

PRODUCTS CONTAINING PROCLIN®

SECTION 1 – IDENTIFICATION OF SUBSTANCE/MIXTURE AND OF THE COMPANY/U-NDERTAKING

Please Note: Kits may contain several different components for which there may be additional hazards. When applicable, additional safety sheets with those specific hazards have been included.

1.1 PRODUCT IDENTIFIER: Product components containing ProClin®.

KIT #	PRODUCT	COMPONENT #
1148	BUFFERED DILUENT	24456
1624 / 1660 / 1662 / 6624	ANAFUOR™ HEP 2 MOUNTING MEDIA	1084
1670	ANAFAS™ HEP 2 MOUNTING MEDIA	1084
1740 / 1741	FLUORO KIT™ CT MOUNTING MEDIA	1084
1790 / 1860	FLUORO KIT™ NDNA MOUNTING MEDIA AND CONJUGATE	1084 / 1157
1884	MOUNTING MEDIA	1084
1970	FLUORO KIT™ RS MOUNTING MEDIA	1084
6100	CAE CONJUGATE HPR MAB ASSAY AND DILUENT	26110 / 26113
6200	CAE REAGENT SET	6100
310410	LIAISON® TESTOSTERONE PMP AND CALIBRATORS 1 – 2	25427 – 25429
310411	LIAISON® TESTOSTERONE CONTROLS 1 - 2	25430 / 25431
310420	LIAISON® PROGESTERONE CALIBRATORS 1 – 2 AND DILUENT	24792 / 24793 / 24834
310421	LIAISON® PROGESTERONE CONTROLS 1 – 2	24794 / 24795
310450	LIAISON® ALDOSTERONE CONJUGATE, CALIBRATORS 1 – 2 AND BUFFER	25411 – 25413 / 25415
310451	LIAISON® ALDOSTERONE CONTROLS 1 – 2	25416 – 25417
310453	LIAISON® ALDOSTERONE VERIFIERS A – D	25447 – 25450
310502	LIAISON® EBV IGM SERUM CONTROLS	25819 – 25820
310512	LIAISON® VCA IGG SERUM CONTROLS	25817 – 25818
310522	LIAISON® EBNA IGG SERUM CONTROLS	25821 – 25822
310542	LIAISON® EA IGG SERUM CONTROLS	25827 – 25828
310600	LIAISON® 25 OH VITAMIN D TOTAL ASSAY BUFFER	25244
310602	LIAISON® 25 OH VITAMIN D TOTAL SPECIMEN DILUENT	25019
310620	LIAISON® HSV SPECIMEN DILUENT, CONJUGATE AND CALIBRATORS 1 – 2	24936 / 25061 – 25063
310621	LIAISON® HSV 2 NEGATIVE AND POSITIVE CONTROLS	25127 / 25128
310630	LIAISON® 1-84 PTH COATED PMP, CONJUGATE, CALIBRATORS 1 – 2 AND BUFFER	25190 – 25194
310631	LIAISON® 1-84 PTH CONTROLS 1 – 2	25195 / 25196
310632	LIAISON® 1-84 PTH SPECIMEN DILUENT	25197
310633	LIAISON® 1-84 PTH CALIBRATION VERIFIERS A – D	25396 – 25399
310650	LIAISON® CALCITONIN II-GEN PMP AND CALIBRATORS 1 – 2	25151 / 25153 / 25154
310651	LIAISON® CALCITONIN II-GEN CONTROLS 1 – 2	25155 / 25156
310652	LIAISON® CALCITONIN II-GEN SPECIMEN DILUENT	25158
310670	LIAISON® 25 TOTAL-D ASSAY BUFFER	25175
310672	LIAISON® 25 TOTAL-D SPECIMEN DILUENT	25247
310680	LIAISON® ESTRADIOL II GEN CONJUGATE, CALIBRATORS 1 – 2, DILUENT AND BUFFER	25361 – 25365
310681	LIAISON® ESTRADIOL II GEN CONTROLS 1 – 2	25366 – 25367
310690	LIAISON® PROGESTERONE II GEN CALIBRATORS 1 – 2 AND SPECIMEN DILUENT	25372 – 25374
310691	LIAISON® PROGESTERONE II GEN CONTROLS 1 – 2	25375 – 25376
310742	LIAISON® CMV IGG SERUM CONTROLS	25823 – 25824
310752	LIAISON® CMV IGM SERUM CONTROLS	25825 – 25826
310830	LIAISON® HSV DILUENT, CONJUGATE AND CALIBRATORS 1 - 2	24936 / 25051 – 25053
310831	LIAISON® HSV 1 NEGATIVE AND POSITIVE CONTROLS	25054 / 25055
310842	LIAISON® TREPONEMA NEGATIVE AND POSITIVE CONTROLS	24950 / 24951
310870	LIAISON® BORRELIA CONJUGATE, CALIBRATORS 1 - 2 AND DILUENT	24933 – 24936
310871	LIAISON® BORRELIA NEGATIVE AND POSITIVE CONTROLS	24937 / 24938
310930	LIAISON® SCLEROSTIN CONJUGATE, CALIBRATORS 1-2 AND ASSAY BUFFER	25741-25743 / 25744
310931	LIAISON® SCLEROSTIN CONTROLS 1-2	25745 / 25746
310932	LIAISON® SCLEROSTIN SPECIMEN DILUENT	25747
310933	LIAISON® SCLEROSTIN CALIBRATION VERIFIERS A-D	25748-25751
310950	LIAISON® OSTEOCALCIN PMP AND CALIBRATORS 1 - 2	24988 / 25602 / 25603
310951	LIAISON® OSTEOCALCIN CONTROLS 1 - 2	24992 / 24993
310952	LIAISON® OSTEOCALCIN SPECIMEN DILUENT	24995
310960	LIAISON® TK ASSAY BUFFER	25006

