

15.11.2021

Kit Components

Product code	Description
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16090/35	Troponin I HumaFIA SR
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Components:

[RGT]	Reagent Cartridge
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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.11.2021

Version number 1

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· **Trade name:** Troponin I HumaFIA SR

· **Article number:** 16090/35

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

No further relevant information available.

· **Application of the substance / the mixture** In Vitro Diagnostic

· 1.3 Details of the supplier of the safety datasheet

· **Manufacturer/Supplier:**

HUMAN Diagnostics Product (Beijing) Co., Ltd.

Unit 703, Yongchang Industry Park, No.3 Yongchang North Road, BDA 100176, Beijing, China

Tel: +86 10-6357-9937

· **Further information obtainable from:** Head office, phone: +86 10-6357-9937

· **1.4 Emergency telephone number:** During usual business hours: +86 10-6357-9937

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the CLP regulation.

· 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Precautionary statements**

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- **3.1 Substances.**

- **Information not relevant**

- **3.2 Chemical characterisation: Mixtures**

The product does not contain substances classified as being hazardous to human health or the environment pursuant to provisions set forth in Directive 76/548/EEC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to the statement.

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SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

- **After skin contact:**

In case of contact, immediately flush with plenty of water. Consult doctor in case of complaints.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** If symptoms persist consult doctor.

- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

- **5.3 Advice for firefighters**

- **Protective equipment:** Fire-fighters should wear appropriate protective equipment.

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective equipment. Keep unprotected persons away.

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

- **6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**

Extractors are required on all machines used for thermal processing or splinter removal processes.

- **Information about fire - and explosion protection:** No special measures required.

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- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Like Plastic
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Not applicable.
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Initial boiling point and boiling range:	Not applicable.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	Not applicable.
· Decomposition temperature:	Not applicable.
· Auto-ignition temperature:	Not applicable.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not applicable.
Upper:	Not applicable.
· Vapour pressure:	Not applicable.
· Density:	Not applicable.
· Relative density	Not applicable.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	Not applicable.
Solids content:	Not applicable.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

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- **Additional toxicological information:**

According to the currently available data, this product has not yet produced health damage. Anyway, it must be handle according to the good practices

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
18 01 07* | chemicals consisting of or containing hazardous substances
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|---------------------------------------|---------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· 14.4 Packing group	
· ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	not regulated
· UN "Model Regulation":	not regulated

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements**
 - P234 Keep only in original packaging.
 - P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 - P262 Do not get in eyes, on skin, or on clothing.
 - P281 Use personal protective equipment as required.
 - P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P337+P313 If eye irritation persists: Get medical advice/attention.
 - P401 Store in accordance with local/regional/national/international regulations.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.

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· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses 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 Harmonised 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.

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