12.06.2023

Kit Components

Product code Description	
ITC70024	IMTEC-SS-B/La-Antibodies
Components:	
ITC70024 [CAL]	Calibrators IgG 1 - 5
ITC70024 [NC]	Negative Control Serum
ITC70024 [PC]	Positive Control Serum
ITC70024 [WASH][20x]	Washing Buffer (Concentrate 20x)
ITC70024 [DIL]	Dilution Buffer
ITC70024 [CON]	Conjugate Solution
ITC70024 [SUB]	TMB Solution
ITC70024 [STOP]	Stop Solution
ITC70024 [MTP]	Mikrotiter Plate

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: <u>Calibrators IgG 1 - 5</u> · Article number: ITC70024 [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:

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

vPvB:

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

- IE

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Description: Serum, human origin, liquid

· Dangerous components: Void

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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:** 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: 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).

Dispose contaminated material as waste according to section 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.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

(Contd. of page 2)

Prevent formation of aerosols.

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

No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Keep away from foodstuffs, beverages and feed.
- · Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection

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

Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- · General Information

· Colour: Odour: Odourless

Odour threshold: No information available.

Melting point/freezing point:

(Contd. on page 4)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

(Contd. of page 3)

 $^{\cdot}$ Boiling point or initial boiling point and boiling

range

100 °C (CAS: 7732-18-5 water, distilled, conductivity

or of similar purity)

· Flammability No information available.

· Lower and upper explosion limit

Lower: No information available.
Upper: No information available.
Flash point: Not applicable.

• Auto-ignition temperature:
• Decomposition temperature:

No information available.

No information available.

· pH at 20 °C 6.9-7.3

· Viscosity:

· Kinematic viscosity No information available

· **Dynamic at 20 °C:** 0.952 mPas

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

Density and/or relative density

· Density at 20 °C: 1 g/cm³

Relative densityVapour densityNo information available.No information available.

• 9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

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

· Solvent content:

Water: 95.0 %
Solids content: 1.7 %
Molecular weight 18.02 g/mol

· Change in condition

• **Evaporation rate** No information available.

Information with regard to physical hazard

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

Self-reactive substances and mixtures
 Pyrophoric liquids
 Pyrophoric solids
 Self-heating substances and mixtures

Void
Void

Substances and mixtures, which emit flammable

gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

(Contd. of page 4)

· Organic peroxides	Void
Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 21,816 mg/kg (rat)
Dermal LD50 16,160 mg/kg (rabbit)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:

All 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.

- 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)





Revision: 12.06.2023 Printing date 12.06.2023 Version number 6 (replaces version 5)

Trade name: Calibrators IgG 1 - 5

(Contd. of page 5)

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- European waste catalogue
- 18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection
- · Uncleaned packaging:
- · **Recommendation:** Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport informatio	n	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according instruments	to IMO Not applicable.	
· Transport/Additional information:		
· ADR · Limited quantities (LQ)	not regulated	
· UN "Model Regulation":	not regulated	

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

(Contd. of page 6)

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.

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

- Date of previous version: 12.06.2023
 Version number of previous version: 5
- Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

(Contd. on page 8)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Calibrators IgG 1 - 5

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

* Data compared to the previous version altered.

(Contd. of page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

Trade name: Negative Control Serum

· Article number: ITC70024 [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

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

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

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT:

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

vPvB:

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

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Description: Serum, human origin, liquid

· Dangerous components: Void

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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: 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: 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).

Dispose contaminated material as waste according to section 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.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 2)

Prevent formation of aerosols.

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

No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Keep away from foodstuffs, beverages and feed.
- · Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection

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

Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- · General Information

· Colour: Odour: Odourless

Odour threshold: No information available. **Melting point/freezing point:** No information available.

(Contd. on page 4)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 3)

· Boiling point or initial boiling point and boiling

range

100 °C (CAS: 7732-18-5 water, distilled, conductivity

or of similar purity)

· Flammability No information available.

· Lower and upper explosion limit

No information available. · Lower: · Upper: No information available.

· Flash point: Not applicable.

