03.02.2021	Kit Components
Product code	Description
ITC59050	IMTEC-B2-Glycoprotein I-Antibodies Screen
Components:	
ITC59050 [CAL]	Calibrators IgGAM 1 - 6
ITC59050 [NC]	Negative Control Serum
ITC59050 [PC]	Positive Control Serum
ITC59050 [WASH][20x]	Washing Buffer (Concentrate 20x)
ITC59050 [DIL]	Dilution Buffer
ITC59050 [CON]	Conjugate Solution
ITC59050 [SUB]	TMB Solution
ITC59050 [STOP]	Stop Solution
ITC59050 [MTP]	Mikrotiter Plate

Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1 Product identifier · Trade name: Calibrators IgGAM 1 - 6 · Article number: ITC59050 [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, availibility 24h per day (in german and english) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void Precautionary statements P234 Keep only in original packaging. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P281 Use personal protective equipment as required. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · 2.3 Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. SECTION 3: Composition/information on ingredients

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

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Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Calibrators IgGAM 1 - 6

(Contd. of page 1)

- · 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 7 for information on sale handling.
- See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- No further requirements.
- Keep container tightly sealed.

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Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Calibrators IgGAM 1 - 6

(Contd. of page 2)

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

• 9.1 Information on basic physical a · General Information	nd chemical properties	
· Appearance:		
Form:	Liquid	
Colour:	Red	
· Odour:	Odourless	
· Odour threshold:	Not determined.	
· pH-value at 20 °C:	7.5	
 Change in condition Melting point/freezing point: Initial boiling point and boiling rate 	Undetermined. nge: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
· Ignition temperature:	Not determined.	
· Decomposition temperature:	Not determined.	
		(Contd. on page 4)



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Calibrators IgGAM 1 - 6

		(Contd. of page 3)
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
 Explosion limits: Lower: Upper: 	Not determined. Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
 Density at 20 °C: Relative density Vapour density Evaporation rate 	1 g/cm ³ Not determined. Not determined. Not determined.	
 Solubility in / Miscibility with water: 	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
 Solvent content: Organic solvents: Water: 	0.0 % 97.9 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Additional toxicological information: All donor units of human origin have been tested for HBsAg, HIV and HCV-antibodies and found to be negative using approved methods. However, the material should still be regarded as potentially infectious.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.

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Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

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Trade name: Calibrators IgGAM 1 - 6

- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

· Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informat	tion	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated	
 · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA 	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
 14.4 Packing group ADR, IMDG, IATA 	not regulated	
 · 14.5 Environmental hazards: · Marine pollutant: 	No	
		(Contd. on page 6)



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Version number 5

Revision: 03.02.2021

Trade name: Calibrators IgGAM 1 - 6

		(Contd. of page 5
 14.6 Special precautions for user 	Not applicable.	
· 14.7 Transport in bulk according to An	nex II of	
Marpol and the IBC Code	Not applicable.	
· Transport/Additional information:		
· ADR		
 Limited quantities (LQ) 	not regulated	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void · Precautionary statements Keep only in original packaging. P234 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. If eye irritation persists: Get medical advice/attention. P337+P313 Store in accordance with local/regional/national/international regulations. P401 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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

 Abbreviations and acronyms:
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

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

- · 1.1 Product identifier
- · Trade name: Negative Control Serum
- · Article number: ITC59050 [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, availibility 24h per day (in german and english)

SECTION 2: Hazards identification

· Classification ac	n of the substance or mixture cording to Regulation (EC) No 1272/2008 t classified, according to the CLP regulation.
· 2.2 Label elemen	
-	ing to Regulation (EC) No 1272/2008 Void
Hazard pictogram	
· Signal word Void	
· Hazard statemen	
Precautionary st	
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	3 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	3 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 hazard	•
	nd vPvB assessment

• **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Negative Control Serum

(Contd. of page 1)

- · 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 7 for information on sale 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.

