DETECTFOB COMBO SAFETY DATA SHEET

This Safety Datasheet complies with the requirements of Regulation (EC) No 1907/2006

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

1.1 Product Identifier: DetectFOB Combo
101005, 101006, 101007, 101008

Composition: R1 & R2 reagents, haemoglobin diluted calibrators and Control C1 & Control C2.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:

DetectFOB Combo is a latex turbidimetric assay for the quantitative detection of human haemoglobin in human stool samples.

DetectFOB Calibrators must be used only for the calibration of the DetectFOB Combo assay.

DetectFOB C1 & C2 controls must be used only to verify the performance of the DetectFOB.

For professional in vitro diagnostic use only.

DetectFOB Reagent 1 (R1): buffer and sodium azide <0.1%.

DetectFOB Latex Reagent (R2): suspension of latex particles coated with antibodies anti-haemoglobin.

DetectFOB diluted Calibrators: Protein in solution with preservatives.

DetectFOB Control C1: Protein solution with preservatives.

DetectFOB Control C2: Protein solution with preservatives.

Uses advised against: No information available.

1.3 Details of the supplier of the Safety Data Sheet: Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, United Kingdom
+44 (0) 118 979 5566
technical@apacor.com

1.4 Emergency telephone number:
+44 (0)118 979 5566
(Monday-Friday 0900-1700 excluding UK Public Holidays)

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Non-hazardous preparation (Regulation 1272/2008/EC).

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]: Non-hazardous.

2.1.2 Classification according to Directive 1999/45/EC: Non-hazardous.

2.1.3 Additional information: See SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Signal Word: **None**

2.3 Other hazards

No hazards known.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Mixture description:

DetectFOB R1 contains buffer and <0.1% of sodium azide as preservative. DetectFOB R2 contains latex coated particles and buffer. Diluted Calibrators contains protein, buffer and preservatives. DetectFOB Control C1 contains buffer and preservatives. DetectFOB Control C2 contains buffer and preservatives.

3.2.1 Hazardous components:

***Note*:** DetectFOB Combo components are not dangerous preparation (Regulation (EC) No 1272/2008 [CLP]).

DetectFOB diluted Calibrators is a protein solution containing buffer, detergent and <0.1% of sodium azide as preservative.

DetectFOB Controls are a protein solution with <0.1% of sodium azide as preservative.

3.3 Other Information

For full text of H-phrases: see SECTION 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

Consult a physician. Show this safety data sheet to the doctor in attendance.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.

In case of skin contact: Wash off immediately with soap and plenty of water. Consult a physician.

If swallowed: Clean mouth with water and drink afterwards plenty of water. Consult a physician.

If inhaled: Ensure sufficient ventilation of workplace. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media: Water or CO_2. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons: No information available.

5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation.

6.2 Environmental precautions

Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up
Soak up with inert absorbent material. Clean contaminated surface thoroughly.
6.4 Reference to other sections
If appropriate Sections 8 and 13 shall be referred to.

SECTION 7 HANDLING AND STORAGE
7.1 Precautions for safe handling
Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves. Specimens should be handled as potentially infectious materials.
7.2 Conditions for safe storage, including any incompatibilities
Store in a dry place at +2°C to +8°C, protect form the light.
7.3 Specific end use(s)
Only use these reagents with other DetectFOB reagents (Latex reagents and Calibrator).

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control parameters
Any specific protection and prevention measures should not be taken during use of the product.
8.2 Exposure controls
All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
Appropriate engineering controls: No relevant for this material.
Personal protective equipment
Handle with disposable gloves (EN 374). Wear appropriate protective safety eyewear and clothing, such as a lab coat.
Environmental exposure controls: No special measures are required.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties
Appearance/Physical State:
DetectFOB Reagent 1 (R1): Slightly yellowish solution
DetectFOB Latex Reagent 2 (R2): White coloured solution
DetectFOB Diluted calibrators (Cal 0-5): Transparent solution
DetectFOB Control C1: Transparent solution
DetectFOB Control C2 : Transparent solution
The following applies to R1, R2, FOB diluted Calibrator and Controls C1 & C2:
Odor: Odorless
PH: 7.5 – 8.5
Boiling Point: Similar to water (100°C)
Flash Point: Not applicable
Vapor Pressure: Similar to water (23hPa)
Melting Point: Similar to water (0°C)
Autoignition Temperature: Not determined
Partition Coefficient (n-octanol/water): Not determined
Explosion Limits: Not applicable
Vapor Density: Not determined
Relative Density: Similar to water (1g/cm^3)
Solubility: Soluble
Flammability: Not applicable
Viscosity: Not determined
Explosive Properties: Not explosive
Oxidizing Properties: Not determined