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KIT #	PRODUCT	COMPONENT #
310970	LIAISON® BAP CONJUGATE, CALIBRATORS 1 - 2 AND BUFFER	25841 – 25843 / 25844
310971	LIAISON® BAP CONTROLS 1 – 2	25074 / 25075
310972	LIAISON® BAP SPECIMEN DILUENT	25076
310980 / 310985	LIAISON® XL 1, 25 DIHYDROXYVITAMIN D CONJUGATE, CALIBRATORS 1 – 2 AND BUFFER	25621 – 25623 / 25625
310981	LIAISON® XL 1, 25 DIHYDROXYVITAMIN D CONTROLS 1 – 2	25626 – 25627
310982	LIAISON® XL 1, 25 DIHYDROXYVITAMIN D SPECIMEN DILUENT	25628
310983	LIAISON® XL 1, 25 DIHYDROXYVITAMIN D VERIFIERS A – D	25629 – 25632
310984	LIAISON® XL 1, 25 DIHYDROXYVITAMIN D CONTROLS 1 – 2	26037 - 26038
317130	LIAISON® XL ZIKA CAPTURE IGM REAGENT INTEGRALS, CONJUGATES, AND CALIBRATORS	25951 / 25961–25963 / 317060 / 317090
317131	LIAISON® XL ZIKA CAPTURE IGM CONTROLS	25956 – 25957 / 25966 – 25967
317150	LIAISON® XL ZIKA CAPTURE IGM II REAGENT INTEGRALS, CONJUGATES, AND CALIBRATORS 1-2	26577/ 26759-26760 / 26752–26754 / 267500 / 267510
317151	LIAISON® XL ZIKA CAPTURE IGM II NEGATIVE AND POSITIVE CONTROLS	26755-26756 / 26757-26758
317910	LIAISON® N-TACT® PTH GEN II (ALL COMPONENTS)	25530 – 25534
317911	LIAISON® N-TACT® PTH GEN II CONTROLS 1 – 2	25535 – 25536
317913	LIAISON® N-TACT® PTH GEN II VERIFIERS A – D	25538 – 25541
318080	LIAISON® CAMPYLOBACTER AG PMP, CONJUGATE, CALIBRATORS 1-2, ASSAY BUFFER AND SAMPLE DILUENT	26530 – 26534 / 25875
318081	LIAISON® CAMPYLOBACTER AG NEGATIVE AND POSITIVE CONTROLS	26535 / 26536
318200	LIAISON® MERIDIAN H.PYLORI SA PMP, CONJUGATE, CALIBRATORS 1-2, ASSAY BUFFER AND SAMPLE DILUENT	25870 – 25875
318201	LIAISON® MERIDIAN H.PYLORI SA NEGATIVE AND POSITIVE CONTROLS	25876 – 25877
318320	LIAISON® B12 ASSAY BUFFER 3	26686
318870	LIAISON® ANDROSTENEDIONE CONJUGATE, CALIBRATORS 1 - 2 AND ASSAY BUFFER	25901 - 25904
318871	LIAISON® ANDROSTENEDIONE CONTROLS 1 - 2	25905 - 25906
318873	LIAISON® ANDROSTENEDIONE VERIFIERS A-D	25908 – 25911
318900	LIAISON® C. DIFFICILE TOXIN A/B PMP, CONJUGATE, CALIBRATORS 1 – 2 AND DILUENT	25280 – 25284
318901	LIAISON® C. DIFFICILE TOXIN A/B CONTROLS	25285 – 25286
318910	LIAISON® C. DIFFICILE GDH PMP, CONJUGATE, CALIBRATORS 1 – 2 AND DILUENT	25400 – 25403 / 25284
318911	LIAISON® C. DIFFICILE GDH CONTROLS	25405 – 25406
318920	LIAISON® H. PYLORI SA PMP, CONJUGATE, CALIBRATORS 1 – 2 AND DILUENT	25314 – 25315 / 25792 / 25793 / 25795
318921	LIAISON® H. PYLORI SA CONTROLS	25319 / 25797
318930	LIAISON® EHEC TOXINS	25500 – 25504
318931	LIAISON® EHEC TOXINS CONTROLS	25505 – 25506
318940	LIAISON® ROTAVIRUS (ALL COMPONENTS)	25570 – 25574
318941	LIAISON® ROTAVIRUS CONTROLS	25575 – 25576
318950	LIAISON® ADENOVIRUS (ALL COMPONENTS)	25574 / 25670 – 25673
318951	LIAISON® ADENOVIRUS CONTROLS	25674 – 25675
318960	LIAISON® CALPROTECTIN (ALL COMPONENTS)	25690 – 25695 / 25713
318961	LIAISON® CALPROTECTIN CONTROLS 1 - 2	25696 – 25697
318962	LIAISON® CALPROTECTIN EXTRACTION BUFFER	25713
318963	LIAISON® CALPROTECTIN VERIFIERS A – D	25701 – 25704
318970	LIAISON® CAMPYLOBACTER (ALL COMPONENTS)	25720 – 25723 / 25284 / 25765 / 25766
318971	LIAISON® CAMPYLOBACTER CONTROLS	25726 – 25727 / 25767
318980	LIAISON® H PYLORI IGG CONJUGATE, CALIBRATORS 1-2 AND SPECIMEN DILUENT	25831-25833 / 24936
318981	LIAISON® H PYLORI IGG NEGATIVE AND POSITIVE CONTROLS	25835 / 25836
318990	LIAISON® C. DIFFICILE SAMPLE DILUENT	25284
319020	LIAISON® SHBG CONJUGATE, CALIBRATORS 1-2, AND SPECIMEN DILUENT	25981 – 25983 / 25987
319021	LIAISON® SHBG CONTROLS 1-2	25985 – 25986
319023	LIAISON® SHBG VERIFIERS A-D	25988 – 25991
319135	LIAISON® Q.S.E.T. BUFFER	25713
364701	S100 ELISA CONJUGATE AND DILUENT	30781081 / 30785081