No information available. · Auto-ignition temperature: · Decomposition temperature: No information available.

pH at 20 °C 6.9 - 7.3

· Viscosity:

· Kinematic viscosity No information available · Dynamic: No information available.

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

Density and/or relative density

Density at 20 °C: 1 g/cm³

· Relative density No information available. No information available. · Vapour density

· 9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

· Ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

· Solvent content:

· Water: 94.6 % · Solids content: 1.7 %

· Change in condition

· Evaporation rate No information available.

· Information with regard to physical hazard

classes

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

Substances and mixtures, which emit flammable

gases in contact with water Void · Oxidising liquids Void Oxidising solids Void Void Organic peroxides

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 4)

· Corrosive to metals Void · Desensitised explosives Void

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

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

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 21,925 mg/kg (rat)
Dermal LD50 16,241 mg/kg (rabbit)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · **Aspiration hazard** Based on available data, the classification criteria are not met.
- · Additional toxicological information:

All 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.

- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)

- IE



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 5)

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- · European waste catalogue
- 18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection
- · 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	on	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according instruments	g to IMO Not applicable.	
· Transport/Additional information:		
· ADR · Limited quantities (LQ)	not regulated	
· UN "Model Regulation":	not regulated	

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

(Contd. of page 6)

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.

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

- Date of previous version: 12.06.2023
 Version number of previous version: 5
- · Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

(Contd. on page 8)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Negative Control Serum

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

* Data compared to the previous version altered.

(Contd. of page 7)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: Positive Control Serum

· Article number: ITC70024 [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

- 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

PB1:

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

vPvB:

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

- IE

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· Description: Serum, human origin, liquid

· Dangerous components: Void

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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: 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: 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).

Dispose contaminated material as waste according to section 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.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

(Contd. of page 2)

Prevent formation of aerosols.

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

No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Keep away from foodstuffs, beverages and feed.
- · Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection

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

Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- · General Information

· Colour: Odour: Odourless

Odour threshold: No information available. **Melting point/freezing point:** No information available.

(Contd. on page 4)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

(Contd. of page 3)

 \cdot Boiling point or initial boiling point and boiling

range

100 °C (CAS: 7732-18-5 water, distilled, conductivity

or of similar purity)

· Flammability No information available.

· Lower and upper explosion limit

Lower: No information available.Upper: No information available.

Flash point: Not applicable.

Auto-ignition temperature:
 Decomposition temperature:
 No information available.

· pH at 20 °C 6.9-7.3

· Viscosity:

Kinematic viscosityDynamic:No information availableNo information available.

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

Density and/or relative density

· Density at 20 °C: 1 g/cm³

Relative density
 Vapour density
 No information available.
 No information available.

· 9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

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

· Solvent content:

· Water: 95.0 % · Solids content: 1.7 %

Change in condition

• **Evaporation rate** No information available.

Information with regard to physical hazard

classes

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

Substances and mixtures, which emit flammable

gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

(Contd. of page 4)

· Corrosive to metals Void · Desensitised explosives Void

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

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

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 21,818 mg/kg (rat)
Dermal LD50 16,161 mg/kg (rabbit)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · **Aspiration hazard** Based on available data, the classification criteria are not met.
- · Additional toxicological information:

All 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.

- · 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)

- IE



Revision: 12.06.2023 Printing date 12.06.2023 Version number 6 (replaces version 5)

Trade name: Positive Control Serum

(Contd. of page 5)

· 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- European waste catalogue
- 18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection
- · Uncleaned packaging:
- · **Recommendation:** Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

not regulated	
not regulated	
not regulated	
not regulated	
No	
Not applicable.	
Not applicable.	
not regulated	
not regulated	
	not regulated not regulated not regulated No Not applicable. Not applicable. not regulated

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

(Contd. of page 6)

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.

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

- Date of previous version: 12.06.2023
 Version number of previous version: 5
- Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

(Contd. on page 8)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Positive Control Serum

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

* Data compared to the previous version altered.