(Contd. on page 3)



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Negative Control Serum

• 7.3 Specific end use(s) No further relevant information available. (Contd. of page 2)

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical ar General Information 	nd chemical properties	
· Appearance:	Linuid	
Form: Colour:	Liquid	
· Odour:	Red Odourless	
· Odour threshold:	Not determined.	
· pH-value at 20 °C:	7.5	
 Change in condition Melting point/freezing point: Initial boiling point and boiling rar 	Undetermined. ige: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
Ignition temperature:	Not determined.	
· Decomposition temperature:	Not determined.	
		(Contd. on page 4)

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Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Negative Control Serum

		(Contd. of page 3)
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
· Density at 20 °C:	1 g/cm ³	
· Relative density	Not determined.	
· Vapour density	Not determined.	
 Evaporation rate 	Not determined.	
 Solubility in / Miscibility with 		
water:	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· Solvent content:		
Organic solvents:	0.0 %	
Water:	97.4 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- \cdot Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

• Additional toxicological information: All donor units of human origin have been tested for HBsAg, HIV and HCV-antibodies and found to be negative using approved methods. However, the material should still be regarded as potentially infectious.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- \cdot Reproductive toxicity Based on available data, the classification criteria are not met.

(Contd. on page 5)



Printing date 03.02.2021

Version number 5

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Trade name: Negative Control Serum

- **STOT-single exposure** Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

· Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informat	ion	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated	
 · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA 	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
 14.4 Packing group ADR, IMDG, IATA 	not regulated	
 • 14.5 Environmental hazards: • Marine pollutant: 	No	
		(Contd. on page 6)



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

ade name: Negative Control Serum		
		(Contd. of pag
· 14.6 Special precautions for user	Not applicable.	
 14.7 Transport in bulk according to Ann Marpol and the IBC Code 	ex II of 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 Keep only in original packaging. P234 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. If eye irritation persists: Get medical advice/attention. P337+P313 Store in accordance with local/regional/national/international regulations. P401 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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

 Abbreviations and acronyms:
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.

Human Diagnostics Worldwide

Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

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

· 1.1 Product identifier

- · Trade name: Positive Control Serum
- · Article number: ITC59050 [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, availibility 24h per day (in german and english)

SECTION 2: Hazards identification

· Classification ac	n of the substance or mixture cording to Regulation (EC) No 1272/2008 classified, according to the CLP regulation.
 2.2 Label elemen Labelling accord Hazard pictogram Signal word Void 	ing to Regulation (EC) No 1272/2008 Void ns Void
Hazard statemen	
· Precautionary sta	
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	BIF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	BIF 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	S
· Results of PBT a	nd vPvB assessment
DDT NUCCESSION	

• **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)



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Trade name: Positive Control Serum

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:
- In case of contact, immediately flush with plenty of water. Consult doctor in case of complaints.
- · After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Fire-fighters should wear appropriate protective equipment.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures 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 7 for information on sale handling.
 - See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- No further requirements.
- Keep container tightly sealed.

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· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical a General Information 	nd chemical properties	
· Appearance:		
Form:	Liquid	
Colour:	Red	
· Odour:	Odourless	
· Odour threshold:	Not determined.	
· pH-value at 20 °C:	7.5	
 Change in condition Melting point/freezing point: Initial boiling point and boiling ra 	Undetermined. nge: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
 Ignition temperature: 	Not determined.	
· Decomposition temperature:	Not determined.	
		(Contd. on page 4)



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Trade name: Positive Control Serum

		(Contd. of page 3)
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
 Density at 20 °C: Relative density Vapour density Evaporation rate 	1 g/cm ³ Not determined. Not determined. Not determined.	
 Solubility in / Miscibility with water: 	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
 Solvent content: Organic solvents: Water: 	0.0 % 97.9 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

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

SECTION 11: Toxicological information

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

• Additional toxicological information: All donor units of human origin have been tested for HBsAg, HIV and HCV-antibodies and found to be negative using approved methods. However, the material should still be regarded as potentially infectious.

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.

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Trade name: Positive Control Serum

- **STOT-single exposure** Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

· Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informat	ion	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated	
 · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA 	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
 • 14.5 Environmental hazards: • Marine pollutant: 	No	
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Frade name: Positive Control Serum		
		(Contd. of page 5
· 14.6 Special precautions for user	Not applicable.	
 14.7 Transport in bulk according to Ann Marpol and the IBC Code 	ex II of 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 Keep only in original packaging. P234 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. If eye irritation persists: Get medical advice/attention. P337+P313 Store in accordance with local/regional/national/international regulations. P401 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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

 Abbreviations and acronyms:
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.

