

21.04.2020

### **Kit Components**

Product code	Description
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<b>ITC59082</b>	<b>IMTEC-Cardiolipin-Antibodies Combi</b>
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Components:

ITC59082 [CALG]	Calibrators IgG 1 - 5
ITC59082 [CALM]	Calibrators IgM 1 - 5
ITC59082 [NC]	Negative Control Serum
ITC59082 [PCG]	Positive Control Serum IgG
ITC59082 [PCM]	Positive Control Serum IgM
ITC59082 [WASH][20x]	Washing Buffer (Concentrate 20x)
ITC59082 [DIL]	Dilution Buffer
ITC59082 [CONG]	Conjugate Solution
ITC59082 [CONM]	Conjugate Solution
ITC59082 [SUB]	TMB Solution
ITC59082 [MTP]	Mikrotiter Plate

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Calibrators IgG 1 - 5
- **Article number:** ITC59082 [CALG]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Serum, human origin, liquid

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Trade name: Calibrators IgG 1 - 5

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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### according to 1907/2006/EC, Article 31

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Trade name: Calibrators IgG 1 - 5

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.3 - 7.7
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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Trade name: Calibrators IgG 1 - 5

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.9 %
· <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.
- **Additional toxicological information:**  
All sera or plasmas used to prepare the calibrator have been tested for the presence of HBsAg as well as HIV and HCV antibodies and found to be negative by validated methods. Since no test method can ultimately rule out the presence of infectious agents, the material should be considered potentially infectious.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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Trade name: Calibrators IgG 1 - 5

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No            |

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- |  |                 |
|--|-----------------|
| <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.

- **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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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Calibrators IgM 1 - 5
- **Article number:** ITC59082 [CALM]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Serum, human origin, liquid

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Trade name: Calibrators IgM 1 - 5

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.3 - 7.7
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.9 %
· <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.
- **Additional toxicological information:**  
All sera or plasmas used to prepare the calibrator have been tested for the presence of HBsAg as well as HIV and HCV antibodies and found to be negative by validated methods. Since no test method can ultimately rule out the presence of infectious agents, the material should be considered potentially infectious.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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Trade name: Calibrators IgM 1 - 5

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No            |

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**Human**

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## Safety data sheet

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Trade name: Calibrators IgM 1 - 5

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- |  |                 |
|--|-----------------|
| <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.

- **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.**

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Negative Control Serum
- **Article number:** ITC59082 [NC]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Serum, human origin, liquid

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Trade name: Negative Control Serum

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

#### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

#### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

#### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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**Human**

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## Safety data sheet

### according to 1907/2006/EC, Article 31

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Trade name: Negative Control Serum

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.3 - 7.7
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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Trade name: Negative Control Serum

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.5 %
· <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.
- **Additional toxicological information:**  
Each donor unit used in the preparation of negative control material [NC] has been tested and found non-reactive for the presence of HBsAg, anti-HCV and anti-HIV-1/HIV-2 (EN 13641). However, no known test method can offer complete assurance that products derived from human blood will not transmit Hepatitis, HIV or any other infectious agents. Therefore adequate safety precautions are recommended.

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |

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**Trade name: Negative Control Serum**

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- |  |                 |
|--|-----------------|
| • <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.

- **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.**

GB


**Human**

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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Positive Control Serum IgG
- **Article number:** ITC59082 [PCG]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Serum, human origin, liquid

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## according to 1907/2006/EC, Article 31

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Trade name: Positive Control Serum IgG

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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Trade name: Positive Control Serum IgG

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.3 - 7.7
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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Trade name: Positive Control Serum IgG

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.8 %
· <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.
- **Additional toxicological information:**  
Positive control [PC] is prepared from inactivated blood of positive donors. However, heat inactivation at 56 °C cannot offer complete assurance that the product will not transmit infectious agents. Adequate safety precautions are highly recommended. All products derived from human blood should be treated as potentially infectious.

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## Safety data sheet

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Trade name: Positive Control Serum IgG

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
-----------	---

- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |

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- |  |                 |
|--|-----------------|
| • <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.