(Contd. of page 7)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

Trade name: Washing Buffer (Concentrate 20x)

· Article number: ITC70024 [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

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

2-Methyl-2H-isothiazol-3-on

Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 1)

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

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

· vPvB:

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

SECTION 3: Composition/information on ingredients

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

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

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.

(Contd. on page 3)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 2)

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

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

No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

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

- · **Additional information:** The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- · Respiratory protection: Not required.
- · Hand protection

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

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

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

Material of gloves

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

Penetration time of glove material

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

· Eye/face protection Goggles recommended during refilling

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(Contd. on page 4)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 3)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

· General Information

· Colour: Colourless · Odour: Odourless

Odour threshold:
 Melting point/freezing point:
 No information available.
 No information available.

· Boiling point or initial boiling point and boiling

range 100 °C (CAS: 7732-18-5 water, distilled, conductivity

or of similar purity)

• Flammability No information available.

· Lower and upper explosion limit

Lower: No information available.Upper: No information available.

· Flash point: Not applicable.

Auto-ignition temperature:
 Decomposition temperature:
 No information available.
 No information available.

· pH at 20 °C 6.7-7.1

· Viscosity:

Kinematic viscosityDynamic:No information availableNo information available

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

· Density at 20 °C: 1 g/cm³

Relative densityVapour densityNo information available.No information available.

· 9.2 Other information

· Appearance:

· Form: Liquid

Important information on protection of health and environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

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

Solvent content:

• Water: 78.1 % • Solids content: 17.9 %

· Change in condition

• **Evaporation rate** No information available.

· Information with regard to physical hazard

classes

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

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

 Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids Oxidising solids Organic peroxides 			(Contd. of page 4)
· Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void	· Pyrophoric liquids	Void	
 Substances and mixtures, which emit flammable gases in contact with water Oxidising liquids Oxidising solids Void 	Pyrophoric solids	Void	
gases in contact with water Void Oxidising liquids Void Oxidising solids Void	Self-heating substances and mixtures	Void	
· Oxidising liquids Void · Oxidising solids Void	Substances and mixtures, which emit flamma	able	
· Oxidising solids Void	gases in contact with water	Void	
	· Oxidising liquids	Void	
· Organic peroxides Void	· Oxidising solids	Void	
organio perezitado	· Organic peroxides	Void	
· Corrosive to metals Void	Corrosive to metals	Void	
· Desensitised explosives Void	Desensitised explosives	Void	

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

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

· LD/LC50 v	· LD/LC50 values relevant for classification:			
ATE (Acu	ATE (Acute Toxicity Estimates)			
Oral	LD50	52,632 mg/kg		
Dermal	LD50	157,895 mg/kg		
Inhalative	LC50/4 h	26.3 mg/l		
CAS: 77-8	CAS: 77-86-1 TRIS			
Oral	LD50	5,900 mg/kg (rat)		
CAS: 2682	CAS: 2682-20-4 2-Methyl-2H-isothiazol-3-on			
Oral	LD50	100 mg/kg (ATE)		
Dermal	LD50	300 mg/kg (ATE)		
Inhalative		0.05 mg/l (ATE)		

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

(Contd. on page 6)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 5)

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

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

SECTION 14: Transport information		
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
		(Contd. on page 7





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

(Contd. of page 6) · 14.5 Environmental hazards:

· Marine pollutant: No

· 14.6 Special precautions for user Not applicable.

14.7 Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· Limited quantities (LQ) not regulated

· UN "Model Regulation": not regulated

SECTION 15: Regulatory information

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

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

2-Methyl-2H-isothiazol-3-on

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

- Directive 2012/18/EU
- Named dangerous substances ANNEX I None of the ingredients is listed.
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

(Contd. on page 8)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Washing Buffer (Concentrate 20x)

· REGULATION (EU) 2019/1148

(Contd. of page 7)

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

CAS: 7647-01-0 hydrogen chloride

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

CAS: 7647-01-0 hydrogen chloride

3

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

SECTION 16: Other information

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

Relevant phrases

- Toxic if swallowed. H301
- H311 Toxic in contact with skin.
- Causes severe skin burns and eye damage. H314
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- Causes serious eye irritation. H319
- H330 Fatal if inhaled.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- EUH071 Corrosive to the respiratory tract.
- Date of previous version: 12.06.2023
- · Version number of previous version: 5
- Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3 Acute Tox. 2: Acute toxicity – Category 2

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

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

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

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1A: Skin sensitisation - Category 1A

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

* Data compared to the previous version altered.