Human Diagnostics Worldwide

Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1 Product identifier Trade name: Washing Buffer (Concentrate 20x) · Article number: ITC59050 [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, availibility 24h per day (in german and english) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void Precautionary statements P234 Keep only in original packaging. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P281 Use personal protective equipment as required. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. Additional information: EUH208 Contains 2-Methyl-2H-isothiazol-3-on. May produce an allergic reaction. · 2.3 Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable.

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Revision: 03.02.2021

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

· Dangerous components:

<u> </u>			
CAS: 77-86-1 EINECS: 201-064-4		Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤2.5%
	Level Elevel a series		

• 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.
- \cdot 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 precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.

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Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 2)

• Further information about storage conditions: No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemic	cal properties
 9.1 Information on basic physical and c General Information Appearance: Form: Colour: Odour: Odour threshold: 	chemical properties Liquid Colourless Odourless Not determined.
· pH-value at 20 °C:	6.7 - 7.1
 Change in condition Melting point/freezing point: Initial boiling point and boiling range: 	Undetermined. : 100 °C
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
	(Contd. on page 4)



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Trade name: Washing Buffer (Concentrate 20x)

		(Contd. of page 3)
Ignition temperature:	Not determined.	
· Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
 Density at 20 °C: Relative density Vapour density Evaporation rate 	1 g/cm ³ Not determined. Not determined. Not determined.	
 Solubility in / Miscibility with water: 	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
 Solvent content: Organic solvents: Water: 	0.0 % 79.9 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

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

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acu	te Toxicity	y Estimates)
Oral	LD50	52,632 mg/kg
Dermal	LD50	157,895 mg/kg
Inhalative	LC50/4 h	26.3 mg/l
		(Contd. on page 5)

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Trade name: Washing Buffer (Concentrate 20x)

CAS: 7647-14-5 sodium chloride

Oral LD50 3,000 mg/kg (rat)

CAS: 77-86-1 TRIS

Oral LD50 5,900 mg/kg (rat)

- · Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

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

- 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· 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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Trade name: Washing Buffer (Concentrate 20x)

SECTION 14: Transport information

ted

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

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void Signal word Void · Hazard statements Void · Precautionary statements P234 Keep only in original packaging. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P281 Use personal protective equipment as required. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. P337+P313 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.

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Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 6) • 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 STOT SE 3: Specific target organ toxicity (single exposure) - Category 3 • * Data compared to the previous version altered. GE



Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1 Product identifier · Trade name: Dilution Buffer · Article number: ITC59050 [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, availibility 24h per day (in german and english) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void Precautionary statements P234 Keep only in original packaging. P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P281 Use personal protective equipment as required. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · 2.3 Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)



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Trade name: Dilution Buffer

(Contd. of page 1)

- · 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 7 for information on sale handling.
- See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- No further requirements.
- Keep container tightly sealed.

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• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical an General Information 	d chemical properties	
· Appearance:		
Form:	Liquid	
Colour:	Red	
· Odour:	Odourless	
· Odour threshold:	Not determined.	
· pH-value at 20 °C:	7.1 - 7.5	
 Change in condition Melting point/freezing point: Initial boiling point and boiling ran 	Undetermined. ge: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
 Ignition temperature: 	Not determined.	
· Decomposition temperature:	Not determined.	
		(Contd. on page 4)



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		(Contd. of page 3)
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
 Vapour pressure at 20 °C: 	23 hPa	
· Density at 20 °C:	1 g/cm ³	
· Relative density	Not determined.	
 Vapour density 	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· Solvent content:		
Organic solvents:	0.0 %	
Water:	97.9 %	
Solids content:	0.8 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Additional toxicological information: This product contains components from animal origin. Being of non-primate origin, these components avoid most of the risks associated with components based on human origin (e.g. Hepatitis B and C and HIV). Nevertheless this product should be handled as if potentially infectious.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.

