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## **SECTION 1: Identification of the Substance/ Mixture and of the Company/ Undertaking**

### **1.1 Product identifier**

Product name: **Imidazole Buffer Solution used within ULTRASENSE Fibrinogen Assay Kit (HB-2222-FG) and The Fiix™ Test Kit (HB-4952-FG)**  
Product number: **HB-0346-SA for Kit HB-2222-FG**  
**HB-0481-SA for Kit HB-4952-FG**

### **1.2. Relevant identified uses of the substances or mixtures and uses advised against**

Imidazole Buffer Solution is a component of Hart Biologicals ULTRASENSE Fibrinogen Assay Kit and is supplied for the dilution of control samples, calibration standards and patient samples. Imidazole Buffer Solution is also a component within The Fiix™ Test Kit, supplied as a diluting fluid for the test system.  
The Imidazole Buffer Solution is provided liquid stable and ready to use.

### **1.3. Details of the supplier of the Safety Data Sheet**

Manufacturer: Hart Biologicals Ltd.  
Address: 2 Rivergreen Business Centre, Queens Meadow, Hartlepool, United Kingdom  
Postcode: TS25 2DL  
Telephone: +44 (0)1429 271100  
Fax: +44 (0)1429 277085  
Email: technical@hartbio.co.uk

### **1.4. Emergency Telephone Number**

Telephone Number: +44 (0)1429 271100  
Opening hours (UK, GMT): Monday - Thursday 08.00-16.30  
Friday 08.00-15.00

## **SECTION 2: Hazards Identification**

### **2.1 Classification of the substance/ mixture**


**2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]**  
Reproductive Toxicity Category 1B H360D

**2.1.2 Additional information**  
For the full text of H-phrases mentioned, see SECTION 16.

### **2.2 Label elements**

**Labelling according to Regulation (EC) No 1272/2008 [CLP]**

Hazard pictogram:  
Health Hazard Pictogram

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Signal word:  
Danger

Hazard statement(s):  
H360D May Damage the unborn child.

Precautionary statements:

P260 Do not breath dusts or mists.  
P280 Wear protective gloves/ protective clothing/eye protection/face protection.  
P301 + P312 IF SWALLOWED: Call a poison centre/doctor if you feel unwell.  
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison centre/doctor.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

Supplement Hazard Information: None.  
Intended to be used by professional users of IVD reagents.

### 2.3 Other hazards

None

## **SECTION 3: Composition/ Information on Ingredients**

### 3.1 Substances


Not Applicable, this product is regulated as a mixture.

### 3.2 Mixtures

Description of the mixture: Imidazole Buffer comprises of Imidazole 0.33% and 0.092% Sodium Azide as preservative. Imidazole is classifiable as hazardous in the mixture.

#### **Hazardous Ingredients:**

CAS No.	EC No.	Index No.	% Weight	Name	Classification (EC) No 1272/2008
288-32-4	206-019-2	613-319-00-0	0.33	Imidazole (1,3-Diaza-2,4-cyclopentadiene Glyoxaline)	Reproductive Toxicity Category 1B H360D >0.1% Limit.

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## **SECTION 4: First Aid Measures**

### **4.1 Description of first aid measures**

**General advice:** Consult a physician. Show this SDS to the doctor in attendance.

**After Inhalation:** If inhaled, remove person to fresh air. If breathing becomes difficult obtain immediate medical attention, give artificial respiration. Consult a physician.

**After Skin Contact:** Take off contaminated clothing and shoes immediately. Immediately wash skin with soap and copious amounts of water. Consult a physician.

**After Eye Contact:** Irrigate with copious amounts of clean fresh water for at least 15 minutes and consult an ophthalmologist. Remove contact lenses.

**After Ingestion:** Do NOT induce vomiting. Wash out mouth with water and make victim drink water, provided person is conscious. Never give anything by mouth to an unconscious person. Consult a doctor/ physician immediately. Do not attempt to neutralise.

**Self-protection for first aider:** Personal protective equipment for first aid responder is recommended.

### **4.2 Most important symptoms and effects both acute and delayed**

The most important symptoms and effects are described in section 2.2.

### **4.3 Indication of any immediate medical attention and special treatment**

No data available.