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1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST: Kits contain laboratory chemicals for In Vitro diagnostic use only. ProClin® is used as a preservative in Section 1.1 products. See package insert for instructions. Do not use products for purposes other than those designated. Improper use could result in uncalculated safety or exposure risks.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET:

Manufacturer: DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082 USA
Tel: 651-439-9710

Authorized Representative for EU: DiaSorin S.p.A.
Via Crescentino s.n.c.
13040 SALUGGIA (VC) – ITALY
Tel.: 0039.0161.487526/947
Fax: 0039.0161.487670

Responsible Person: E-mail: EHS@diasorin.com

1.4 EMERGENCY TELEPHONE NUMBER:


DiaSorin Inc: Tel: 651-439-9710 (8:00a.m. – 4:30p.m. CST)

US Poison Control Center: Tel: 800-222-1222

SECTION 2 – HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE: Skin sensitization, Category 1

2.2 LABEL ELEMENTS:

SIGNAL WORD:	Warning!
PICTOGRAMS:	 GHS07 – Exclamation mark
HAZARD STATEMENTS:	H317 – May cause an allergic skin reaction.
PRECAUTIONARY STATEMENTS:	P261 – Avoid breathing mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P280 – Wear protective gloves and clothing, and eye protection.

2.3 OTHER HAZARDS: NA

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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES: NA

3.2 MIXTURES: Product components listed in Section 1.1 utilize ProClin[®] that contains the following regulated active ingredients.