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: Dilution Buffer · Article number: ITC70024 [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

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

vPvB:

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

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

In case of contact, immediately flush with plenty of water. Consult doctor in case of complaints.

- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

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

(Contd. on page 3)

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Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 2)

· Further information about storage conditions:

No further requirements.

Keep container tightly sealed.

7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

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

- · Respiratory protection: Not required.
- · Hand protection

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

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

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

· Material of gloves

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

· Penetration time of glove material

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

· Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

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

· **Colour:** Red · **Odour:** Odourless

· Odour threshold: No information available.

Melting point/freezing point: 0 °C

· Boiling point or initial boiling point and boiling

range 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)

• Flammability No information available.
• Lower and upper explosion limit

Lower: No information available.
Upper: No information available.
Flash point: Not applicable.

· **Auto-ignition temperature:** No information available.

(Contd. on page 4)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 3)

• **Decomposition temperature:** No information available.

pH at 20 °C 7.1-7.5

· Viscosity:

· Kinematic viscosity No information available

Dynamic at 20 °C: 0.952 mPas

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

· Density at 20 °C: 1.012 g/cm³

Relative densityVapour densityNo information available.No information available.

9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

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

· Solvent content:

Water: 96.0 %
Solids content: 1.8 %
Molecular weight 18.02 g/mol

· Change in condition

• **Evaporation rate**No information available.

Information with regard to physical hazard

classes

· Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void **Pyrophoric solids** Void · Self-heating substances and mixtures Void Substances and mixtures, which emit flammable gases in contact with water Void **Oxidising liquids** Void

gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void
Corrosive to metals Void
Desensitised explosives Void

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 4)

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

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:

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

- 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

(Contd. on page 6)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 5)

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

- · European waste catalogue
- 18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated
 14.2 UN proper shipping name ADR, ADN, IMDG, IATA 	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk accordin instruments	g to IMO 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.

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Dilution Buffer

(Contd. of page 6)

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

Directive 2012/18/EU

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

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

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

- · Date of previous version: 12.06.2023
- · Version number of previous version: 5
- Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

* * Data compared to the previous version altered.

Human

Diagnostics Worldwide

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Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: Conjugate Solution
· Article number: ITC70024 [CON]

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture In Vitro Diagnostic

· 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Max-Planck-Ring 21 65205 Wiesbaden

Germany

phone +49 (0) 6122 99 88 0 fax: +49 (0) 6122 99 88 100 eMail: human@human.de

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

· 1.4 Emergency telephone number:

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

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

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

· Hazard pictograms



GHS07

· Signal word Warning

· Hazard-determining components of labelling:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 1)

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

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

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT:

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

· vPvB:

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

SECTION 3: Composition/information on ingredients

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

CAS: 55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247- ≥0.0025-<0.025%

500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; Skin Corr. 1C, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100); Skin Sens. 1A, H317,

EUH071

Specific concentration limits: Skin Corr. 1C; H314: C ≥ 0.6 %

Skin Irrit. 2; H315: $0.06 \% \le C < 0.6 \%$ Eye Dam. 1; H318: $C \ge 0.6 \%$ Eye Irrit. 2; H319: $0.06 \% \le C < 0.6 \%$ Skin Sens. 1A; H317: $C \ge 0.0015 \%$

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

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

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
- Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 2)

5.3 Advice for firefighters

· Protective equipment: Fire-fighters should wear appropriate protective equipment.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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

No further requirements.

Keep container tightly sealed.

· 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection:

Not required.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

(Contd. on page 4)

- IE



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 3)

· Hand protection



Protective gloves

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

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

Material of gloves

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

· Penetration time of glove material

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

· Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

· Colour: Yellowish Odourless

Odour threshold:
 Melting point/freezing point:
 No information available.
 No information available.

