



Section 1: COMPANY AND PRODUCT INFORMATION

1.1 Product Name:	PCOCheck ELISA														
1.2 Product Code:	AL-196, AL-196-i														
1.3 Product Category:	GMDN 58413														
1.4 Manufacturer:	<table border="0"> <tr> <td>Manufacturer:</td> <td>EC Representative:</td> </tr> <tr> <td>Ansh Labs</td> <td>Dr C.R.Bhaduri</td> </tr> <tr> <td>445 Medical Center Blvd</td> <td>RD-RatioDiagnostics GmbH</td> </tr> <tr> <td>Webster, TX 77598</td> <td>Westerbachstrabe 47</td> </tr> <tr> <td>Ph: (281) 404-0260</td> <td>60489 Frankfurt/Main</td> </tr> <tr> <td>techsupport@anshlab.com</td> <td>Germany</td> </tr> <tr> <td></td> <td>Ph: +49 7807-4942</td> </tr> </table>	Manufacturer:	EC Representative:	Ansh Labs	Dr C.R.Bhaduri	445 Medical Center Blvd	RD-RatioDiagnostics GmbH	Webster, TX 77598	Westerbachstrabe 47	Ph: (281) 404-0260	60489 Frankfurt/Main	techsupport@anshlab.com	Germany		Ph: +49 7807-4942
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1.5 Emergency telephone number:	In the event of a medical emergency, please dial 911.														
1.6 Relevant identified uses of the substance/mixture:	Research Use Only. For <i>in vitro</i> professional laboratory use.														
uses advised against:	For the quantitative measurement of anti-Müllerian hormone (AMH) in human serum, Li-Heparin and K2 EDTA plasma.														
1.7 Kit content (name and label reference):															

Component	Part Number	Quantity	Main Ingredients
PCOCheck Calibrator A (Lyophilized)	CAL-196A	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Calibrator B (Lyophilized)	CAL-196B	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Calibrator C (Lyophilized)	CAL-196C	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Calibrator D (Lyophilized)	CAL-196D	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Calibrator E (Lyophilized)	CAL-196E	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Calibrator F (Lyophilized)	CAL-196F	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Control I (Lyophilized)	CTR-196-I	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
PCOCheck Control II (Lyophilized)	CTR-196-II	1 vial	Protein based Buffer with Pro-clean 400 (0.05%)
AMH Antibody Coated Microtitration Strips	PLT-145	1 Each	Antibody Coated Polystyrene Plate
PCOCheck Biotin Conjugate Ready-to-Use (RTU)	BCR-196	12 mL	Protein based Buffer with Sodium Azide
PCOCheck Streptavidin-Enzyme Conjugate Ready-to-Use (RTU)	SAR-196	12 mL	Protein based Buffer with Pro-Clean 400
Stopping Solution	STP-100	12 mL	0.2 M Sulfuric Acid
TMB Solution	TMB-100	12 mL	Buffer with trace amounts of DMSO and hydrogen peroxide
Wash Concentrate A	WSH-100	60 mL	Buffer with a nonionic detergent

Section 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:	None of the material of this product may be classified as dangerous according to REACH and EC Directives 1272/2008/EC due to the low concentration of hazardous ingredients.
2.2 Label elements	<p><u>Stopping solution:</u></p>  <p>DANGER H314 Causes severe skin burns and eye damage. P280 Wear protective gloves, protective clothing and eye/ face protection. P301+P330+P331 If swallowed: rinse mouth. P303+P361+P353 If on skin (or hair): Rinse skin with water. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Continue rinsing. P310 Immediately seek physician assistance.</p> <p><u>Pro-clean 400:</u></p>  <p>R23/24/25: Harmful if inhaled, in contact with skin and if swallowed</p>
2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:	<p>Not applicable. Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.</p> <p>The Calibrators and Controls are formulated with a buffer base, Protein Based Buffer Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product.</p> <hr/> <p>BSA has been derived from US origin and processed in USDA licensed facilities, and are free from known infections, however, it should be considered that no available test method can offer complete assurance of eliminating potential biohazardous risk. The antibodies are from monoclonal origin and are free from human or animal source.</p>

Section 3 : COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

<u>Stopping Solution</u>		<i>Hazard Classification of Pure Ingredients</i>			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	WHMIS
Sulfuric Acid CAS # 7664-93-9 EINECS # 231-639-5 Index # 016-020-00-8	<2	C;R35	Eye Dam. 1 Skin Corr. 1A H314; H318	Water- Reactive Carcinogen Corrosive Highly Toxic	D1A; E

3.2 Mixtures

2 - Substance with Community workplace exposure limits

8 - Present at concentration below the cut-off limits.