- **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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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Positive Control Serum IgM
- **Article number:** ITC59082 [PCM]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Serum, human origin, liquid

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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Trade name: Positive Control Serum IgM

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.3 - 7.7
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.8 %
· <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.
- **Additional toxicological information:**  
Positive control [PC] is prepared from inactivated blood of positive donors. However, heat inactivation at 56 °C cannot offer complete assurance that the product will not transmit infectious agents. Adequate safety precautions are highly recommended. All products derived from human blood should be treated as potentially infectious.

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Trade name: Positive Control Serum IgM

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
-----------	---

- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |

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Revision: 21.04.2020

Trade name: Positive Control Serum IgM

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- |  |                 |
|--|-----------------|
| • <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.

- **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.**

GB


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# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Washing Buffer (Concentrate 20x)
- **Article number:** ITC59082 [WASH][20x]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.
- **Additional information:**  
EUH208 Contains 2-Methyl-2H-isothiazol-3-on. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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Trade name: Washing Buffer (Concentrate 20x)

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### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances in aqueous solution.

- **Dangerous components:**

CAS: 77-86-1	TRIS	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤2.5%
EINECS: 201-064-4			

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** Goggles recommended during refilling

## 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 at 20 °C:** 6.7 - 7.1
- **Change in condition**

Melting point/freezing point:	Undetermined.
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**Human**

Diagnostics Worldwide

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

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Trade name: Washing Buffer (Concentrate 20x)

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<b>Initial boiling point and boiling range:</b> 100 °C	
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	Not determined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	79.9 %
· <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.

#### · LD/LC50 values relevant for classification:

#### ATE (Acute Toxicity Estimates)

Oral	LD50	52,632 mg/kg
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**Human**

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## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

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**Trade name: Washing Buffer (Concentrate 20x)**

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Dermal	LD50	157,895 mg/kg
Inhalative	LC50/4 h	26.3 mg/l

**CAS: 7647-14-5 sodium chloride**

Oral	LD50	3,000 mg/kg (rat)
------	------	-------------------

**CAS: 77-86-1 TRIS**

Oral	LD50	5,900 mg/kg (rat)
------	------	-------------------

- **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.
- **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 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **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.

<b>European waste catalogue</b>	
18 01 06*	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.

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## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 21.04.2020

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Trade name: Washing Buffer (Concentrate 20x)

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#### 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   |
| · 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   |

#### 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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## Safety data sheet

### according to 1907/2006/EC, Article 31

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Trade name: Washing Buffer (Concentrate 20x)

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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.

- **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

- **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **\* Data compared to the previous version altered.**

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Dilution Buffer
- **Article number:** ITC59082 [DIL]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances in aqueous solution.

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# Safety data sheet

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Trade name: Dilution Buffer

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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Trade name: Dilution Buffer

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- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:** Goggles recommended during refilling

## SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Red
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value at 20 °C:** 7.1 - 7.5
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not determined.

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Trade name: Dilution Buffer

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Water:	97.1 %
· <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.

### LD/LC50 values relevant for classification:

CAS: 7647-14-5 sodium chloride

Oral LD50 3,000 mg/kg (rat)

- **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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Trade name: Dilution Buffer

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- **Additional toxicological information:**

This product contains components from animal origin. Being of non-primate origin, these components avoid most of the risks associated with components based on human origin (e.g. Hepatitis B and C and HIV). Nevertheless this product should be handled as if potentially infectious.

- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **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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## Safety data sheet

### according to 1907/2006/EC, Article 31

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Revision: 21.04.2020

**Trade name: Dilution Buffer**

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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

## 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.

- **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

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**Human**

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## Safety data sheet

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**Trade name: Dilution Buffer**

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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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

. \* **Data compared to the previous version altered.**

GB

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

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

- **1.1 Product identifier**
- **Trade name:** Conjugate Solution
- **Article number:** ITC59082 [CONG]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.
- **Additional information:**  
EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

GB

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**Human**

Diagnostics Worldwide

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.04.2020

Version number 4

Revision: 21.04.2020

Trade name: Conjugate Solution

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### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances in aqueous solution.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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## Safety data sheet according to 1907/2006/EC, Article 31

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Trade name: Conjugate Solution

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- **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:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Yellowish
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.2
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.