Boiling point or initial boiling point and boiling range

range 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)

• Flammability No information available.

· Lower and upper explosion limit

Lower and upper explosion limit

Lower: No information available.
Upper: No information available.
Flash point: Not applicable.

• Auto-ignition temperature:
• Decomposition temperature:

No information available.

No information available.

· pH at 20 °C 7.2

· Viscosity:

Kinematic viscosityDynamic:No information availableNo information available

Solubility

water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

Density at 20 °C: 1 g/cm³

Relative density
 Vapour density
 No information available.
 No information available.

(Contd. on page 5)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 4)

· 9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

• Ignition temperature: Product is not selfigniting.

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

· Solvent content:

· Water: 75.3 % · Solids content: 0.7 %

· Change in condition

• Evaporation rate No information available.

Information with regard to physical hazard

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

Substances and mixtures, which emit flammable gases in contact with water Void
Oxidising liquids Void
Oxidising solids Void
Organic peroxides Void
Corrosive to metals Void
Desensitised explosives

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

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

(Contd. on page 6)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 5)

LD/LC50 values relevant for classification:

CAS: 55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

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

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:

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

- · 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation

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

· European waste catalogue

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

(Contd. on page 7)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 6)

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

SECTION 14: Transport information	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
 14.7 Maritime transport in bulk according instruments 	g to IMO Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ)	not regulated
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

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

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

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

(Contd. on page 8)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

(Contd. of page 7)

· Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

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

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

Relevant phrases

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH071 Corrosive to the respiratory tract.

- · Date of previous version: 12.06.2023
- · Version number of previous version: 5
- · Abbreviations and acronyms:

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

(Contd. on page 9)

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Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Conjugate Solution

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity – Category 3 Acute Tox. 2: Acute toxicity – Category 2 Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1A: Skin sensitisation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

* Data compared to the previous version altered.

(Contd. of page 8)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: TMB Solution

· Article number: ITC70024 [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.

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

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

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT:

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

vPvB:

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

- IE

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

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

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

In case of contact, immediately flush with plenty of water. Consult doctor in case of complaints.

- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.

(Contd. on page 3)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

(Contd. of page 2)

- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions:

No further requirements.

Keep container tightly sealed.

· 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

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

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

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Do not eat, drink, smoke or sniff while working.
- · Respiratory protection: Not required.
- · Hand protection

Protective gloves for handling chemicals must meet the requirements of the European standard EN 374.

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

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

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

· Material of gloves

Nitrile rubber, NBR

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

· Penetration time of glove material

Penetration time (maximum wearing time): 480 min

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

· Eye/face protection Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Colour: Colourless Odourless

Odour threshold: No information available.

Melting point/freezing point: 0 °

· Boiling point or initial boiling point and boiling

range

100 °C (CAS: 7732-18-5 water, distilled, conductivity

or of similar purity)

• Flammability No information available.

· Lower and upper explosion limit

· **Lower:** No information available.

(Contd. on page 4)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

(Contd. of page 3)

· Upper: No information available.

Not applicable. · Flash point:

No information available. **Auto-ignition temperature:** No information available. **Decomposition temperature:**

pH at 20 °C 3.5-3.9

· Viscosity:

· Kinematic viscosity No information available

0.952 mPas Dynamic at 20 °C:

· Solubility

Fully miscible. · water:

No information available. · Partition coefficient n-octanol/water (log value)

 Vapour pressure at 20 °C: 23 hPa

Density and/or relative density

· Density at 20 °C: 1 g/cm³

· Relative density No information available. · Vapour density No information available.

· 9.2 Other information

· Appearance:

· Form: Liquid

· Important information on protection of health and

environment, and on safety.

· Ignition temperature: Product is not selfigniting.

 Explosive properties: Product does not present an explosion hazard.

· Solvent content:

· Water: 95.0 % · Solids content: 0.0 % · Molecular weight 18.02 g/mol

Change in condition

· Evaporation rate No information available.

