	TITLE:	Safety Data Sheet – Imidazole Buffer for ULTRASENSE Fibrinogen Assay Kit				
	ID:	SDS013	Version:	1.0	Issue Date:	18-Dec-18

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Regulation (EU) No. 453/2010

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

1.1 Product identifier

Product name: **Imidazole Buffer for ULTRASENSE Fibrinogen Assay Kit**
Product number: **HB-0346-SA for Kit HB-2222-FG**

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

Imidazole Buffer is a component of Hart Biologicals ULTRASENSE Fibrinogen Assay Kit and is supplied for the dilution of control samples, calibration standards and patient samples. The Buffer 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 contact

Telephone Number: +44 (0)1429 271100
Opening hours (UK, GMT): Monday - Thursday 08.00-16.30
Friday 08.00-13.30

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:

P201	Obtain special instructions for use
P260	Do not breath dust/ fume/ gas/ mist/ vapours/ spray
P280	Wear protective gloves/ protective clothing/eye protection/face protection
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
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.
P308+P313	If exposed or concerned: Get medical advice/ attention.

Supplement Hazard Information: Not applicable
Intended to be used by professional users of IVD reagents

2.3 Other hazards

None

SECTION 3: Composition/ Information on Ingredients

3.1 Mixtures

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


Hazardous Ingredients:

CAS No	EC No	REACH No	% Weight	Name	Classification (EC) No 1272/2008
288-32-4	206-019-2	None available	0.33	Imidazole 1,3-Diaza-2,4-cyclopentadiene Glyoxaline	Reproductive Toxicity Category 1B H360D

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.

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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 a physician.

After Ingestion: Do NOT induce vomiting. Wash out mouth with water, provided person is conscious. Never give anything by mouth to an unconscious person. Consult a doctor/physician or poison centre.

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

SECTION 5: Fire-fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: Water, alcohol resistant foam, CO₂, Dry Chemical Extinguisher.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), 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.

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

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- 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:** 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.


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.

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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.

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.

8.2.3 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) | Appearance: | - Clear colourless solution housed in a HDPE bottle with screw cap seal |
| b) | Odour: | Odourless |
| c) | Odour threshold: | No data available |
| d) | pH: | Neutral |
| e) | Melting point/ freezing point: | Melting point/range: No data available |
| f) | Initial boiling point and boiling range: | No data available |
| g) | Flash Point: | No data available |
| h) | Evaporation Weight | No data available |
| i) | Flammability (solid, gas): | No data available |
| j) | Upper/ lower flammability or explosive limits: | No data available |
| k) | Vapour Pressure: | No data available |
| l) | Vapour Density: | No data available |
| m) | Relative Density | No data available |
| n) | Water Solubility | 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) | Oxidising Properties | No data available |

9.2 Other safety information

Water soluble

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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, copper.

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

Additional Information: RTECS: NI3325000

SECTION 12: Ecological Information

12.1 Toxicity: Toxicity to fish	static test LC50 – Leuciscus idus (Golden orfe) - 280mg/l 48 hours
Toxicity to daphnia	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	Micro-organisms – 45mg/l 0.5 hours


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

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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: 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

14.6 Special precautions for user: Not required

14.7 Transport in bulk according to Annex II MARPOL73/78 and the IBC Code: 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: No data available.

15.2 Chemical Safety Assessment: No chemical safety assessment has been carried out for this substance/ mixture by the supplier.

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.