## **SECTION 5: Fire-fighting Measures**

### **5.1 Extinguishing media**

Suitable extinguishing media: Water, alcohol resistant foam, CO<sub>2</sub>, Dry Chemical Extinguisher.

### **5.2 Special hazards arising from the substance or mixture**

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>), Hydrogen cyanide (hydrocyanic acid).

### **5.3 Advice for firefighters**


Wear suitable protective clothing/ equipment. Wear self-contained breathing apparatus for firefighting if necessary.

## **SECTION 6: Accidental Release Measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

#### **6.1.1 For non-emergency personnel**

Protective Equipment: Exercise appropriate precautions to minimise direct contact with skin or eyes and prevent inhalation of vapours – Wear personal protective equipment (PPE) such as gloves, safety glasses.

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Emergency Procedures: Wear respiratory protection, avoid dust formation and avoid breathing vapours, dust, mist or gas. Ensure adequate ventilation and evacuate personnel to safe areas.

**6.1.2 For emergency responders**

Personal protective equipment for first aid responder/s is/ are recommended.

**6.2 Environmental precautions**

**6.2.1** Prevent further leakage or spillage if safe to do so and do not let product enter drains.

**6.3 Methods and material for containment and cleaning up**

**6.3.1 For containment:** Spillages should be contained using absorbent material to prevent contamination of drains and watercourses.

**6.3.2 For cleaning up:** Pick up and arrange disposal without additional leaking of material. Use adsorbent materials and wash spill site for decontamination after material pickup. Waste material from spillages should be disposed of in accordance with local regulations.

**6.3.3 Other information:** Spilled material may cause surfaces to become slippery, clear spills immediately.

**6.4 Reference to other sections**

Refer to section 8 for exposure controls and personal protection and sections 13 for disposal considerations.

**SECTION 7: Handling and Storage**

**7.1 Precautions for safe handling**

**7.1.1 Recommendations:** Wear appropriate PPE. Avoid contact with eyes, skin and clothing. For IVD Use Only. Not for medicinal use. DO NOT INGEST. Reduce the release of substance to the environment by avoiding spillages. For precautions see section 2.2.


**7.1.2 General occupational hygiene:** Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance. Do not eat, drink or smoke in work areas. Wash hands after use. Remove protective equipment before entering eating areas.

**7.2 Conditions for safe storage including any incompatibilities:**

Store securely in the original labelled container. Storage conditions according to product label.

**7.3 Specific end use:**

Use in accordance with product Instructions For Use provided in Kit. For In Vitro Diagnostic use only.

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## **SECTION 8: Exposure Controls/ Personal Protection**

### **8.1 Control Parameters**

**8.1.1 Components with workplace control parameters:** Contains no substances with occupational exposure limit values.

### **8.2 Exposure controls**

#### **8.2.1 Appropriate engineering controls:**

Follow good clinical hygiene practices adopting suitable individual protective measures. Avoid contact with skin, eyes and clothing. Do not eat or smoke while handling the product. Wash hands before breaks and immediately after handling the product.

#### **8.2.2 Personal Protection Equipment:**

##### **8.2.2.1 Eye/ face Protection:**

Wear safety glasses or goggles. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).

##### **8.2.2.2 Skin Protection:**

Handle with gloves. Gloves must be inspected prior to use to ensure good condition. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with good laboratory practice and applicable laws. Wash hands and dry. The selected protective gloves have to satisfy the specifications of Regulation (EU)2016/425 and the standard EN 374 derived from it.

##### **8.2.2.3 Body Protection:**

Wear laboratory coat/ work coat or apron in line with protective equipment at the specific work place.

##### **8.2.2.4 Respiratory Protection:**

Wear simple mask to prevent inhalation of dust / vapour.

##### **8.2.2.5 Thermal Hazards:**

Not applicable.


#### **8.2.3 Environmental Exposure Controls**

Prevent further leakage or spillage if safe to do so as described in section 6.3. Do not let product enter drains.

## **SECTION 9: Physical and Chemical Properties**

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

- a) **Physical State:** - Clear colourless solution housed in a HDPE bottle with screw cap seal.
- b) **Colour:** Colourless.
- c) **Odour:** Odourless.
- d) **Melting point/ freezing point:** No data available.