· Information with regard to physical hazard classes

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

Substances and mixtures, which emit flammable

gases in contact with water Void **Oxidising liquids** Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals Void · Desensitised explosives Void

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

(Contd. of page 4)

SECTION 10: Stability and reactivity

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

Light sensitive.

Store away from heat.

Stable if the recommended storage and handling instructions are followed.

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

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 10,937 mg/kg (rat)

CAS: 616-45-5 2-pyrrolidone

Oral LD50 328 mg/kg (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications

(Contd. on page 6)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

· General notes: Not hazardous for water.

(Contd. of page 5)

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

· European waste catalogue

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

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

SECTION 14: Transport information		
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
 14.7 Maritime transport in bulk according instruments 	g to IMO 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.

(Contd. on page 7)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

(Contd. of page 6)

P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

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

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

· Relevant phrases

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- · Date of previous version: 12.06.2023
- Version number of previous version: 5
- Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

Acute Tox. 4: Acute toxicity – Category 4

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

(Contd. on page 8)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: TMB Solution

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

* Data compared to the previous version altered.

(Contd. of page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: Stop Solution

· Article number: ITC70024 [STOP]

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture In Vitro Diagnostic

· 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Max-Planck-Ring 21 65205 Wiesbaden

Germany

phone +49 (0) 6122 99 88 0 fax: +49 (0) 6122 99 88 100 eMail: human@human.de

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

· 1.4 Emergency telephone number:

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

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008

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

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

sulphuric acid

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 1)

≥2.5-<5%

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

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

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· PBT:

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

· vPvB:

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

SECTION 3: Composition/information on ingredients

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

· Dangerous	components:
-------------	-------------

CAS: 7664-93-9 EINECS: 231-639-5

sulphuric acid Met. Corr.1, H290; Skin Corr. 1A, H314

Specific concentration limits: Skin Corr. 1A; H314: C ≥ 15 % Skin Irrit. 2; H315: 5 % ≤ C < 15 %

Eye Irrit. 2; H319: $5 \% \le C < 15 \%$

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact:

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

- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · **6.2 Environmental precautions:** Dilute with plenty of water.

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 2)

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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

No further requirements.

Keep container tightly sealed.

• 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 7664-93-9 sulphuric acid

OEL Long-term value: 0.05 mg/m³

IOELV

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Hand protection



Protective gloves

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

(Contd. on page 4)





Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 3)

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

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

Material of gloves

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

· Penetration time of glove material

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

· Eye/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

· General Information

· Colour: Colourless Odourless

· **Odour threshold:** No information available.

 $^{\circ}$ Melting point/freezing point: 0 $^{\circ}$

Boiling point or initial boiling point and boiling

range 100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)

• Flammability No information available.

· Lower and upper explosion limit

Lower: No information available.
 Upper: No information available.

· Flash point: Not applicable.

• Auto-ignition temperature:
• Decomposition temperature:
• No information available.
• No information available.

pH at 20 °C

· Viscosity:

· Kinematic viscosity No information available

• **Dynamic at 20 °C:** 0.952 mPas

· Solubility

· water: Fully miscible.

· Partition coefficient n-octanol/water (log value) No information available.

· Vapour pressure at 20 °C: 23 hPa

· Density and/or relative density

Density at 20 °C: 1.0233 g/cm³

Relative density
 Vapour density
 No information available.
 No information available.

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 4)

· 9.2 Other information

· Appearance:

Liquid · Form:

· Important information on protection of health and

environment, and on safety.

· Ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Solvent content:

· Water: 97.2 % · Solids content: 0.0 % · Molecular weight 18.02 g/mol

· Change in condition

· Evaporation rate No information available.

