication
1907/2006/EC	Registration, evaluation and authorization of chemicals regulation (REACH)
1272/2008/EC	Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC, amending 1907/2006/EC
453/2010/EC	Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.2 Chemical safety assessment

Not applicable



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16. OTHER INFORMATION

16.1 "H code" used in this Safety Data Sheet

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H413	May cause long-lasting harmful effects to aquatic life

Note: H317 is the Hazard Statement Code for the components that contain ProClin 300 or its active ingredients.

All the other H codes above are supplied for reference only as they are valid for the concentrated chemical only and are not applicable to the concentrations supplied.

NFPA Rating

Health Hazard: 2
Fire Hazard: 0
Reactive Hazard: 0

16.2 Legal disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The company shall not be held liable for any damage resulting from handling or from contact with the above product/reagents.