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- e) **Boiling point or Initial boiling point and boiling range:** No data available
- f) **Flammability (solid, gas):** No data available
- g) **Upper/ lower explosive limits:** No data available
- h) **Flash Point:** No data available
- i) **Auto-ignition temperature:** No data available
- j) **Decomposition temperature:** No data available
- k) **pH:** No data available
- l) **Kinematic viscosity:** No data available
- m) **Solubility:** No data available
- n) **Partition coefficient n-octanol/water (log value):** No data available
- o) **Vapour Pressure:** No data available
- p) **Density and/or relative density:** No data available
- q) **Relative vapour density:** No data available
- r) **Particle characteristics** No data available

## 9.2 Other safety information

### 9.2.1 – Information with Regard to Physical Hazard Classes

### 9.2.2 – Other Safety Characteristics.

## SECTION 10: Stability and Reactivity

**10.1 Reactivity:** No data available

**10.2 Chemical stability:** This product is stable in normal conditions of use and storage.

**10.3 Possibility of hazardous reactions:** No data available

**10.4 Conditions to avoid:** No data available

**10.5 Incompatible materials:** Bases, oxidising agents, iron and irons salts.

**10.6 Hazardous decomposition products:** No known hazardous decomposition products.

## SECTION 11: Toxicological Information

### 11.1 Information on toxicological effects:

**Acute Toxicity:** LD50 Oral – Rat – 970mg/kg

**Skin corrosion/ irritation:** Skin – Rabbit. Result – Causes Burns.

**Serious Eye damage/ irritation:** No data available

**Respiratory or skin sensitisation:** No data available

**Germ cell mutagenicity:** Did not show mutagenic effects in animal experiments.

**Carcinogenicity: IARC:** No data available


**Reproductive Toxicity:** May damage the unborn child. Presumed human reproductive toxicant.

**Summary of evaluation of the CMR properties:** No data available

**STOT-single exposure:** No data available

**STOT-repeated exposure:** No data available

**Aspiration hazard:** No data available

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**Additional Information:** RTECS: NI3325000

**11.2 Information on other hazards:**

**Endocrine disrupting properties:** The substance/mixture does not contain components considered to have endocrine disrupting properties.

**Other information:** None available.

**SECTION 12: Ecological Information**

**12.1 Toxicity:** Toxicity to daphnia and other aquatic invertebrates

	EC50 Daphnia (water flea) – 341.5mg/l 48 hours
Toxicity to Algae	static test EC50 – Scenedesmus quadricauda (Green algae) – 133mg/l 72 hours
Toxicity to bacteria	static test EC50 - activated sludge-> 1,000 mg/l-30 min

**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 Endocrine disrupting properties:** The substance/mixture does not contain components considered to have endocrine disrupting properties.

**12.7 Other adverse effects:** No data available

Use according to good clinical hygiene practices; avoid dispersion of the product in the environment.

**SECTION 13: Disposal Considerations**

**13.1 Waste treatment methods**

**Product:** Disposal of waste must always comply with existing EEC, national and local regulations. Registered waste carriers and licensed disposal sites must be used.

**Contaminated packaging:** Dispose of as unused product.

**SECTION 14: Transport Information**


**14.1 UN number or ID number:** No number available/ not required for mixture.

**14.2 UN Proper Shipping name:** Not required.

**14.3 Transport Hazard Classes:** Not required.

**14.4 Packaging Group:** Not required.

**14.5 Environmental Hazards:** Not required.

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**14.6 Special precautions for user:** Not required.

**14.7 Maritime transport in bulk according to IMO instruments:** It is not intended that this product is transported as bulk and therefore the shipping/ transport regulations for bulk hazardous material do not apply.

**SECTION 15: Regulatory Information**

**15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture:** This material safety data sheet complies with the requirements of Regulation (EC) No.1907/2006.

**15.2 Chemical Safety Assessment:** A product hazard assessment has been carried out for this product.

**SECTION 16: Other Information**

**Full text of H-Statements referred to under sections 2 and 3**

H360 D      May damage the unborn child

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

- Reproductive Toxicity Category 1B      Calculation Method

**Note for the user:** The data contained in this sheet is the result of the most up to date information available in our company. The user must ensure that the information is suitable and complete in relation to the specific use of the product.