NAME OF MATERIAL	CAS NO.	INDEX NO.	CONC.	CLASSIFICATION EC No. 1272/2008
Regulated active ingredients at a mixture of 3:1: 5-chloro-2-methyl-4-isothiazolin-3-one (CAS No: 26172-55-4; EC No: 247-500-7); and 2-methyl-4-isothiazolin-3-one (CAS No: 2682-20-4; EC No: 220-239-6)	55965-84-9	613-167-00-5	C <.06%	Acute Tox. 3, inhalation – H331: Toxic if inhaled. Acute Tox. 3, skin – H311: Toxic in contact with skin. Acute Tox. 3, oral – H301: Toxic if swallowed. Skin Corr. 1B – H314: Causes severe skin burns and eye damage. Skin Sens. 1 – H317: May cause an allergic skin reaction. Aquatic Acute 1 – H400: Very toxic to aquatic life. Aquatic Chronic 1 – H410: Very toxic to aquatic life with long lasting effects.

SECTION 4 – FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EXPOSURE ROUTE	FIRST AID MEASURES
SKIN CONTACT:	IF ON SKIN: Wash with plenty of soap and water (P302+P352). Immediately remove any contaminated clothing and cautiously wash affected area with plenty of water for at least 15 minutes. If skin irritation or rash occurs: Get medical attention (P333+P313). Wash clothing and shoes thoroughly before reuse (P363).
EYE CONTACT:	IF IN EYES: Immediately wash eyes thoroughly with copious amounts of water for at least 15 minutes. While flushing, lift lower and upper eyelids occasionally, and look around to get a good flushing. Remove contact lenses if present and easy to do. Get medical attention immediately.
INHALATION:	IF INHALED: Move victim to fresh air and keep at rest in a position comfortable for breathing. Treat symptomatically. If breathing stops, administer artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.
INGESTION:	IF SWALLOWED: Immediately rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a Poison Center or doctor/physician if you feel unwell.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Symptoms for Inhalation Exposure: May be harmful if inhaled. Materials may be destructive to the tissue of the mucous membranes and upper respiratory tract.

Symptoms of Skin Contact: May be harmful if absorbed through the skin. May cause irritation to the skin.

Symptoms of Eye Contact: May cause irritation with redness, pain or burning.

Symptoms after Ingestion: Harmful if swallowed. May cause burns.

Chronic Exposure: No data available, but is known to target the liver.

Potential Medical Conditions Affected: Persons with pre-existing skin disorders or eye problems, or impaired respiratory function may be more susceptible. May cause asthmatic response in person with asthma.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: NE

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SECTION 5 – FIRE-FIGHTING MEASURES

5.1 EXTINGUISHING MEDIA:

Suitable Extinguishing Media: Use dry chemical or powder, foam, carbon dioxide or water.

Unsuitable Extinguishing Media: NE

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

Hazardous Combustion Products: NE

5.3 **ADVICE FOR FIREFIGHTERS:** May give off irritating or toxic gases in a fire. Wear full fire protection clothing, chemical resistant gloves and NIOSH-approved self-contained breathing apparatus (SCBA). Approach fire from upwind to avoid fumes. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water and fire remains according to applicable regulations. See Section 8 for additional information.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

6.1 **PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:** Evacuate personnel to a safe area. Isolate the hazard area and keep unnecessary personnel from entering. If outdoors, keep people upwind of the spill. Wear chemical resistant gloves, personal protective equipment for the eyes and face, impervious clothing, and NIOSH approved respirator or SCBA. Ventilate area. Avoid inhaling vapors or fumes, and prevent skin contact.

6.2 **ENVIRONMENTAL PRECAUTIONS:** Do not let the material enter drains, or contact surface water or ground water, and do not flush the spill to the sewer.

6.3 **METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:** Ventilate area. Isolate hazard area and keep unnecessary personnel from entering. Wear appropriate personal protective equipment as specified in Section 8. Contain the spill by surrounding with absorbent or inert material (e.g. vermiculite, dry sand). Do not use combustible materials such as saw dust for containing or absorbing the spill. Do not allow the spill to enter drains or flush to the sewer. Carefully clean up spilled material and place into dry container for disposal. After collection, decontaminate area with water and dry with absorbent material. If spill contained biological reagents or materials used in the assay, consider as though potentially infectious and decontaminate with 10% bleach solution (containing 0.5% sodium hypochlorite) or equivalent disinfectant.