Information with regard to physical hazard

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

Pyrophoric liquids Void · Pyrophoric solids Void Self-heating substances and mixtures Void

Substances and mixtures, which emit flammable gases in contact with water

Void · Oxidising liquids Void Oxidising solids Void Void Organic peroxides Corrosive to metals Void Desensitised explosives Void

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

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

(Contd. on page 6)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 5)

LD/LC50 values relevant for classification:

CAS: 7664-93-9 sulphuric acid

Inhalative inhalative 510 mg/m3 (rat)

- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- General notes:

Not hazardous for water.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

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

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 6)

SECTION 14: Transport information	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	not regulated
· 14.4 Packing group · ADR, IMDG, IATA	not regulated
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments Not applicable.	
· Transport/Additional information:	
· ADR · Limited quantities (LQ)	not regulated
· UN "Model Regulation":	not regulated

SECTION 15: Regulatory information

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

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

Hazard pictograms



- · Signal word Warning
- Hazard-determining components of labelling:

sulphuric acid

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· Precautionary statements

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.
P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with

water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

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(Contd. on page 8)

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Stop Solution

(Contd. of page 7)

P337+P313 If eye irritation persists: Get medical advice/attention.

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

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

regulations.

Directive 2012/18/EU

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

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

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

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

CAS: 7664-93-9 sulphuric acid

|3

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

CAS: 7664-93-9 sulphuric acid

3

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

SECTION 16: Other information

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

· Relevant phrases

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

- Date of previous version: 06.06.2023
- · Version number of previous version: 5
- · Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Met. Corr.1: Corrosive to metals – Category 1

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

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

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

* Data compared to the previous version altered.



- 16

Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

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

· 1.1 Product identifier

· Trade name: Mikrotiter Plate
· Article number: ITC70024 [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, 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.

P281 Use personal protective equipment as required.

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

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

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

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

· vPvB:

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

SECTION 3: Composition/information on ingredients

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

(Contd. on page 2)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(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:** No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

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

No further requirements.

Keep container tightly sealed.

· 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2, no other specific uses are foreseen

(Contd. on page 3)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

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

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

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

- · Respiratory protection: Not required.
- · Hand protection

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

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

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

Material of gloves

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

· Penetration time of glove material

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

· Eye/face protection Not required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

· General Information

· Colour: Colourless · Odour: Odourless

Odour threshold:
No information available.
Melting point/freezing point:
No information available.

Boiling point or initial boiling point and boiling

range No information available.

Flammability No information available.

Lower and upper explosion limit

Lower: No information available.
Upper: No information available.
Flash point: Not applicable.

Decomposition temperature: No information available.

· **pH** Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

· water: Insoluble.

(Contd. on page 4)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(Contd. of page 3)

· Partition coefficient n-octanol/water (log value) No information available.

Not applicable. · Vapour pressure:

Density and/or relative density

No information available. Density: Relative density No information available. · Vapour density Not applicable.

Particle characteristics

See section 3.

· 9.2 Other information

· Appearance:

Form: Solid

· Important information on protection of health and

environment, and on safety.

Ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Solvent content:

100.0 % · Solids content:

· Change in condition

· Evaporation rate Not applicable.

· Information with regard to physical hazard

classes

 Explosives Void Void · Flammable gases **Aerosols** Void Oxidising gases Void Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void

Oxidising liquids Void · Oxidising solids Void Organic peroxides Void · Corrosive to metals Void Void Desensitised explosives

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.

(Contd. on page 5)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(Contd. of page 4)

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

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information: No further relevant indications
- · General notes: Not hazardous for water.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

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

· European waste catalogue

18 01 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.

(Contd. on page 6)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(Contd. of page 5)

SECTION 14: Transport information	on	
· 14.1 UN number or ID number · ADR, ADN, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according to IMO instruments Not applicable.		
· Transport/Additional information:		
· ADR · Limited quantities (LQ)	not regulated	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Precautionary statements
- P234 Keep only in original packaging.
- P281 Use personal protective equipment as required.
- P401 Store in accordance with local/regional/national/international regulations.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II
- None of the ingredients is listed.
- · REGULATION (EU) 2019/1148
- Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))
- None of the ingredients is listed.
- · Annex II REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

(Contd. on page 7)



Printing date 12.06.2023 Version number 6 (replaces version 5) Revision: 12.06.2023

Trade name: Mikrotiter Plate

(Contd. of page 6)

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

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

None of the ingredients is listed.

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

SECTION 16: Other information

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

· Date of previous version: 06.06.2023 · Version number of previous version: 5

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the

International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

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

* Data compared to the previous version altered.