9 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6] (3:1) is the active ingredient of Pro-Clean 400

<u>PCOCheck Calibrators and Controls, PCOCheck Biotin Conjugate Ready-to-Use (RTU), PCOCheck Streptavidin-Enzyme Conjugate Ready-to-Use (RTU)</u>		<i>Hazard Classification of Pure Ingredients</i>			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	WHMIS
Pro-Clean 400 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) CAS # 55965-84-9 EINECS # Not available Index # 613-167-00-5	≤ 0.5	T;R23/24/25-34-43 N;R50/53	Acute Tox. Dermal 3 Acute Tox. Inhal. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Longterm 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Corrosive Sensitizer Toxic	D1B; D2B; E 2, 9

<u>PCOCheck Biotin Conjugate RTU</u>		<i>Hazard Classification of Pure Ingredients</i>			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	WHMIS
Sodium Azide CAS # 26628-22-8 EINECS # 247-852-1 Index # 011-004-00-7	< 0.1	T+;R28-32 N;R50/53	T+;R28-32 N;R50/53 Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410	Highly Toxic Irritant	D1A 2, 8

Section 4: FIRST AID MEASURES
4.1 Description of first aid measures

General advice:	No special measures required. Consult a physician in case of complaints.
If inhaled:	If product is inhaled, move exposed individual to fresh air.
In case of skin contact:	In case of skin contact, flush with water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.

In case of eye contact:

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

If swallowed:

If ingested, wash mouth out with water. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed:

To the best of our knowledge, the chemical, physical a toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

Section 5: FIREFIGHTING MEASURES**5.1 Flammable Properties:**

Nonflammable solution.

5.2 Extinguishing media:

Chemical or water fire extinguisher.

5.3 Special hazards arising from the substance or mixture:

No special hazards determined.

5.4 Advise for Firefighters

Wear self-contained breathing apparatus for firefighting, if necessary.

5.5 NFPA Rating

Health: 2

Flammability: 0

Reactivity: 1

Section 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures:**

Use appropriate personal protective equipment (Wear rubber gloves, safety goggles, impermeable shoe covers and long laboratory coat).

6.2 Spill and Leak Procedures:

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.

6.3 Environmental precautions:

Contain the spill to the smallest area possible. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Methods and material for containment and cleaning up:

Absorb with inert absorbent material and dispose of a waste (see section 13).

6.5 Reference to other sections:

For disposal see section 13.

Section 7: HANDLING AND STORAGE**7.1 Precautions for safe handling:**

Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.

7.2 Recommended Storage and Conditions:

Keep away from incompatible material (see Section 10).
To maintain efficacy, store according to the instructions in the product labelling

7.3 Specific end use(s):

This product is intended for laboratory use by professional users only.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**8.1 Control parameters:**

Component with exposure limits: it doesn't contain substances with exposure limit value.

8.2 Exposure controls

Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks at the end of workday.

8.3 Personal protective equipment:

US OSHA: None established.

ACGIH: None established.

DFG MAK: None established.
 NIOSH: None established.
 Japan: None established.
 Engineering Controls: Use in well-ventilated area.
 Eye/face protection: Safety glasses or chemical goggles should be worn to prevent eye contact.
 Skin protection: Lab coats, non-permeable rubber, neoprene, latex or nitrile disposable gloves.
 Body protection: Lab coats.
 Respiratory protection: Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Component	a) Appearance	b) Odor	c) pH
PCOCheck Calibrators A-F	Lyophilized powder	odorless	7.4
PCOCheck Controls	Lyophilized powder	odorless	7.4
AMH Ab Plate	Plastic, clear plate	odorless	N/A
PCOCheck Biotin Conjugate Ready-to-Use	Liquid, clear	odorless	7.4
PCOCheck Streptavidin-Enzyme Conjugate Ready-to-Use (RTU)	Liquid, colorless	Odorless	6.2
Stop Solution	Liquid, colorless	odorless	1.2
TMB Solution	Liquid, colorless	odorless	4.0
Wash Concentrate A	Liquid, colorless	odorless	7.2

For all components

d) odor threshold	no data available
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) vapor pressure	no data available
l) vapor 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) oxidizing properties	no data available

9.2 Other information:

No other information available

Section 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No data available.

10.2 Chemical stability:

No data available.

10.3 Possibility of hazardous reactions:

Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. May react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up.

10.4 Conditions to avoid:

For the functional stability and reactivity of "TMB Substrate" avoid its exposure to direct sunlight, metals or oxidants and do not freeze the solution.

10.5 Incompatible materials:

Strong acids; strong bases; strong oxidizers.

10.6 Hazardous decomposition products:

No decomposition products posing significant hazards would be expected from this product.

