

01.02.2022

### Kit Components

Product code	Description
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16090/20	CRP 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 01.02.2022

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:** CRP HumaFIA SR

- **Article number:** 16090/20

- **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:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Not applicable.
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<b>Initial boiling point and boiling range:</b>	Not applicable.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not applicable.
· <b>Auto-ignition temperature:</b>	Not applicable.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not applicable.
<b>Upper:</b>	Not applicable.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not applicable.
· <b>Relative density</b>	Not applicable.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Not applicable.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	Not applicable.
<b>Solids content:</b>	Not applicable.
· <b>9.2 Other information</b>	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 (carcinogenity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenity** 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

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

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

### 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.

### 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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**Trade name:** CRP HumaFIA SR**· 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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