6.4 **REFERENCE TO OTHER SECTIONS:** See Section 8 for exposure control and personal protection information, and Section 13 for disposal information.

SECTION 7 – HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Protective Measures: Prevent generation of mists or fumes. Avoid splashing or forming an aerosol during assay. Keep away from drains.

Recommendations for Safe Use: Handle in accordance with good industrial hygiene practices. Do not eat, drink, smoke or apply cosmetics during the assay. Avoid contact with skin, eyes, mucous membranes or clothing. Avoid direct contact with potentially infectious material by wearing lab coats, protective eye/face wear and protective gloves. Do not inhale fumes. Avoid prolonged or repeated exposure. Do not pipette solutions by mouth. Wash hands thoroughly after performing the assay. Remove contaminated clothing and protective equipment prior to entering eating areas.

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- 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBLES: Store in original container. Keep container tightly closed. Store material at 2 – 8°C, in a well ventilated area and away from light. Do not freeze. Protect against physical damage. Store away from incompatibles (see Section 10 for incompatible materials). See package insert for further information.
- 7.3 SPECIFIC END USE(S): All samples, biological reagents and materials used in the diagnostic assay must be considered potentially able to transmit infectious agents. Follow universal precaution guidelines for handling infectious agents and good laboratory practices such as those established by the US Centers for Disease Control and the National Institutes of Health, or the World Health Organization.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS:

PROCLIN [®] active ingredients (CAS Nos. 26172-55-4 and 2682-20-4)					
Country	Limit Value – 8 Hrs		Limit Value – Short Term		Legal Basis
	ppm	mg/m ³	Ppm	mg/m ³	
Austria	-	0.05	-	-	Ministry of the Economy and Labour (BMWA) – Austrian Governmental Journal <u>Grenzwerte für Arbeitsstoffe und über krebserzeugende Arbeitsstoffe</u>
Belgium	-	-	-	-	Ministry of Employment and Work – Liste de valeurs limites d'expositions professionnelle aux agents chimiques Annex 1
Canada	-	-	-	-	Occupational Health and Safety Commission – Règlement sur la santé et la sécurité du travail
Denmark	-	-	-	-	Limit Values for Substances and Materials
EU	-	-	-	-	Official Journal of the European Union – Directive 98/24/EC and 2004/37/EC
France	-	-	-	-	Order of 30 June 2004 and Decree No. 2006-133
Germany	-	0.20 Inhalable aerosol	-	0.4 Inhalable aerosol	Federal Institute for Occupational Safety and Health – Technical Rule for Hazardous Substances No. 900
Hungary	-	-	-	-	Hungarian Ordinance No. 25 / 2000
Ireland	-	-	-	-	Health and Welfare at Work Regulation 2001
Italy	-	-	-	-	Valori Limite di Esposizione Professionale
Japan	-	-	-	-	Japan Society for Occupational Health (JSOH) –Sangyo Eiseigaku Zasshi (Journal of Occupational Health)
Poland	-	-	-	-	Ministry of Labour and Social Policy Bureau for Chemical Substances and Preparations – Dziennik Ustaw
Singapore	-	-	-	-	NA
Spain	-	-	-	-	National Institute for Occupational Safety and Health (INSHT) – Límites de exposición profesional para agentes químicos en España
Sweden	-	-	-	-	Swedish Work Environment Authority – Occupational Exposure Limit Values and Measures Against Air Contaminants
Switzerland	-	0.2 Inhalable aerosol	-	0.4 Inhalable aerosol	Swiss Accident Insurance Institute (SUVA) – Valeurs limites d'exposition aux postes de travail
The Netherlands	-	-	-	-	Deputy Minister for Social Affairs and Employment – Databank of the Social and Economic Council of the Netherlands (SER)
United Kingdom	-	-	-	-	Health and Safety Executive – Guidance Note EH40 Workplace Exposure Limits
United States	-	-	-	-	OSHA – 29 CFR 1910 PEL
	-	-	-	-	ACGIH / NIOSH – Threshold Limit Values

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8.2 EXPOSURE CONTROLS:

Personal protective equipment must comply with the rules in force.

Appropriate Engineering Controls: To maintain air concentrations below occupational exposure standards recommend use of local or general exhaust system. Local ventilation is adequate under normal use conditions. Assure an adequate ventilation system. Hand washing and chemical flushing equipment should be readily available in the work area.

