



Section 1: COMPANY AND PRODUCT INFORMATION

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|---|---|--|
| 1.1 Product Name: | Dried Blood Spot (DBS) FSH ELISA | |
| 1.2 Product Code: | AL-187, AL-187-i | |
| 1.3 Product Category: | GMDN 54186 / EDMA N.A | |
| 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>in vitro</i> professional laboratory use. | |
| uses advised against: | For the quantitative measurement of human FSH in dried blood spot. | |

1.7 Kit content (name and label reference):

| Component | Part Number | Quantity | Main Ingredients |
|---|-------------|----------|--|
| FSH Calibrator A | CAL-186A | 3 mL | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Calibrator B (Lyophilized) | CAL-186B | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Calibrator C (Lyophilized) | CAL-186C | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Calibrator D (Lyophilized) | CAL-186D | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Calibrator E (Lyophilized) | CAL-186E | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Calibrator F (Lyophilized) | CAL-186F | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Control I (Lyophilized) | CTR-186-I | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Control II (Lyophilized) | CTR-186-II | 1 vial | Protein based buffer (BSA) with Pro-clean 400 ($\leq 0.5\%$) |
| FSH Coated Microtitration Strips | PLT-186 | 1 Each | Antibody Coated Polystyrene Plate |
| FSH Assay Buffer | ASB-183 | 12 mL | Protein based Buffer with Sodium Azide (0.09%) |
| Extraction Buffer/Sample Diluent | EXB-129 | 45 mL | Protein based Buffer with Sodium Azide (0.09%) |
| US FSH Biotin Conjugate Ready-to-Use (RTU) | BCR-186 | 12 mL | Protein based Buffer (BSA) with Sodium Azide (0.045%) |
| US FSH Streptavidin-Enzyme Conjugate Ready-to-Use (RTU) | SAR-186 | 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 hydrogen peroxide |
| Wash Concentrate A | WSH-100 | 60 mL | Buffer with a nonionic detergent |

Section 2: HAZARDS IDENTIFICATION

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| 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 | <p><u>Sulfuric acid:</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 contain serum matrix. The 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.</p> <p>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.</p> |

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.

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

| FSH Calibrator A-F, FSH Controls I-II, US FSH Streptavidin-Enzyme Conjugate 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 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 | 2, 9 |

| FSH Assay Buffer, Extraction Buffer/Sample Diluent, US FSH Biotin 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 | |
| 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 Long-term 1 H300; H400; H410 | Highly Toxic Irritant | D1A | 2, 8 |

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

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|--------------------------|---|
| 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 and 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:** 2**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 |
|---|----------------------|----------|-------|
| FSH Calibrator A | Liquid, clear | Odorless | 7.4 |
| FSH Calibrator B-F | Lyophilized powder | Odorless | 7.4 |
| FSH Control I-II | Lyophilized powder | Odorless | 7.4 |
| FSH Coated Microtitration Strips | Plastic, clear plate | Odorless | N/A |
| FSH Assay Buffer | Liquid, colorless | Odorless | 7.4 |
| Extraction Buffer/Sample Diluent | Liquid, colorless | Odorless | 7.4 |
| US FSH Biotin Conjugate Ready-to-Use (RTU) | Liquid, colorless | Odorless | 7.4 |
| US FSH Streptavidin-Enzyme Conjugate Ready-to-Use (RTU) | Liquid, yellow | 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. |

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| 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 0=None 1=Slight 2=Caution 3=Severe |
| | Health: 2 | |
| | Reactivity with Water: 0 | |
| | Contact: 2 | |

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 SDS: Regulatory Affairs Department / Document Control.

Contact: TechSupport@AnshLabs.com