

Trade name: hPL ELISA
Product number: 20-HPLHU-E01

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

1.1 Product identifier

Trade name: hPL ELISA Product number: 20-HPLHU-E01

Kit Components:

1. Microtiterwells
2. Standard
3. Zero Standard
4. Control Low & High
5. Enzyme Conjugate
6. Substrate Solution
7. Stop Solution

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 manufacturer

DRG Instruments GmbH Phone.: +49-(0)6421 / 1700-0
Frauenbergstraße 18 Fax: +49-(0)6421 / 1700-50
D-35039 Marburg E-Mail: drg@drg-diagnostics.de
Germany http://www.drg-diagnostics.de

1.4 Details of the supplier of the safety data sheet

ALPCO Phone: 800-592-5726
26-G Keewaydin Drive Fax: 603-898-6854
Salem, NH 03079 E-Mail: cs@alpc.com
US <http://www.alpc.com>

1.5 Emergency telephone number

+49-(0)6421 / 1700-0 (during opening time: 8:00 h – 16:30 h)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Product is **not classified as hazardous** according to the European Regulation 67/548/EEC and 1999/45/EC or 1272/2008/EC.

2.2 Label elements

No labelling required.

2.3 Other hazards

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Description of the mixture:

Mixture of nonhazardous substances, with additions listed below.

Hazardous ingredients:

Chemical name	CAS No. (EC No.) [Index No.]	Amount in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)		Classification according to Directive 67/548/EEC (related to the concentrated form)
			Hazard class/ Hazard categories	Hazard- statement	
Kit component: <i>Standard, Zero Standard, Control Low & High, Enzyme Conjugate</i>					
Proclin 300 *	55965-84-9 (---) [613-167-00-5]	< 0,0015 %	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	T; R23/24/25 C; R34 R43 N; R50-53
* Proclin 300 is a mixture of substances including the components 5-chloro-2-methyl-4-isothiazolin-3-one (CIT) [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (MIT) (3:1)					
Kit component: <i>Stop Solution</i>					
sulphuric acid ... %	7664-93-9 (231-639-5) [016-020-00-8]	< 5.0 %	Skin Corr. 1A	H314	C; R35

Full text of R-, and H-phrases: see section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information: No special measures required.
 Following inhalation: Supply fresh air; consult doctor in case of complaints.
 Following skin contact: Wash with plenty amounts of water.
 Following eye contact: Rinse opened eye for several minutes under running water.
 Following swallowing: If symptoms persist consult doctor.

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

Suitable extinguishing media:

No restriction; use any means suitable for extinguishing surrounding fire.

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Unsuitable extinguishing media:

None

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:

No further relevant information available.

5.3 Advice for firefighters

No special measures required.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment.

6.2 Environmental precautions

Dilute with plenty of water.

Do not allow to enter surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material.

Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See section 8 for information on personal protection equipment.

See section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use all reagents in accordance with the relevant instruction for use.

Observe laboratory safety regulations.

Do not eat, drink, smoke or apply cosmetics in areas where kit reagents are handled.

Wear disposable latex gloves when handling reagents.

Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

7.2 Conditions for safe storage, including any incompatibilities

No special requirements.

Store all reagents as directed in the relevant instruction for use.

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

Respiratory protection: Not required.

Hand protection: Protective gloves.

Eye protection: Goggles recommended during aspiration, dispensing or refilling.

Skin protection: Lab coat.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Kit Component	Standard; Zero Standard; Control;	Enzyme Conjugate	Substrate Solution	Stop Solution
(a) Appearance: The physical state Colour	liquid diverse (has no influence to the properties of the mixture)			
(b) Odour	odourless			
(c) Odour threshold	no data available			
(d) pH	7,2 ± 0,1	7,2 ± 0,2	3.5 - 3.9	< 1.0
(e) Melting point/freezing point	no data available			
(f) Initial boiling point and boiling range	no data available			
(g) Flash point	no data available			
(h) Evaporation rate	no data available			
(i) Flammability (solid, gas)	no data available			
(j) Upper/lower flammability or explosive limits	no data available			
(k) Vapour pressure	no data available			
(l) Vapour density	no data available			
(m) Relative density	no data available			
(n) Solubility(ies)	no data available			
(o) Partition coefficient: n-octanol/water	no data available			
(p) Auto-ignition temperature	no data available			
(q) Decomposition temperature	no data available			
(r) Viscosity	no data available			
(s) Explosive properties	no data available			
(t) Oxidising properties	no data available			

9.2 Other information

No other information available.

10. STABILITY AND REACTIVITY

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|--|--|
| 10.1 Reactivity | No data available. |
| 10.2 Chemical stability | No data available. |
| 10.3 Possibility of hazardous reactions | No data available. |
| 10.4 Conditions to avoid | No conditions known. |
| 10.5 Incompatible materials | No materials known. |
| 10.6 Hazardous decomposition products | No dangerous decomposition products known. |

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- (a) Acute toxicity: No data available.
 (b) Irritation: Due to its low pH value Substrate Solution and Stop Solution are irritant to the eye.
 (c) Corrosivity: Sulfuric acid induces tissue injury after contact.
 (d) Sensitisation: No data available.
 (e) Repeated dose toxicity: No data available.

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- (f) Carcinogenicity: No data available.
(g) Mutagenicity: No data available.
(h) Toxicity for reproduction: No data available.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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:

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

Uncleaned packaging:

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

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14. TRANSPORT INFORMATION

This product is not subject to official transport regulations.

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|---|-----------------|
| 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. |
| 14.7 <u>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</u> | Not applicable. |

15. REGULATORY INFORMATION

This Safety Data Sheet is according to:

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**"H code" and "R Phrases" used in this Safety data sheet**

<i>Reg. 1272/2008</i>	<i>Dir. 67/548/EEC</i>	
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.
/	R34	Causes burns.
/	R35	Causes severe burns.
/	R43	May cause sensitisation by skin contact.
/	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
/	R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.