SECTION 10 STABILITY AND REACTIVITY
10.1 Reactivity
No hazardous reactivity known.
10.2 Chemical stability
Under storage at normal ambient temperatures the product is stable. No known hazardous reactions.
10.3 Possibility of hazardous reactions
Thermal decomposition can lead to release of irritating gases and vapors.
10.4 Conditions to avoid
Direct contact with a flame. Temperatures outside the range of 2-8°C. Avoid storing in places with high humidity and protect from light.
10.5 Incompatible materials
The stool sample should be treated only with buffer that is provided with the product before testing.
10.6 Hazardous decomposition products
No known hazardous decomposition products.

SECTION 11 TOXICOLOGICAL INFORMATION
11.1 Information of toxicological effects
Acute toxicity: Product does not present an acute toxicity hazard based on known or supplied information.
Skin corrosion/irritation: Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation: Based upon the available data, the classification criteria are not met.
Respiratory or skin sensitisation: Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity: Based upon the available data, the classification criteria are not met.
Carcinogenicity: A4-Not classifiable as a Human Carcinogen.
Reproductive toxicity: Based upon the available data, the classification criteria are not met.
Summary of evaluation of the CMR properties: Based upon the available data, the classification criteria are not met.
STOT - single exposure: Based upon the available data, the classification criteria are not met
STOT - repeated exposure: Based upon the available data, the classification criteria are not met
Aspiration hazard: Based upon the available data, the classification criteria are not met

SECTION 12 ECOLOGICAL INFORMATION
12.1 Toxicity
Based upon the available data, the classification criteria are not met. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.
12.2 Persistence and degradability
Based upon the available data, the classification criteria are not met.

12.3 Bioaccumulative potential
Based upon the available data, the classification criteria are not met.
12.4 Mobility in soil
Based upon the available data, the classification criteria are not met.
12.5 Results of PBT and vPvB assessment
No data available for assessment.
12.6 Other adverse effects
Based upon the available data, the classification criteria are not met.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Waste from residues: After testing, the product must be disposed of compliance with the respective local, state or national regulations. One option would be possible inactivation of infectious agents in the product after use. Performed in autoclave at a pressure and a certain temperature.
Non-contaminated packaging: The containers can be recycled.

SECTION 14 TRANSPORT INFORMATION

Maritime transport (IMDG/IMO): Not dangerous preparations not required transport regulations.
Land transport (ADR): Not dangerous preparations not required transport regulations.
Air Transport (IATA): Not dangerous preparations not required transport regulations.

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture:
This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE, do not carry the CE marking for marketing outside the EU. The product is a mixture which is not subject to Regulation (EC) No 1005/2009, (EC) No 850/2004.
National regulations: Please ask your national/regional authorities.
15.2 Chemical Safety Assessment
A Chemical Safety Assessment/Report has not been conducted.

SECTION 16 OTHER INFORMATION

Recommendations: Consult instructions for use prior to product use. Professional use only for *in vitro* diagnosis.
References (Previous version): RD 255/2003, of February 28, approving the Regulation on classification, packaging and labeling of dangerous preparations, which incorporates into Spanish law Directive 1999/45/CE, Directive 2001/60/CE and partly Directive 2001/58/CE. Directive 91/155/CE.
Changes: Update in accordance with Regulation (EC) No 1272/2008 and EU No 2015/830 (changes to all sections).
Abbreviations and acronyms:
STOT – Specific Target Organ Toxicity
PBT – Persistent, Bioaccumulative and Toxic
vPvB – very Persistent and very Bioaccumulative
Key literature references and sources for data: see instruction for use, Safety Data sheet and ECHA.
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: Annex I section 3 and 4; Annex VI Table 3.1 of Regulation (EC) No 1272/2008 was used for the purpose of classification.
Relevant H-statements (number and full text): None.
Training advice: No special training is required.
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Amended sections are indicated by a line in the border. The information supplied in this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text. We do not accept any liability for loss, injury or damage, which may result from its use.

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