Safe Practices: Follow good occupational hygiene practices in conjunction with the other control measures. Keep food and drinks away from work area. Wash hands thoroughly after handling. Immediately remove any contaminated clothing or personal protective equipment. Wash contaminated clothing and shoes before wearing again.

Personal Protection:

EYE/FACE:	Wear appropriate eye protection to prevent eye contact. Protect eyes with safety glasses or goggles based upon the hazards in the workplace and the potential exposure risks. Safety glasses and goggles should meet, at a minimum, the ANSI standard Z87.1 (US) / EN 166 (EU) or an equivalent level of protection.
SKIN – CLOTHING/GLOVES:	Prevent skin contact and protect clothing. Wear a suitable impervious lab coat and use chemical resistant gloves to prevent skin contact. With normal use of products for diagnostic purposes, disposable nitrile gloves or equivalent protection is adequate. Handle materials in accordance with good industrial hygiene and safety practices. Wash hands thoroughly after handling, and before eating or drinking. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. For EU, reference Directive 89/686/EEC, and Standards EN 344 and EN 374.
RESPIRATORY:	None required with normal use of products for diagnostics purposes and adequate ventilation conditions exist. The use of adequate ventilation must always take priority over PPE. If it is not possible to keep the concentration below the permitted workplace exposure thresholds, then respiratory protection must be used. For EU, reference Standards EN 138 and EN 141.
THERMAL HAZARDS:	NA

Environmental Exposure Controls: See Section 6.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

PROPERTY	DATA
APPEARANCE:	Colorless or slightly yellow liquid
ODOR:	Mild (sweet)
ODOR THRESHOLD:	NE
PH:	4.1 (10% aqueous solution)
MELTING POINT/RANGE:	NE
BOILING POINT/RANGE:	189°C (372°F)
FLASH POINT:	66°C (151°F) – Closed cup
EVAPORATION RATE(Bu Acetate = 1):	< 1
FLAMMABILITY:	Nonflammable
UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS:	NE
VAPOR PRESSURE:	0.06
VAPOR DENSITY (AIR = 1):	> 1
RELATIVE DENSITY OR SPECIFIC GRAVITY (WATER = 1):	1.03 at 22°C
SOLUBILITY IN WATER:	100% soluble and completely miscible
PARTITION COEFFICIENT (N-OCTANOL/WATER):	NE
AUTO-IGNITION TEMPERATURE:	NE
DECOMPOSITION TEMPERATURE:	NE
VISCOSITY:	58 cPs
EXPLOSIVE PROPERTIES:	NE
OXIDIZING PROPERTIES:	NE

9.2 OTHER INFORMATION: NA

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SECTION 10 – STABILITY AND REACTIVITY

- 10.1 REACTIVITY: Stable.
- 10.2 CHEMICAL STABILITY: Stable under normal ambient and anticipated use and storage conditions of temperature and pressure.
- 10.3 POSSIBILITY OF HAZARDOUS REACTIONS: Not expected to polymerize.
- 10.4 CONDITIONS TO AVOID: Heat, high Ph and incompatibles.
- 10.5 INCOMPATIBLE MATERIALS: Strong oxidizing agents, reducing agents, amines, mercaptans and aggressive nucleophiles.
- 10.6 HAZARDOUS DECOMPOSITION PRODUCTS: Forms carbon, nitrogen and sulfur oxides, hydrogen chloride gas, and organic acids (acetic and formic).

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

No toxicity information for components listed in Section 1.1. The following is toxicity Information for the ProClin® active ingredients.

ACUTE TOXICITY:	ROUTE	TEST / RESULT
	Oral	Rat LD50: 53 mg/kg
		Rat LD50: 862 mg/kg
	Dermal	Rabbit LD50: 2,800 mg/kg

SKIN CORROSION / IRRITATION:	ROUTE – ORGANISM	DOSE	EFFECT
	Skin – Rabbit	30,000 ppm	Corrosive
		5,600 ppm (conc. 18.6%)	Severe irritant
		2,800 ppm (conc. 9.3%)	Moderate irritant
		560 ppm (conc. 1.8%)	Non-irritant

SERIOUS EYE DAMAGE / IRRITATION:	ROUTE – ORGANISM	DOSE	EFFECT
	Eye – Rabbit	30,000 ppm	Irreversible damage
		5,600 ppm	Moderate irritant
		2,800 ppm	Slight irritant
		560 ppm	Non-irritant

RESPIRATORY OR SKIN SENSITIZATION:	May cause allergic reaction when in contact with skin.			
CARCINOGENICITY:	NTP: N	IARC: N	OSHA: N	CA: N
MUTAGENICITY:	Not considered mutagenic.			
REPRODUCTIVE TOXICITY:	Not considered teratogenic.			
STOT EXPOSURE:	No data available.			
ASPIRATION HAZARD:	No data available.			
IDLH:	NE			

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SECTION 12 – ECOLOGICAL INFORMATION

12.1 TOXICITY:

No ecological toxicity information for components listed in Section 1.1. The following is toxicity information for the ProClin[®] active ingredients.

