12.04.2022	Kit Components
Product code	Description
ITC60201	MYSITIS-LIA PL
Components:	
ITC60201[STRIP]	Test Strip (coated with antigen)
ITC60201[CON]	Conjugate Solution (anti-human IgG-HRP-Conjugate)
ITC60201[SUB][LIA]	Substrate Solution
ITC60201[WASH][20x]	Washing Buffer concentrate (20x)
ITC60201[DIL][LIA]	Dilution buffer
ITC60201[STOP][LIA]	Stop Solution

Printing date 12.04.2022

· 1.1 Product identifier

Version number 4

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

Revision: 12.04.2022

· Trade name: Test Strip (coated with antigen) Article number: ITC60201[STRIP] 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 GB 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:** Colour coded test strips coated with antigens detecting autoantibodies of different specificity. **Dangerous components:** cellulose nitrate 2.5-5% 🚸 Flam. Sol. 1, H228

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

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Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

Trade name: Test Strip (coated with antigen)

(Contd. of page 1)

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: 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.

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Printing date 12.04.2022

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Trade name: Test Strip (coated with antigen)

(Contd. of page 2) 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: Not required.

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical and c General Information 	hemical properties	
· Appearance:		
Form:	Like plastic	
Colour:	White	
Odour:	Odourless	
· Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
· Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range:	Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not determined.	
· Ignition temperature:	180 °C	
· 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.	
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Trade name: Test Strip (coated with antigen)

		(Contd. of page
· Vapour pressure at 20 °C:	23 hPa	
· Density:	Not determined.	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
water:	Insoluble.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100.0 %	
• 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 ingredients from human or animal blood. Each blood unit used for this product has been tested and found non-reactive for the presence of HBsAg, anti-HCV and anti-HIV-1/HIV-2 (EN 13641). However, no known test method can offer complete assurance that products derived from human or animal blood will not transmit Hepatitis, HIV or any other infectious agents. Therefore adequate safety precautions are recommended.

- · 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.

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Trade name: Test Strip (coated with antigen)

• 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	not regulated	
	not regulated	
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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Trade name: Test Strip (coated with antigen)

	(Contd. of page 5
Not applicable.	
nex II of	
Not applicable.	
not regulated	
not regulated	
	not regulated

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture • Labelling according to Regulation (EC) No 1272/2008 Void

· Hazard pictograms Void

· Signal word Void

- · Hazard statements Void
- · Precautionary statements
- P234 Keep only in original packaging.

P281 Use personal protective equipment as required.

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

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

· Directive 2012/18/EU

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

· 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

H228 Flammable solid.

Abbreviations and acronyms:

- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative Flam. Sol. 1: Flammable solids Category 1
- * * Data compared to the previous version altered.



Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate) · Article number: ITC60201[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 GB 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. Do not get in eyes, on skin, or on clothing. P262 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. P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. Additional information: EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction. · 2.3 Other hazards Results of PBT and vPvB assessment · **PBT:** Not applicable. vPvB: Not applicable.

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Revision: 12.04.2022

Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate)

(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.
- 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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Revision: 12.04.2022

Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate)

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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 chemical properties

9.1 Information on basic physical and chemical properties		
 General Information Appearance: 		
Form:	Liquid	
Colour:	Green	
· 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 ranges 	Undetermined. : 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
		(Contd. on page 4



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Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate)

		(Contd. of page 3)
· 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:	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.
- · 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.

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Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate)

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• **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	not regulated	
	not regulated	
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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Trade name: Conjugate Solution (anti-human IgG-HRP-Conjugate)

		(Contd. of page
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Anr	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. Do not get in eyes, on skin, or on clothing. P262 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.

• 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 relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

** Data compared to the previous version altered.



Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier Trade name: Substrate Solution · Article number: ITC60201[SUB][LIA] 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 GB 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: Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9. 2.3 Other hazards Results of PBT and vPvB assessment · **PBT:** Not applicable. vPvB: Not applicable.

(Contd. on page 2)

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Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

Trade name: Substrate 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.
- 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:
- 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: Substrate Solution

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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:	Colourless	
· Odour:	Characteristic	
· Odour threshold:	Not determined.	
· pH-value:	4.9 - 5.1	
· Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range:	: 100 °C	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Not applicable.	
· Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
	(Contd. on page 4)	



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Trade name: Substrate Solution

		(Contd. of page
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:	1.013 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:	99.9 %	
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:
- · 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.

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· 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 07 chemicals other than those mentioned in 18 01 06
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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

SECTION 14: Transport information

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	not regulated	
 14.2 UN proper shipping name 		
· ADR	not regulated	
	not regulated	
· 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 Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
		(Contd on page 6)

(Contd. on page 6)



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Trade name: Substrate Solution

• Transport/Additional information:

· ADR

Limited quantities (LQ)

· UN "Model Regulation":

SECTION 15: Regulatory information

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

not regulated

not regulated

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

Hazard statements Void

Precautionary statements

- P234 Keep only in original packaging.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P262 Do not get in eyes, on skin, or on clothing.
- P281 Use personal protective equipment as required.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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

- P337+P313 If eye irritation persists: Get medical advice/attention.
- P401 Store in accordance with local/regional/national/international regulations.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Directive 2012/18/EU

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

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

SECTION 16: Other information

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

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

* * Data compared to the previous version altered.



Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier Trade name: Washing Buffer concentrate (20x) · Article number: ITC60201[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 GB 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. GB

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Revision: 12.04.2022

Trade name: Washing Buffer concentrate (20x)

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SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

· Dangerous components:

 CAS: 77-86-1
 TRIS
 Image: Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
 ≤2.5%

 EINECS: 201-064-4
 Image: Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
 ≤2.5%

 Additional information: For the wording of the listed bazard phrases refer to section 16
 ≤2.5%

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

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 - See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special 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)

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• Further information about storage conditions:

No further requirements.

Keep container tightly sealed.

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

SECTION 8: Exposure controls/personal protection

- · 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

9.1 Information on basic physical ar General Information	nd chemical properties	
Appearance:		
Form:	Liquid	
Colour:	Colourless	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value at 20 °C:	6.7-7.1	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling ran	ige: 100 °C	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	



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Trade name: Washing Buffer concentrate (20x)

		(Contd. of page 3)
· 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 % 78.1 %	
· 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 (Acute Toxicity Estimates)		
Oral		52,632 mg/kg
Dermal	LD50	157,895 mg/kg
Inhalative	LC50/4 h	26.3 mg/l

CAS: 7647-14-5 sodium chloride

Oral LD50 3,000 mg/kg (rat)

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Trade name: Washing Buffer concentrate (20x)

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:

Tween 20

- EC50 >10 mg/kg (daphnia)
- 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 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)

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SECTION 14: Transport informat	tion	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name		
ADR	not regulated	
	not regulated	
· 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 Ani	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

- 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

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

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GB

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

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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 relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative 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.



Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: Dilution buffer · Article number: ITC60201[DIL][LIA] 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 GB 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. GB

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Trade name: Dilution buffer

(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.
- 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: 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 precautions are necessary if used correctly. • Information about fire - and explosion protection: No special measures required.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- No further requirements.

Keep container tightly sealed.

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Printing date 12.04.2022

Version number 4

Revision: 12.04.2022

Trade name: Dilution buffer

• 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: Not required.

9.1 Information on basic physical a	and chemical properties	
General Information		
Appearance:		
Form:	Liquid	
Colour:	Clear	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	7.6	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling ra	ange: Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gas):	Product is not flammable.	
Ignition temperature:	Not determined.	
Decomposition temperature:	Not determined.	



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· Auto-ignition temperature:	Not determined.	
· 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.	
 Evaporation rate 	Not applicable.	
· Solubility in / Miscibility with		
water:	Soluble.	
· Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100.0 %	
· 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:
- · 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.

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• **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 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: 1	ransport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name		
ADR	not regulated	
	not regulated	
· 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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Not applicable.	
Not applicable.	
not regulated	
not regulated	
	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. Do not get in eyes, on skin, or on clothing. P262 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.

• 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 relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

** 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>Stop Solution</u>

· Article number: ITC60201[STOP][LIA]

- **1.2 Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- · Application of the substance / the mixture In Vitro Diagnostic

· 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier:

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

• Further information obtainable from: Head office, phone: +49 (0) 6122 99 88 0

· 1.4 Emergency telephone number:

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

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

· 2.2 Label elements

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

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms



· Signal word Warning

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

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Additional information:

Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.

2.3 Other hazards

• Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

· Dangerous components: 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: Immediately remove any clothing soiled by the product.
- 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. Then consult a doctor.
- After swallowing: Drink plenty of water and provide fresh air. Call for a doctor immediately.
- 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). Use neutralising agent.

Dispose contaminated material as waste according to item 13.

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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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:

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:

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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· 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:



Tightly sealed goggles

General Information Appearance: Appearance: Liquid Colour: Colourless Odour threshold: Not determined. pH-value at 20 °C: < 2.0 Change in condition Undetermined. Initial boiling point and boiling range: 100 °C Flash point: Undetermined. Initial boiling point and boiling range: 100 °C Flash point: Not applicable. Flammability (solid, gas): Not applicable. Decomposition temperature: Not determined. Auto-ignition temperature: Product does not present an explosion hazard. Explosion limits: Lower: Lower: Not determined. Upper: Not determined. Vapour pressure at 20 °C: 23 hPa Density at 20 °C: 1.0046 g/cm³ Relative density Not determined. Vapour density Not determine	9.1 Information on basic physical and c	hemical properties	
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Organic solvents: 0.0 %	Kinematic:	Not determined.	
	Solvent content:		
	Organic solvents:		



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• 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
- 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.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

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.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

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· 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, IMDG, IATA	not regulated
· 14.2 UN proper shipping name	
ADR	not regulated
	not regulated
· 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	c 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

The product is classified and labelled according to the GB CLP regulation.

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(Contd. of page 6) · Hazard pictograms · Signal word Warning · 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. P401 Store in accordance with local/regional/national/international regulations. P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Directive 2012/18/EU

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

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

SECTION 16: Other information

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

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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.

