Section 1: COMPANY AND PRODUCT INFORMATION

1.1 Product Name:	AFP ELISA
1.2 Product Code:	AL-104
1.3 Product Category:	**GMDN N.A / EDMA 12.03.90.01**

1.4 Manufacturer:

Manufacturer:

Ansh Labs
445 Medical Center Blvd
Webster, TX 77598
Ph: (281) 404-0260
techsupport@anshlabs.com

EC Representative:

Dr C.R.Bhaduri
RD-RatioDiagnostics GmbH
Westerbachstrabe 47
60489 Frankfurt/Main
Germany
Ph: +49 7807-4942

1.5 Emergency telephone number: In the event of a medical emergency, please dial 911.

1.6 Relevant identified uses of the substance/mixture: For i*n vitro* professional laboratory use.

uses advised against: For the quantitative measurement of in human serum.

1.7 Kit content (name and label reference):

Component	Part Number	Quantity	Main Ingredients
AFP Calibrator A	CAL-104A	2 mL	Protein Based Buffer with 1% Pro-Clean 400
AFP Calibrator B	CAL-104B	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Calibrator C	CAL-104C	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Calibrator D	CAL-104D	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Calibrator E	CAL-104E	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Calibrator F	CAL-104F	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Control I	CTR-104-I	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Control II	CTR-104-II	0.5 vial	Protein Based Buffer with 1% Pro-Clean 400
AFP Antibody Coated Microtitration Strips	PLT-104	1 Each	Antibody Coated Polystyrene Plate
AFP Assay Buffer	ASB-104	8 mL	Tris and Protein Based Buffer with Pro-Clean 400
AFP Antibody-Enzyme Conjugate Ready-to-Use	ECR-104	13 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	Solution of Tetramethylbenzidine (TMB)
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 regulations and EC Directives

	1272/2008/EC due to the low concentration of hazardous ingredients.
2.2 Label elements	**<u>Pro-clean 400</u>:**  H317 May cause an allergic skin reaction P261 Avoid breathing vapors P272 Contaminated work clothing should not be allowed out of the workplace P280 Wear protective gloves, protective clothing and eye/face protection P302+P352 If on skin: Wash with plenty of soap and water P333+P313 If skin irritation or rash occurs, seek medical assistance **<u>Sulfuric acid</u>:**  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.
2.3 Hazards not otherwise classified (HNOC) or not covered by GHS:	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. The Calibrators and Controls are formulated with a buffer base, Protein Based Buffer. The human serums are tested by a CE/FDA licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. 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.
	Bovine products (BSA) have 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Stopping Solution		Hazard Classification of Pure Ingredients			
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.

AFP Assay Buffer, AFP Antibody-Enzyme Conjugate Ready-to-Use (RTU)		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**US OSHA**	**WHMIS**
Pro-Clean 400[2,8] 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. Inhale. 3 Acute Tox. Oral 3 Aquatic Acute 1 Aquatic Long-term 1 Skin Corr. 1B Skin Sens. 1 H301; H311; H314; H317; H331; H400; H410	Corrosive Sensitizer Toxic	D1B; D2B; E

AFP Calibrators and Controls		Hazard Classification of Pure Ingredients			
Chemical Name	**% by wt.**	**EU-67/548/EEC**	**EU 1272/2008 CLP/GHS**	**US OSHA**	**WHMIS**
Sodium Azide[2,8] **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 Long-term 1 H300; H400; H410	Highly Toxic Irritant	D1A

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**
AFP Calibrators	Liquid, white	odorless	7.8
AFP Controls	Liquid, white	odorless	7.8
AFP Plate	Plastic, clear plate	odorless	N/A
AFP Assay Buffer	Liquid, clear	odorless	7.0
AFP Antibody-Enzyme Conjugate Ready-to-Use (RTU)	Liquid, clear	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.

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.

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:
Updated to include REACH regulation

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

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.

WHMIS Classes	
D1A, D1B	• *Division 1*: **Materials Causing Immediate and Serious Toxic Effects** ○ **Subdivision A: Very Toxic Material** ○ **Subdivision B: Toxic Material**
D2B	• *Division 2*: **Materials Causing Other Toxic Effects (generally appear over time following one or several exposures)** ○ **Subdivision B: Toxic Material**
E	Corrosive Material

Advice for training:
The product is intended for professional laboratory use.
Department issuing SDS: Regulatory Affairs Department / Document Control.
Contact: TechSupport@AnshLabs.com