COMPONENT	TEST	RESULT
Fish	LC50, 96 hr	0.19 mg/L
Fish	LC50, 96 hr	2.13 mg/L
Crustaceans	LC50, 48 hr	0.56 mg/L
Crustaceans	EC50, 48 hr	0.18 mg/L
Crustaceans	EC50, 48 hr	1.07 mg/L
Algae	EC50, 76 hr	0.13 mg/L
Algae	EC50, 96 hr	0.06 mg/L

12.2 PERSISTENCE AND DEGRADABILITY: When released into water the ProClin[®] is totally miscible.

12.3 BIOACCUMULATIVE POTENTIAL: No data available.

12.4 MOBILITY IN SOIL: No data available

12.5 RESULTS OF PBT AND vPvB ASSESSMENT: No data available.

12.6 OTHER ADVERSE EFFECTS: NA

SECTION 13 – DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Processing, use or contamination of the components may change the waste management options. Do not reuse the empty container.

United States (US): Dispose of unused material, waste, empty container and packaging in accordance with all federal, state and local environmental regulations.

European Union (EU): Reuse when possible. The hazard level of the waste should be evaluated according to applicable regulations. Do not discharge waste material into drains or the environment. Do not dispose of waste with household waste. P501: Dispose of contents, container and packaging according to the national, federal, state and international directives in force.

SECTION 14 – TRANSPORT INFORMATION

14.1 UN NUMBER: Not applicable

14.2 UN PROPER SHIPPING NAME: Not applicable

14.3 TRANSPORT HAZARD CLASS(ES): Not applicable

14.4 PACKING GROUP: Not applicable

14.5 ENVIRONMENTAL HAZARDS: No

14.6 SPECIAL PRECAUTIONS FOR USER: Not classified as a hazardous material or dangerous good under DOT or IATA regulations.

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14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE: Material will not be transported in bulk.

SECTION 15 – REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:

Canada	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.	
	WHMIS Hazard Class:	D2B – Materials causing other toxic effects – Toxic material
	DSL:	Y
	NDSL:	N
EU	Classification and procedures used to derive the classification for products listed in Section 1.1 according to European Union regulations and directives: 67/548/EEC, 1999/45/EC, 2001/60/EC and Regulation (EC) 1272/2008. This MSDS complies with regulations on Safety Data Sheet preparation, Directive 2001/58/CE and REACH Regulation 1907/2006/CE, article 31.	
	Seveso Category:	None
	EC No. 1907/2006 – Candidate List:	N
	EC No. 1907/2006 Annex XIV – Authorization:	N
	EC No. 1907/2006 Annex XVII - Restrictions:	Component Preparation: 3
	Healthcare Controls:	NE
	Rotterdam Protocol:	N
Stockholm Protocol:	N	
Germany	Water hazard class:	WGK-1
NFPA	Health: 1	Flammability: 0 Reactivity: 0
United States	Product components listed in Section 1.1 are classified in accordance with OSHA Hazard Communication Standard, 29 CFR 1910.1200, and individual US state Right-to-Know laws.	
	CAA:	N – Does not contain any hazardous air pollutants (HAPs) or Class 1 Ozone depleters.
	CWA:	N
	CERCLA:	N
	SARA 302:	N
	SARA 311/312:	Acute: Y Chronic: Y Fire: N Pressure: N Reactivity: N
	SARA 313:	N
	TSCA:	Y
CA Prop 65:	N	

15.2 CHEMICAL SAFETY ASSESSMENT: No chemical safety assessment has been conducted.

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SECTION 16 – OTHER INFORMATION