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

a) acute toxicity	no data available
b) skin corrosion/irritation	no data available
c) serious eye damage / irritation	no data available
d) respiratory or skin sensitization	no data available
e) germ cell mutagenicity	no data available
f) carcinogenicity	no data available
g) reproductive toxicity	no data available
h) STOT-single exposure	no data available
i) STOT-repeated exposure	no data available

Potential health effects

Inhalation	no data available
Ingestion	no data available

Skin	no data available
Eyes	no data available
11.2 Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.	
11.3 Additional Information: Not applicable.	

Section 12: ECOLOGICAL INFORMATION

12.1 Toxicity: No data available.
12.2 Persistence and degradability: No data available.
12.3 Bio accumulative 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: No data available.

Section 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods: Reagents must be disposed of in accordance with local regulations. Do not dispose of in wastewater. If appropriate, contact a licensed disposal company.
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Section 14: TRANSPORT INFORMATION

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG, because it is in a very small quantity, the product benefits from a total exemption from the ADR regulation.

14.1 UN Number:

No data available.

14.2 UN proper shipping name:

No data available.

14.3 Transport hazard class(es):

No data available.

14.4 Packing group:

No data available.

14.5 Environmental hazards:

No data available.

14.6 Special precautions for user:

No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

No data available.

Section 15: REGULATORY INFORMATION

This product is not regulated under US Federal and State Regulations, EU labeling Classification, Canada, and WHMIS Classification, with the exception of Sulfuric Acid that is present in low concentration in Stopping Solution (see below). Mixtures are in conformity with 98/79/EC IVDMD Directive and REACH regulations.

US Federal and State Regulations

SARA 313	Sulfuric Acid is subject to reporting requirements of Section 313, Title III of SARA.
CERCLA RG's 40 CFR 302.4	Sulfuric Acid, Sodium Azide is listed.
California Proposition 65	Sulfuric Acid has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Ansh Labs advises you of the following warning: WARNING: This product contains a chemical known to the State of California to cause cancer.
Massachusetts MSL	Sulfuric Acid, Sodium Azide is listed.

New Jersey Dept. of Health RTK List	Sulfuric Acid, Sodium Azide is listed.
Pennsylvania RTK	Sulfuric Acid, Sodium Azide is listed.
EU Labeling Classification	Preparation not classified.
Canada	
WHMIS Classification	D1A - Poisonous and Infections Material: Division 1 - Immediate and Serious Toxic Effects: Very Toxic (Acute Inhalation Toxicity) E - Corrosive Material.
PIN	2796
Ingredients on Ingredient Disclosure List	Sulfuric Acid, Sodium Azide
Ingredients with unknown toxicological properties:	None
Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.	

Section 16: OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Changing against the last version:

N/A (initial version)

Ansh Labs Safety Rating	Flammability: 0	Code 0=None 1=Slight 2=Caution 3=Severe
	Health: 3	
	Reactivity with Water: 0	
	Contact: 0	

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises danger euses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 * Data compared to the previous version altered

Key literature references and sources for data:

N/A

Hazard Classification codes and phrases used in this Safety Data Sheet as per regulation:

Reg. 1272/2008	
H228	Flammable solid
H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed.
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation

H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Dir. 67/548/CEE	
R11	Highly flammable
R21	Harmful in contact with skin
R22	Harmful if swallowed
R23	Toxic by inhalation
R24	Toxic in contact with skin
R25	Toxic if swallowed
R26	Very toxic by inhalation
R27	Very toxic in contact with skin
R28	Very toxic if swallowed
R29	Contact with water liberates toxic gas.
R30	Can become highly flammable in use
R31	Contact with acids liberates toxic gas
R32	Contact with acids liberates very toxic gas
R33	Danger of cumulative effects
R34	Causes burns
R35	Causes severe burns
R36	Irritating to eyes
R37	Irritating to respiratory system
R38	Irritating to skin
R39	Danger of very serious irreversible effects
R40	Limited evidence of a carcinogenic effect
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitization by skin contact
R50	Very toxic to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
C	Corrosive
F	Highly Flammable
Xi	Irritant
Xn	Harmful
N	Dangerous for the Environment

WHMIS Classes	
D1A, D1B	<ul style="list-style-type: none"> • Division 1: Materials Causing Immediate and Serious Toxic Effects <ul style="list-style-type: none"> ○ Subdivision A: Very Toxic Material ○ Subdivision B: Toxic Material
D2B	<ul style="list-style-type: none"> • Division 2: Materials Causing Other Toxic Effects (generally appear over time following one or several exposures) <ul style="list-style-type: none"> ○ Subdivision B: Toxic Material
E	Corrosive Material

Advice for training:

The product is intended for professional laboratory use.

Department issuing MSDS: Regulatory Affairs Department / Document Control.

Contact: TechSupport@AnshLabs.com