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Trade name: Dilution Buffer

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- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name		
ADR, ADN, IMDG, IATA	not regulated	
14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
Class	not regulated	
· 14.4 Packing group		
ADR, IMDG, IATA	not regulated	

– GB –



5)

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

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Trade name: Dilution Buffer		
		(Contd. of page s
 · 14.5 Environmental hazards: · Marine pollutant: 	No	

 · 14.6 Special precautions for user
 Not applicable.

 · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
 Not applicable.

 · Transport/Additional information:
 · ADR

 · Limited quantities (LQ)
 not regulated

 · UN "Model Regulation":
 not regulated

SECTION 15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

· Precautionary statements

- P234 Keep only in original packaging.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P262 Do not get in eyes, on skin, or on clothing.
- P281 Use personal protective equipment as required.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international
 - regulations.

· Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

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

None of the ingredients is listed.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

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GB

Trade name: Dilution Buffer

CAS: Chemical Abstracts Service (division of the American Chemical Society) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

 \cdot * Data compared to the previous version altered.



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

· 1.1 Product identifier

· Trade name: Conjugate Solution

- · Article number: ITC59050 [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 The product is not classified, according to the CLP regulation. 				
 2.2 Label eleme Labelling accord Hazard pictogra Signal word Voi 	ding to Regulation (EC) No 1272/2008 Void ms Void			
 Hazard stateme 	nts 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+P35	3 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].			
P305+P351+P33	8 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.			
P337+P313	If eye irritation persists: Get medical advice/attention.			
P401	Store in accordance with local/regional/national/international regulations.			
P501	Dispose of contents/container in accordance with local/regional/national/international			
	regulations.			
Additional infor				
	s reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl- niazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.			
· 2.3 Other hazard	ds			
· Results of PBT	and vPvB assessment			
• PBT: Not applicable.				
· vPvB: Not applicable.				
	- GB -			

(Contd. on page 2)



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Trade name: Conjugate Solution

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:
- In case of contact, immediately flush with plenty of water. Consult doctor in case of complaints.
- After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- \cdot 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 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.

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Trade name: Conjugate Solution

(Contd. of page 2)

Keep container tightly sealed.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

• Additional information about design of technical facilities: No further data; see item 7.

 \cdot Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · Respiratory protection: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

· Eye protection: Goggles recommended during refilling

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties				
General Information				
· Appearance:				
Form:	Liquid			
Colour:	Yellowish			
· Odour:	Odourless			
· Odour threshold:	Not determined.			
· pH-value at 20 °C:	7.2			
 Change in condition Melting point/freezing point: Initial boiling point and boiling ratio 	Undetermined. ange: 100 °C			
· Flash point:	Not applicable.			
· Flammability (solid, gas):	Not applicable.			
Ignition temperature:	Not determined.			
· Decomposition temperature:	Not determined.			
		(Contd. on page 4)		



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Trade name: Conjugate Solution

		(Contd. of page 3)
Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
 Explosion limits: Lower: Upper: 	Not determined. Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
 Density at 20 °C: Relative density Vapour density Evaporation rate 	1 g/cm ³ Not determined. Not determined. Not determined.	
 Solubility in / Miscibility with water: 	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
 Solvent content: Organic solvents: Water: 	0.0 % 75.3 %	
· 9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

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

• 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

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

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

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.

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Trade name: Conjugate Solution

- 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.
- \cdot STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:

· General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

· Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informat	lion	
· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name		
· ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
· Class	not regulated	
· 14.4 Packing group		
· ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards:		
· Marine pollutant:	No	
		(Contd. on page



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rade name: Conjugate Solution		
		(Contd. of page 5
· 14.6 Special precautions for user	Not applicable.	
 14.7 Transport in bulk according to Anr Marpol and the IBC Code 	nex II of 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 Keep only in original packaging. P234 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. If eye irritation persists: Get medical advice/attention. P337+P313 Store in accordance with local/regional/national/international regulations. P401 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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

 Abbreviations and acronyms:
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.

Human Diagnostics Worldwide

GB

Printing date 03.02.2021

Version number 5

Revision: 03.02.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1 Product identifier · Trade name: TMB Solution · Article number: ITC59050 [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, availibility 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. Store in accordance with local/regional/national/international regulations. P401 P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · 2.3 Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description: Mixture of substances in aqueous solution.