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· Ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	23 hPa
· Density at 20 °C:	1 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
Water:	75.3 %
· 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.
- **Additional toxicological information:**  
This product contains components from animal origin. Being of non-primate origin, these components avoid most of the risks associated with components based on human origin (e.g. Hepatitis B and C and HIV). Nevertheless this product should be handled as if potentially infectious.

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
-----------	---

- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |

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- |  |                 |
|--|-----------------|
| • <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.

- **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.**

GB


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

- **1.1 Product identifier**
- **Trade name:** Conjugate Solution
- **Article number:** ITC59082 [CONM]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.
- **Additional information:**  
EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.
- **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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances in aqueous solution.
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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- **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:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Yellowish
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7.2
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.

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· Ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	23 hPa
· Density at 20 °C:	1 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
Water:	75.3 %
· 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.
- **Additional toxicological information:**  
This product contains components from animal origin. Being of non-primate origin, these components avoid most of the risks associated with components based on human origin (e.g. Hepatitis B and C and HIV). Nevertheless this product should be handled as if potentially infectious.

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- **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:** Not hazardous for water.
- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated |

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- |  |                 |
|--|-----------------|
| • <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.

- **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.**

GB


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

- **1.1 Product identifier**
- **Trade name:** TMB Solution
- **Article number:** ITC59082 [SUB]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Repr. 1B H360D May damage the unborn child.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



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- **Signal word** Danger
- **Hazard-determining components of labelling:**  
N-methyl-2-pyrrolidone
- **Hazard statements**  
H360D May damage the unborn child.
- **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.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances in aqueous solution.

- **Dangerous components:**

CAS: 872-50-4	N-methyl-2-pyrrolidone	2.5-5%
EINECS: 212-828-1	⚠ Repr. 1B, H360D; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

- **SVHC**

CAS: 872-50-4	N-methyl-2-pyrrolidone
---------------	------------------------

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation  
Do not breathe gas/fume/vapours/spray.  
Wear protective clothing.  
Avoid contact with skin, eyes and clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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### 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.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Use local exhaust ventilation for open handling.
- Do not breathe gas/fume/vapours/spray.

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

### 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:

#### CAS: 872-50-4 N-methyl-2-pyrrolidone

WEL	Short-term value: 80 mg/m <sup>3</sup> , 20 ppm
	Long-term value: 40 mg/m <sup>3</sup> , 10 ppm
Sk	

### DNELs

CAS: 872-50-4

Name: N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone

DNEL values:

DNEL employees, long-term; Route of exposure: inhalation; Effect: systemic; Value: 14.4 mg / m<sup>3</sup>

DNEL employees, long-term; Route of exposure: dermal; Effect: systemic; Value: 4.8 mg / kg bw / d

### Additional information: The lists valid during the making were used as basis.

### 8.2 Exposure controls

#### Personal protective equipment:

#### General protective and hygienic measures:

- Establish and observe skin protection plan.
- Do not eat, drink, smoke or sniff while working.
- Wash hands before breaks and at the end of work.

#### Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

#### Protection of hands:

- Protective gloves for handling chemicals must meet the requirements of the European standard EN 374.
- The following glove materials are not suitable due to degradation, strong swelling or low breakthrough time: Natural rubber/ latex, Polychloropren, Nitril rubber, fluororubber, Polyvinyl chloride
- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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**

Butyl rubber, BR

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**

Penetration time (maximum wearing time): 480 min

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Frame glasses with side shield

## SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Liquid
Colour:	Colourless

• Odour:	Odourless
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• Odour threshold:	Not determined.
--------------------	-----------------

• pH-value at 20 °C:	3.7
----------------------	-----

- **Change in condition**

Melting point/freezing point:	Undetermined.
-------------------------------	---------------

Initial boiling point and boiling range:	100 °C
--	--------

• Flash point:	Not applicable.
----------------	-----------------

• Flammability (solid, gas):	Not applicable.
------------------------------	-----------------

