Trade name: R3330000058 Hemo One+, Human haemoglobin (FOB)
R3330000064 Standard Set FOB
R3330000068 Control Set FOB

## *SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING*

### *1.1. Product identifier*

Product name:
**R3330000058 Hemo One+, Human haemoglobin (FOB)**
**R3330000064 Hemo One+, Standard Set FOB**
**R3330000068 Hemo One+, Control Set FOB**

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

*Relevant identified uses*:
Hemo One+, Human haemoglobin (FOB) is a latex turbidimetric assay for the quantitative detection of haemoglobin, Faecal Occult Blood (FOB) in human stool samples and is intended for use on the I.S.E. S.r.l. Hemo One analyser.

- Standard Set FOB must be used only for the calibration of the Human haemoglobin (FOB) assay.
- Control Set FOB C1 & C2 controls must be used only to verify the performance of the Human haemoglobin (FOB)

For professional in vitro diagnostic use only.

- Human haemoglobin (FOB) Reagent 1 (R1): buffer and sodium azide <0.1%.
- Human haemoglobin (FOB)Latex Reagent (R2): suspension of latex particles coated with antibodies anti-haemoglobin. Standard Set FOB: Protein in solution with preservatives.
- Control Set FOB Control C1: Protein solution with preservatives.
- Control Set FOB Control C2: Protein solution with preservatives.
- Uses advised against: No information available.

### *1.3. Company/undertaking identification*

Manufacturer:
I.S.E. S.r.l.
Via delle Driadi, 45
00133 Roma - Italia
Tel. +39 0774 579365; FAX +39 0774579305
E-mail: info@logotech-ise.com www.logotech-ise.com

***1.4. Emergency telephone number:*** Policlinico A. Gemelli - Largo Agostino Gemelli, 8 - Roma - Italy - Tel. + 39 063054343

## *SECTION 2: HAZARD 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***

Signal Word: **None**

***2.3 Other hazards:*** No hazards know***.***

## *SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS*

***3.1 Substances:*** No information available***.***

***3.2 Mixtures***

***Mixture description:***

FOB R1 contains buffer and <0.1% of sodium azide as preservative. FOBTurbilatex R2 contains latex coated particles and buffer.

Diluted Calibrators contains protein, buffer and preservatives.
Human haemoglobin (FOB) Control C1 contains buffer and preservatives. Human haemoglobin (FOB) Control C2 contains buffer and preservatives.

***3.2.1 Hazardous components:***

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

FOB diluted Calibrators is a protein solution containing buffer, detergent and <0.1% of sodium azide as preservative.
Human haemoglobin (FOB) Controls are a protein solution with <0.1% of sodium azide as preservative.

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

## *SECTION 4: FIRST-AID MEASURES*

### *4.1 Description of first aid measures*

- **Following eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.
- **Following skin contact:** Wash off immediately with soap and plenty of water. Consult a physician.
- **Following ingestion:** Clean mouth with water and drink afterwards plenty of water. Consult a physician.
- **Following inhalation:** 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: FIREFIGHTING 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 pressure-demand, 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 +2ºC to +8ºC, protect form the light.

***7.3 Specific end use(s):*** Only use these reagents with other Human haemoglobin (FOB) 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.
**Exposure limits:** Based upon the available data, the classification criteria are not met.

***8.2 Exposure controls:*** All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

***8.2.1 Appropriate engineering controls:*** No relevant for this material.

***8.2.2 Personal protective equipment:*** Handle with disposable gloves (EN 374). Wear appropriate protective safety eyewear and clothing, such as a lab coat.

***8.2.3 Environmental Exposure Controls:*** No special measures are required.

## *SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES*

### *9.1 Information on basic physical and chemical properties*

Trade name: R3330000058 Hemo One+, Human haemoglobin (FOB)
R3330000064 Standard Set FOB
R3330000068 Control Set FOB

**Appearance/Physical State** Human haemoglobin (FOB) Reagent 1 (R1): Slightly yellowish solution Human haemoglobin (FOB) Latex Reagent (R2): White colored solution Diluted calibrators (Cal 0-5): Transparent solution Human haemoglobin (FOB) Control C1: Transparent solution Human haemoglobin (FOB) Control C2: Transparent solution

The following table applies to R1 & R2, FOB diluted Calibrator and Controls C1&C2

| | | | |
|---|---|---|---|
| **Odor** | Odourless | **Explosion Limits** | Not applicable |
| **pH** | 7.5-8.5 | **Vapor Density** | Not determined |
| **Boiling Point** | Similar to water (100ºC) | **Relative density** | Similar to water (1g/cm$^3$) |
| **Flash Point** | Not applicable | **Solubility** | Soluble |
| **Vapor Pressure** | Similar to water (23hPa) | **Flammability** | Not applicable |
| **Melting Point** | Similar to water (0ºC) | **Viscosity** | Not determined |
| **Autoignition Temperature** | Not determined | **Explosive Properties** | Not explosive |
| **Partition Coefficient (n-octanol/water)** | Not determined | **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 on 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.
  - Contact I.S.E. S.r.l.

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  00133 Roma - Italia
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  E-mail: info@logotech-ise.com www.logotech-ise.com