

31.05.2023

Kit Components

Product code	Description
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ITC59071	IMTEC-Cardiolipin-Antibodies IgG
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Components:

ITC59071 [CAL]	Calibrators IgG 1 - 5
ITC59071 [NC]	Negative Control Serum
ITC59071 [PC]	Positive Control Serum
ITC59071 [WASH][20x]	Washing Buffer (Concentrate 20x)
ITC59071 [DIL]	Dilution Buffer
ITC59071 [CON]	Conjugate Solution
ITC59071 [SUB]	TMB Solution
ITC59071 [STOP]	Stop Solution
ITC59071 [MTP]	Mikrotiter Plate

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.05.2023

Version number 6 (replaces version 5)

Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name:** Calibrators IgG 1 - 5
- **Article number:** ITC59071 [CAL]
- **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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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Trade name: Calibrators IgG 1 - 5

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SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Serum, human origin, liquid
- **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** 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.

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- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Red
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** No information available.
- **Lower and upper explosion limit**
- **Lower:** No information available.
- **Upper:** No information available.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** No information available.

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· Decomposition temperature:	No information available.
· pH at 20 °C	7.3-7.7
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	97.9 %
· Solids content:	0.9 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **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.

· Endocrine disrupting properties

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **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.

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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 or ID 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 Maritime transport in bulk according to IMO instruments

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.

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- 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.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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.

- **Version number of previous version:** 5

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

- **1.1 Product identifier**
- **Trade name:** Negative Control Serum
- **Article number:** ITC59071 [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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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Trade name: Negative Control Serum

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SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Serum, human origin, liquid
- **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** 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.

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- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Red
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** No information available.
- **Lower and upper explosion limit**
- **Lower:** No information available.
- **Upper:** No information available.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** No information available.

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Trade name: Negative Control Serum

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· Decomposition temperature:	No information available.
· pH at 20 °C	7.3-7.7
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	97.5 %
· Solids content:	0.9 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **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.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **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.

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Safety data sheet

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Trade name: Negative Control Serum

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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

· 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments

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.

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.05.2023

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Revision: 31.05.2023

Trade name: Negative Control Serum

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- 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.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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.

- **Version number of previous version:** 5

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.05.2023

Version number 6 (replaces version 5)

Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name:** Positive Control Serum
- **Article number:** ITC59071 [PC]
- **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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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Trade name: Positive Control Serum

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SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Serum, human origin, liquid
- **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** 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.

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Safety data sheet

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Version number 6 (replaces version 5)

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Trade name: Positive Control Serum

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- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Red
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** No information available.
- **Lower and upper explosion limit**
- **Lower:** No information available.
- **Upper:** No information available.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** No information available.

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Trade name: Positive Control Serum

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· Decomposition temperature:	No information available.
· pH at 20 °C	7.3-7.7
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information	
· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	97.8 %
· Solids content:	0.9 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.

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Trade name: Positive Control Serum

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **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.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **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.

(Contd. on page 6)

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Version number 6 (replaces version 5)

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Trade name: Positive Control Serum

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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

· 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments

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.

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Trade name: Positive Control Serum

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- 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.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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.

- **Version number of previous version:** 5

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 6 (replaces version 5)

Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name: Washing Buffer (Concentrate 20x)**
- **Article number:** ITC59071 [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**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
2-Methyl-2H-isothiazol-3-on
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **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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Human

Diagnostics Worldwide

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Revision: 31.05.2023

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

(Contd. of page 1)

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.