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1-3%

Trade name: TMB Solution

· Dangerous components:

CAS: 616-45-5 2-pyrrolidone EINECS: 210-483-1

•

Acute Tox. 4, H302; Skin Irrit. 2, H315; Eve Irrit. 2, H319

• 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.
- \cdot 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:
- \cdot Requirements to be met by storerooms and receptacles: No special requirements.
- · 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.

(Contd. on page 3)



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Trade name: TMB Solution

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

· 7.3 Specific end use(s) No further relevant information available.

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures: Do not eat, drink, smoke or sniff while working.
- · Respiratory protection: Not required.
- · Protection of hands:

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 protection: Goggles recommended during refilling

9.1 Information on basic physical General Information	and chemical properties	
Appearance:		
Form:	Liquid	
Colour:	Colourless	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value at 20 °C:	3.5 - 3.7	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling r	ange: 100 °C	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	



according	g to 1907/2006/EC, Article 31	
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rade name: TMB Solution		
		(Contd. of page
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explose	sion hazard.
· Explosion limits: Lower: Upper:	Not determined. Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
 Density: Relative density Vapour density Evaporation rate 	Not determined. Not determined. Not determined. Not determined.	
 Solubility in / Miscibility with water: 	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
 Solvent content: Organic solvents: Water: 	0.0 % 99.9 %	
· 9.2 Other information	No further relevant information ava	ilable.

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid

Light sensitive.

Store away from heat.

Stable if the recommended storage and handling instructions are followed.

- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 10,937 mg/kg (rat)

CAS: 616-45-5 2-pyrrolidone

Oral LD50 328 mg/kg (rat)

(Contd. on page 5)





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· Primary irritant effect:

• Skin corrosion/irritation Based on available data, the classification criteria are not met.

• Serious eye damage/irritation Based on available data, the classification criteria are not met.

• Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- \cdot STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

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

18 01 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 · 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	
		(Contd. on page 6)



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	(Contd	. of page 5)
 · 14.4 Packing group · ADR, IMDG, IATA 	not regulated	
 · 14.5 Environmental hazards: · Marine pollutant: 	No	
· 14.6 Special precautions for user	Not applicable.	
 14.7 Transport in bulk according to Ann Marpol and the IBC Code 	nex II of Not applicable.	
· Transport/Additional information:		
 ADR Limited quantities (LQ) 	not regulated	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Precautionary statements

- P234 Keep only in original packaging.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P262 Do not get in eyes, on skin, or on clothing.
- P281 Use personal protective equipment as required.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P401 Store in accordance with local/regional/national/international regulations.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

 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.

• 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.

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Trade name: TMB Solution

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 Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) 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 - oral - Category 4 Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 • * Data compared to the previous version altered. GB



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

Revision: 03.02.2021

1.1 Product identifier Trade name: Stop Solution Article number: ITC59050 [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, availibility 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 Keep only in original packaging. P234 P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required. P281 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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≥2.5-<5%

Skin Corr. 1A, H314

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

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Trade name: Stop Solution

P401 P501 (Contd. of page 1) Store in accordance with local/regional/national/international regulations. Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

 \cdot Results of PBT and vPvB assessment

• **PBT:** Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description: Mixture of substances in aqueous solution.

· Dangerous components:

CAS: 7664-93-9 sulphuric acid

EINECS: 231-639-5

· 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.
- 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.

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Trade name: Stop Solution

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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) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

• Additional information about design of technical facilities: No further data; see item 7.

· Ingredients with limit values that require monitoring at the workplace:

CAS: 7664-93-9 sulphuric acid

WEL Long-term value: 0.05* mg/m³

*mist: defined as thoracic fraction

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

- · 8.2 Exposure controls
- · 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.

Protection of hands:



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.

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 \cdot 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.