16.1 INDICATION OF CHANGES:

DATE	CHANGE
2010-03-11	Initial MSDS
2010-10-20	NA
2011-04-05	Updated to comply with EU directive 1272/2008.
2011-11-23	Updated MSDS for compliance with EU directive 453/2010.
2011-12-15	Updated to add kits 318900 and 318901
2012-02-23	Updated to add kits 318920 and 318921, and correction to bleach concentration in Section 6.3.
2012-02-29	Adjusted concentration range to incorporate full range of skin sensitizer classification established by the EU directives.
2012-08-09	Removed reference to Italian Ministerial Decree in Sect. 15.1 and in Sect. 3.2 changed column heading EC No. to Index No.
2012-09-27	Updated to add kits 318910 and 318911.
2012-11-15	Updated to add kits 310450, 310451, 310453, 310680, 310681, 310690, 310691 and 318990.
2013-02-01	Replaced USA poison center information with Canadian poison center information.
2013-09-20	Updated to add kits 318930 and 318931.
2013-11-25	Updated to add kits 310633, 317910, 317911, 317913, 318940 and 318941.
2014-04-14	Updated to add kits 310980, 310981, 310982, and 310983, and remove kit P2796.
2014-09-02	Updated to add kits 318950, 318951, 318960, 318961, 318962 and 318963.
2014-12-19	Updated to add kit 310985 and remove 1060 and P3093.
2015-04-17	Updated to add kits 310502, 310512, 310522, 310542, 310742, 310752, 318970 and 318971, and remove kits 7545, 7570, 24300, P000172, P002046 and P2244.
2016-01-25	Updated to add kits 310930, 310931, 310970, 318980 and 318981.
2016-05-20	Updated to add kits 310932, 310933, 318870 and 318873.
2016-08-15	Updated to add kits 317060, 317061, 317090, 317091, and 318871.
2017-01-17	Updated to add kits 317130, 317131, 319020, 319021 and 319023.
2017-09-27	Updated to add kits 318080 and 318081.
2017-11-20	Updated to add kit 310984.
2018-03-12	Discontinued kits 65100E, 32400, 310660, 310661, 310662, 310663, 310910, 310911, 310912, 310913, P2573 and P2714.
2018-06-25	Updated to add kit 318320.
2018-10-18	Updated to add kits 317150, 317151 and 319135.

16.2 ABBREVIATIONS AND ACRONYMS:

ACGIH	American Conference of Governmental Industrial Hygienists
ANSI	American National Standards Institute
C	Concentration
CA	California
CAA	Clean Air Act (USA)
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act (USA)
CMR	Carcinogen, Mutagen or Reproductive toxicant
CPR	Controlled Products Regulations (Canada)
CWA	Clean Water Act (USA)
DOT	United States Department of Transportation
DSL	Domestic Substance List (Canada)
EU	European Union
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IDL	Ingredient Disclosure List
IDLH	Immediately dangerous to life or health
Koc	Partition coefficient of the contaminant in the organic fraction of the soil
Kow	Octanol-water partition coefficient
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population
N	No
NA	Not Applicable or Not Available
NE	Not Established
NDSL	Non-Domestic Substance List (Canada)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration (USA)

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PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
RCRA	Resource Conservation and Recovery Act (USA)
REACH	Registration, Evaluation, Authorisation of Chemical (EU)
RQ	Reportable Quantity
SARA	Superfund Amendments and Reauthorization Act (USA)
SCBA	Self-Contained Breathing Apparatus
STOT	Specific Target Organ Toxicity
TSCA	Toxic Substances Control Act (USA)
TWA	Time weighted average
vPvB	Very Persistent and very Bioaccumulative
WHMIS	Workplace Hazardous Materials Information System (Canada)
Y	Yes

16.3 KEY LITERATURE REFERENCES AND SOURCES FOR DATA:

- a. US OSHA 29 CFR 1910.1200
- b. CDC - NIOSH website – Guide to Chemical Hazards
- c. Directive 67/548/EEC and following amendments
- d. Directive 1999/45/EC and following amendments
- e. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- f. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- g. Regulation (EC) 790/2009 (CLP amendment) of the European Parliament
- h. Regulation (EC) 453/2010 (REACH amendment) of the European Parliament
- i. ECHA website
- j. eChemPortal website
- k. ESIS website
- l. GESTIS website – Substance database and Occupational exposure limits
- m. IARC website – Evaluation of carcinogenic risks to humans
- n. ILO website – Chemical exposure limits
- o. ICSC website
- p. IPCS INCHEM website – Chemical Safety Information
- q. Health Canada website
- r. Canada Labour Health and Safety website
- s. CCOHS website

16.4 OTHER

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