- **vPvB:**

This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 77-86-1 EINECS: 201-064-4	TRIS ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤2.5%
CAS: 2682-20-4 EINECS: 220-239-6	2-Methyl-2H-isothiazol-3-on ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; ⚠ Skin Corr. 1B, H314; Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); ⚠ Skin Sens. 1A, H317, EUH071 Specific concentration limit: Skin Sens. 1A; H317: C ≥ 0.0015 %	≥0.1-<0.25%

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

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.05.2023

Version number 6 (replaces version 5)

Revision: 31.05.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 2)

- **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.
- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Colour:	Colourless
· Odour:	Odourless
· Odour threshold:	No information available.
· Melting point/freezing point:	No information available.
· Boiling point or initial boiling point and boiling range	100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
· Flammability	No information available.
· Lower and upper explosion limit	
· Lower:	No information available.
· Upper:	No information available.
· Flash point:	Not applicable.
· Auto-ignition temperature:	No information available.
· Decomposition temperature:	No information available.
· pH at 20 °C	6.7-7.1
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic:	No information available.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	79.9 %
· Solids content:	17.9 %
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void

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Human

Diagnostics Worldwide

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· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **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
Dermal	LD50	157,895 mg/kg
Inhalative	LC50/4 h	26.3 mg/l

CAS: 77-86-1 TRIS

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

CAS: 2682-20-4 2-Methyl-2H-isothiazol-3-on

Oral	LD50	100 mg/kg (ATE)
Dermal	LD50	300 mg/kg (ATE)
Inhalative	LC50/4 h	0.05 mg/l (ATE)

- **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** May cause an allergic skin reaction.
- **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.

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

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- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.

- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

- **12.7 Other adverse effects**

- **Additional ecological information:** No further relevant indications

- **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.

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

- **14.1 UN number or ID 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

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- | | |
|---|-----------------|
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | 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**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
2-Methyl-2H-isothiazol-3-on
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **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

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

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· REGULATION (EU) 2019/1148
· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

CAS: 7647-01-0 | hydrogen chloride

3

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

CAS: 7647-01-0 | hydrogen chloride

3

· 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

H301 Toxic if swallowed.
 H311 Toxic in contact with skin.
 H314 Causes severe skin burns and eye damage.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 H330 Fatal if inhaled.
 H335 May cause respiratory irritation.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 EUH071 Corrosive to the respiratory tract.

· Date of previous version: 31.05.2023

· Version number of previous version: 5

· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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
 Acute Tox. 3: Acute toxicity – Category 3
 Acute Tox. 2: Acute toxicity – Category 2
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Skin Sens. 1: Skin sensitisation – Category 1
 Skin Sens. 1A: Skin sensitisation – Category 1A
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· * Data compared to the previous version altered.

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Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name:** Dilution Buffer
- **Article number:** ITC59071 [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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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Trade name: Dilution Buffer

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SECTION 3: Composition/information on ingredients

- **3.2 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**
- **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** 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.

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- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Red
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** No information available.
- **Lower and upper explosion limit**
- **Lower:** No information available.
- **Upper:** No information available.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** No information available.

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· Decomposition temperature:	No information available.
· pH at 20 °C	7.1-7.5
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	97.1 %
· Solids content:	1.8 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **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.

· Endocrine disrupting properties

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **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.

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Trade name: Dilution Buffer

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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 or ID 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 Maritime transport in bulk according to IMO instruments

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.

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- 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.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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.

- **Version number of previous version: 5**

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

IE

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.05.2023


Version number 6 (replaces version 5)

Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name:** Conjugate Solution
- **Article number:** ITC59071 [CON]
- **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**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
 - **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**
- 

GHS07
- **Signal word** Warning
 - **Hazard-determining components of labelling:**
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)
 - **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
 - **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.

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Human

Diagnostics Worldwide

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Trade name: Conjugate Solution

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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.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.

- **vPvB:**

This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

- **Description:** Mixture of substances in aqueous solution.

- **Dangerous components:**

CAS: 55965-84-9	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)	≥0.0025-<0.025%
	<ul style="list-style-type: none"> ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; ⚠ Skin Corr. 1C, H314; Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100); ⚠ Skin Sens. 1A, H317 	
	Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 %	
	Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %	
	Eye Dam. 1; H318: C ≥ 0.6 %	
	Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 %	
	Skin Sens. 1A; H317: C ≥ 0.0015 %	

- **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 and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **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.