• Decomposition temperature:	Not determined.
------------------------------	-----------------

• Auto-ignition temperature:	Product is not selfigniting.
------------------------------	------------------------------

• Explosive properties:	Product does not present an explosion hazard.
-------------------------	---

- **Explosion limits:**

Lower:	Not determined.
--------	-----------------

Upper:	Not determined.
--------	-----------------

• Vapour pressure at 20 °C:	23 hPa
-----------------------------	--------

• Density:	Not determined.
------------	-----------------

• Relative density	Not determined.
--------------------	-----------------

• Vapour density	Not determined.
------------------	-----------------

• Evaporation rate	Not determined.
--------------------	-----------------

• Solubility in / Miscibility with water:	Fully miscible.
---	-----------------

• Partition coefficient: n-octanol/water:	Not determined.
---	-----------------

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- |                                |  |
|--------------------------------|--|
| · <b>Viscosity:</b>            |  |
| <b>Dynamic:</b>                | Not determined.                            |
| <b>Kinematic:</b>              | Not determined.                            |
| · <b>Solvent content:</b>      |  |
| <b>Organic solvents:</b>       | 0.0 %                                      |
| <b>Water:</b>                  | 99.9 %                                     |
| · <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**  
 Light sensitive.  
 Store away from heat.  
 Stable if the recommended storage and handling instructions are followed.
- **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.

#### · LD/LC50 values relevant for classification:

CAS: 872-50-4 N-methyl-2-pyrrolidone

Oral	LD50	3,914 mg/kg (rat)
Dermal	LD50	8,000 mg/kg (rabbit)

- **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.
- **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**  
 May damage the unborn child.
- **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.

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- **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 06* | 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   |
| • <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   |

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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**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



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- **Signal word** Danger
- **Hazard-determining components of labelling:**  
N-methyl-2-pyrrolidone
- **Hazard statements**  
H360D May damage the unborn child.
- **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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 30, 71, 72
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**

#### Substances of very high concern (SVHC) according to REACH, Article 57

CAS: 872-50-4 | N-methyl-2-pyrrolidone

- **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.

- **Relevant phrases**
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
  - H360D May damage the unborn child.
- **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

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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)  
DNEL: Derived No-Effect Level (REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
SVHC: Substances of Very High Concern  
vPvB: very Persistent and very Bioaccumulative  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Repr. 1B: Reproductive toxicity – Category 1B  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

• **\* Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** Mikrotiter Plate
- **Article number:** ITC59082 [MTP]
- **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 data sheet**
- **Manufacturer/Supplier:**  
HUMAN Gesellschaft für Biochemica und Diagnostica mbh  
Max-Planck-Ring 21  
65205 Wiesbaden  
Germany  
phone +49 (0) 6122 99 88 0  
fax: +49 (0) 6122 99 88 100  
eMail: human@human.de
- **Further information obtainable from:** Head office, phone: +49 (0) 6122 99 88 0
- **1.4 Emergency telephone number:**  
INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

### 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.  
P281 Use personal protective equipment as required.  
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.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** solid polystyrene strips, breakable, coated with recombinant antigen(s)
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.

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**Trade name: Mikrotiter Plate**

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- **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.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Not required.
- **6.2 Environmental precautions:** No special measures required.
- **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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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**Trade name: Mikrotiter Plate**

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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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:	Solid
Colour:	Colourless
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.

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· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> <b>Dynamic:</b> <b>Kinematic:</b>	Not applicable. Not applicable.
· <b>Solvent content:</b>	
<b>Solids content:</b>	100.0 %
· <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.
- **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:** Not hazardous for water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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## Safety data sheet

### according to 1907/2006/EC, Article 31

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- **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 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | not regulated   |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | not regulated   |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | not regulated   |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | not regulated   |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> </ul>  |                 |
| <ul style="list-style-type: none"> <li>· <b>ADR</b></li> <li>· <b>Limited quantities (LQ)</b></li> </ul>  | not regulated   |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>   | 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.  
P281 Use personal protective equipment as required.

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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.

### · **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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