\cdot Eye protection:

Tightly sealed goggles

SECTION 9: Physical and chemi	cal properties	
· 9.1 Information on basic physical and	chemical properties	
· General Information		
· Appearance:		
Form:	Liquid	
Colour:	Colourless	
· Odour:	Odourless	
· Odour threshold:	Not determined.	
· pH-value at 20 °C:	<1	
· Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	e: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
· Ignition temperature:	Not determined.	
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure at 20 °C:	23 hPa	
· Density at 20 °C:	1.0233 g/cm ³	
· Relative density	Not determined.	
· Vapour density	Not determined.	
 Evaporation rate 	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
· Solvent content:		
Organic solvents:	0.0 %	
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Trade name: Stop Solution

Water:

97.2 %

· 9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

CAS: 7664-93-9 sulphuric acid

Inhalative inhalative 510 mg/m3 (rat)

- · Primary irritant effect:
- · 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.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:
- Not hazardous for water.

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.

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Trade name: Stop Solution

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· 12.5 Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

• Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated
 14.2 UN proper shipping name ADR, ADN, IMDG, IATA 	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
 14.4 Packing group ADR, IMDG, IATA 	not regulated
 · 14.5 Environmental hazards: · Marine pollutant: 	No
· 14.6 Special precautions for user	Not applicable.
 14.7 Transport in bulk according to Annex I Marpol and the IBC Code 	l of 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.

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Hazard pictogr	
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\ i /	
GHS07	
01007	
Signal word W	arning
Hazard-determ	ining components of labelling:
sulphuric acid	
Hazard statem	ents
H315 Causes s	kin irritation.
H319 Causes s	erious eye irritation.
Precautionary	statements
P234	Keep only in original packaging.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	Do not get in eyes, on skin, or on clothing.
P262	Llee personal protective equipment on required
P281	Use personal protective equipment as required.
P281	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin v
P281 P303+P361+P3	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin v water [or shower].
P281 P303+P361+P3	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin v
P281 P303+P361+P3	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin v water [or shower]. 38 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses
P281 P303+P361+P3 P305+P351+P3	 53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin v water [or shower]. 38 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses present and easy to do. Continue rinsing.

• 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.

· 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

H314 Causes severe skin burns and eye damage.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

- Skin Corr. 1A: Skin corrosion/irritation Category 1A
- Skin Irrit. 2: Skin corrosion/irritation Category 2

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Trade name: Stop Solution

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

 \cdot * Data compared to the previous version altered.



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

· 1.1 Product identifier

· Trade name: <u>Mikrotiter Plate</u>

- · Article number: ITC59050 [MTP]
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- · Application of the substance / the mixture In Vitro Diagnostic
- · 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

HUMAN Gesellschaft für Biochemica und Diagnostica mbh Max-Planck-Ring 21 65205 Wiesbaden Germany phone +49 (0) 6122 99 88 0 fax: +49 (0) 6122 99 88 100 eMail: human@human.de

- Further information obtainable from: Head office, phone: +49 (0) 6122 99 88 0
- · 1.4 Emergency telephone number:

INFRASERV, Telephone +49(0) 69-305-6418, availability 24h per day (in german and english)

SECTION 2: Hazards identification

 • 2.1 Classification of the substance or mixture
 • Classification according to Regulation (EC) No 1272/2008 The product is not classified, according to the CLP regulation.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Precautionary statements
- P234 Keep only in original packaging.
- P281 Use personal protective equipment as required.
- P401 Store in accordance with local/regional/national/international regulations.

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

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

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

SECTION 4: First aid measures

4.1 Description of first aid measures

· General information: No special measures required.

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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.
- \cdot 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) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- 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.

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· 8.2 Exposure controls

- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

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

• Eye protection: Not required.

SECTION 9: Physical and chemic	cal properties	
 9.1 Information on basic physical and c General Information Appearance: 	hemical properties	
Form:	Solid	
Colour:	Colourless	
· Odour:	Odourless	
 Odour threshold: 	Not determined.	
· pH-value:	Not applicable.	
 Change in condition Melting point/freezing point: Initial boiling point and boiling range: 	Undetermined. Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not determined.	
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure:	Not applicable.	
· Density:	Not determined.	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
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· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

Solids content:

- 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.

100.0 %

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.

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· 12.5 Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated
 · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA 	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards:	Not applicable.
 14.6 Special precautions for user 	Not applicable.
• 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.	
· Transport/Additional information:	
 ADR Limited quantities (LQ) 	not regulated
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

 \cdot 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

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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.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.