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- **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** 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).
Ensure adequate ventilation.
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Not required.
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· Hand protection



Protective gloves

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/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Colour:	Yellowish
· Odour:	Odourless
· Odour threshold:	No information available.
· Melting point/freezing point:	No information available.
· Boiling point or initial boiling point and boiling range	100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
· Flammability	No information available.
· Lower and upper explosion limit	
· Lower:	No information available.
· Upper:	No information available.
· Flash point:	Not applicable.
· Auto-ignition temperature:	No information available.
· Decomposition temperature:	No information available.
· pH at 20 °C	7.2
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic:	No information available.
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

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- **9.2 Other information**
- **Appearance:**
- **Form:** Liquid
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **Water:** 75.3 %
- **Solids content:** 0.7 %
- **Change in condition**
- **Evaporation rate** No information available.

- **Information with regard to physical hazard classes**

- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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· LD/LC50 values relevant for classification:

CAS: 55965-84-9 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)

Oral	LD50	100 mg/kg (ATE)
Dermal	LD50	50 mg/kg (ATE)
Inhalative	LC50/4 h	0.05 mg/l (ATE)

- **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** May cause an allergic skin reaction.
- **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.
- **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.

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **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.

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 or ID 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 Maritime transport in bulk according to IMO instruments	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**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
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)
- **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

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· 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

· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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.

· Relevant phrases

- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· Version number of previous version: 5

· Abbreviations and acronyms:

- ADR: Accord relatif au transport international 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

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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
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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Revision: 31.05.2023

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

- **1.1 Product identifier**
- **Trade name:** TMB Solution
- **Article number:** ITC59071 [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**
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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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Trade name: TMB Solution

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

· **Description:** Mixture of substances in aqueous solution.

· Dangerous components:

CAS: 616-45-5	2-pyrrolidone	⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	1-3%
EINECS: 210-483-1			

· **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 clothing.
- **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.

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- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:**
No further requirements.
Keep container tightly sealed.
- **7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:** Do not eat, drink, smoke or sniff while working.
- **Respiratory protection:** Not required.
- **Hand protection**
Protective gloves for handling chemicals must meet the requirements of the European standard EN 374.
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**
Nitrile rubber, NBR
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/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Colourless
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** 0 °C
- **Boiling point or initial boiling point and boiling range** 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
- **Flammability** No information available.
- **Lower and upper explosion limit**
- **Lower:** No information available.

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· Upper:	No information available.
· Flash point:	Not applicable.
· Decomposition temperature:	No information available.
· pH at 20 °C	3.7
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Water:	95.0 %
· Solids content:	0.0 %
· Molecular weight	18.02 g/mol
· Change in condition	
· Evaporation rate	No information available.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	10,937 mg/kg (rat)
------	------	--------------------

CAS: 616-45-5 2-pyrrolidone

Oral	LD50	328 mg/kg (rat)
------	------	-----------------

- **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.
- **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.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications

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- **General notes:** Not hazardous for water.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

18 01 07 | chemicals other than those mentioned in 18 01 06

- **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 or ID 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 Maritime transport in bulk according to IMO instruments | 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.

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- 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.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

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.

- **Relevant phrases**

H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.

- **Version number of previous version: 5**

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

Acute Tox. 4: Acute toxicity – Category 4

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

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

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

- **1.1 Product identifier**
- **Trade name:** Stop Solution
- **Article number:** ITC59071 [STOP]
- **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**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
- **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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
sulphuric acid
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **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.

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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.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.

- **vPvB:**

This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**

- **Description:** Mixture of substances in aqueous solution.

- **Dangerous components:**

CAS: 7664-93-9	sulphuric acid	≥2.5-<5%
EINECS: 231-639-5	<ul style="list-style-type: none"> ⚠ Met. Corr. 1, H290; Skin Corr. 1A, H314 Specific concentration limits: Skin Corr. 1A; H314: C ≥ 15 % <li style="padding-left: 20px;">Skin Irrit. 2; H315: 5 % ≤ C < 15 % <li style="padding-left: 20px;">Eye Irrit. 2; H319: 5 % ≤ C < 15 % 	

- **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:** In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **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** Not required.

- **6.2 Environmental precautions:** Dilute with plenty of water.

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- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 7664-93-9 sulphuric acid

OEL	Long-term value: 0.05 mg/m ³
IOELV	

- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



Protective gloves

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**

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/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

- **General Information**

· Colour:	Colourless
· Odour:	Odourless
· Odour threshold:	No information available.
· Melting point/freezing point:	0 °C
· Boiling point or initial boiling point and boiling range	100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
· Flammability	No information available.
· Lower and upper explosion limit	
· Lower:	No information available.
· Upper:	No information available.
· Flash point:	Not applicable.
· Auto-ignition temperature:	No information available.
· Decomposition temperature:	No information available.
· pH at 20 °C	<1
· Viscosity:	
· Kinematic viscosity	No information available
· Dynamic at 20 °C:	0.952 mPas
· Solubility	
· water:	Fully miscible.
· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure at 20 °C:	23 hPa
· Density and/or relative density	
· Density at 20 °C:	1.0232 g/cm ³
· Relative density	No information available.
· Vapour density	No information available.

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- **9.2 Other information**
- **Appearance:**
- **Form:** Liquid
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **Water:** 97.2 %
- **Solids content:** 0.0 %
- **Molecular weight:** 18.02 g/mol
- **Change in condition**
- **Evaporation rate:** No information available.

- **Information with regard to physical hazard classes**

- **Explosives:** Void
- **Flammable gases:** Void
- **Aerosols:** Void
- **Oxidising gases:** Void
- **Gases under pressure:** Void
- **Flammable liquids:** Void
- **Flammable solids:** Void
- **Self-reactive substances and mixtures:** Void
- **Pyrophoric liquids:** Void
- **Pyrophoric solids:** Void
- **Self-heating substances and mixtures:** Void
- **Substances and mixtures, which emit flammable gases in contact with water:** Void
- **Oxidising liquids:** Void
- **Oxidising solids:** Void
- **Organic peroxides:** Void
- **Corrosive to metals:** Void
- **Desensitised explosives:** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity:** Based on available data, the classification criteria are not met.

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· LD/LC50 values relevant for classification:
· CAS: 7664-93-9 sulphuric acid
Inhalative inhalative 510 mg/m ³ (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

· Endocrine disrupting properties
None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **General notes:**
Not hazardous for water.
Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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.

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SECTION 14: Transport information

· 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments	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
The product is classified and labelled according to the CLP regulation.
- Hazard pictograms



GHS07

- Signal word Warning
- Hazard-determining components of labelling:
sulphuric acid
- Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- 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.

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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

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

CAS: 7664-93-9 sulphuric acid	3
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· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

CAS: 7664-93-9 sulphuric acid	3
-------------------------------	---

- **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**

H290 May be corrosive to metals.
 H314 Causes severe skin burns and eye damage.

· **Version number of previous version: 5**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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
 Met. Corr.1: Corrosive to metals – Category 1
 Skin Corr. 1A: Skin corrosion/irritation – Category 1A
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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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:** ITC59071 [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:**
This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) at concentrations of 0.1% or higher.
- **vPvB:**
This substance/mixture does not contain components classified as either very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

SECTION 3: Composition/information on ingredients

- **3.2 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.

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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** 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)** Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

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SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection**
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/face protection** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Colourless
- **Odour:** Odourless
- **Odour threshold:** No information available.
- **Melting point/freezing point:** No information available.
- **Boiling point or initial boiling point and boiling range** No information available.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** No information available.
- **Upper:** No information available.
- **Flash point:** Not applicable.
- **Decomposition temperature:** No information available.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Insoluble.

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· Partition coefficient n-octanol/water (log value)	No information available.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	No information available.
· Relative density	No information available.
· Vapour density	Not applicable.
· Particle characteristics	See section 3.
9.2 Other information	
· Appearance:	
· Form:	Solid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Solids content:	100.0 %
· Change in condition	
· Evaporation rate	Not applicable.
Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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.

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SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:** No further relevant indications
- **General notes:** Not hazardous for water.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
- 18 01 07 | chemicals other than those mentioned in 18 01 06
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, ADN, IMDG, IATA** not regulated

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· 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:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	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.
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.
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.

· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

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- **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.

- **Version number of previous version:** 5

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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