

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

1.1. Product identifier

Product form	: Mixture
Trade name	: NUCLISWAB
Product code	: TS060
Type of product	: Medical Device (Nucleic acid sample collection and transportation kit)
Product group	: Trade product

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

Relevant identified uses

Main use category	: Professional use
Use of the substance/mixture	: For in vitro diagnostic use

1.3. Details of the supplier of the safety data sheet

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1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Tris (77-86-1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Tris (77-86-1)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

(¹) Substance(s) in concentration below 0.1 % and displayed on a voluntary basis

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tris	CAS-No.: 77-86-1 EC-No.: 201-064-4	0.2 – 0.4	Not classified
EDTA	CAS-No.: 6381-92-6 EC-No.: 205-358-3	0.5 – 0.1	Acute Tox. 4 (Inhalation), H332 (ATE=1.5 mg/l/4h) STOT RE 2, H373
HCl (Note B)	EC-No.: 231-595-7 EC Index-No.: 017-002-01-X	< 0.01	Skin Corr. 1B, H314 STOT SE 3, H335

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
HCl	EC-No.: 231-595-7 EC Index-No.: 017-002-01-X	(10 ≤ C < 25) Skin Irrit. 2; H315 (10 ≤ C < 25) Eye Irrit. 2; H319 (10 ≤ C ≤ 100) STOT SE 3; H335 (25 ≤ C ≤ 100) Skin Corr. 1B; H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Never give anything by mouth to an unconscious person. Do not induce vomiting. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂).
Unsuitable extinguishing media	: Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Reactivity in case of fire	: At high temperature may liberate dangerous gases.
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Hazardous decomposition products in case of fire : On heating or during combustion : Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire : Keep away from combustible materials. Keep container closed when not in use. Approach from upwind.
Firefighting instructions : Exercise caution when fighting any chemical fire. Keep upwind. Do not enter fire area without proper protective equipment, including respiratory protection. Eliminate all ignition sources if safe to do so. Contain the extinguishing fluids by bunding.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Do not allow run-off from fire fighting to enter drains or water courses. Notify authorities if product enters sewers or public waters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Keep public away from danger area.

For non-emergency personnel

Protective equipment : For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Ventilate spillage area.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Equip cleanup crew with proper protection. Evacuate unnecessary personnel.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No specific measures are required provided the product is handled in accordance with the general rules of occupational hygiene and safety.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.
Incompatible products : Strong acids. Strong bases. Strong oxidizing agents.
Incompatible materials : Extremely high or low temperatures.

Germany

Storage class (LGK, TRGS 510) : LGK 12 - Non-combustible liquids

Joint storage table

LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

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Joint storage not permitted for	: LGK 1, LGK 6.2, LGK 7
Joint storage with restrictions permitted for	: LGK 4.1A, LGK 4.3, LGK 5.1C
Joint storage permitted for	: LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13

7.3. Specific end use(s)

See Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

HCI	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Hydrogen chloride
IOEL TWA	8 mg/m ³
	5 ppm
IOEL STEL	15 mg/m ³
	10 ppm
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Safety glasses. Wear protective gloves.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Not required for normal conditions of use

Skin protection

Skin and body protection:

No special clothing/skin protection equipment is recommended under normal conditions of use

Hand protection:

Does not require any particular or specific measures. Respect the general rules for occupational hygiene

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Clear
Appearance	: Liquid transport medium in the tube.
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 8 – 8.5
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)

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Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Tris (77-86-1)	
LD50 oral rat	> 5000 mg/kg bodyweight (OECD 425: Acute Oral Toxicity: Up-and-Down Procedure, Rat, Female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 5000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal)

EDTA (6381-92-6)	
LD50 oral rat	2800 mg/kg bodyweight Animal: rat

HCl	
LD50 dermal	> 5010 mg/kg bodyweight

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 8 – 8.5

Tris (77-86-1)	
pH	10 – 11 (5 %)

Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 8 – 8.5

Tris (77-86-1)	
pH	10 – 11 (5 %)

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

HCl	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

EDTA (6381-92-6)	
LOAEC (inhalation, rat, dust/mist/fume, 90 days)	0.015 mg/l air Animal: rat, Animal sex: female, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study)
NOAEL (oral, rat, 90 days)	≥ 500 mg/kg bodyweight Animal: rat, Animal sex: male
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

Tris (77-86-1)	
Viscosity, kinematic	Not applicable (solid)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

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Tris (77-86-1)	
EC50 - Crustacea [1]	> 980 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect)
ErC50 algae	397 mg/l (Equivalent or similar to OECD 201, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration)

EDTA (6381-92-6)	
LC50 - Fish [1]	> 116 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	> 114 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	> 60 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
LOEC (chronic)	50 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	25 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	≥ 25.7 mg/l Test organisms (species): Duration: '35 d'

HCl	
LC50 - Fish [1]	3.25 mg/l
EC50 - Other aquatic organisms [1]	4.92 mg/l waterflea
EC50 - Other aquatic organisms [2]	4.5 mg/l

12.2. Persistence and degradability

NUCLISWAB	
Persistence and degradability	Not rapidly degradable

Tris (77-86-1)	
Persistence and degradability	Readily biodegradable in water.

EDTA (6381-92-6)	
Persistence and degradability	Not rapidly degradable

HCl	
Persistence and degradability	Not rapidly degradable

12.3. Bioaccumulative potential

Tris (77-86-1)	
Partition coefficient n-octanol/water (Log Pow)	-2.31 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C)
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

Tris (77-86-1)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.34 – 1.87 (log Koc, QSAR)
Ecology - soil	Highly mobile in soil.

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12.5. Results of PBT and vPvB assessment

Component

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	Tris (77-86-1)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	Tris (77-86-1)

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

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Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

National regulations

Germany

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CAS-No.	Chemical Abstract Service number
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate

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Abbreviations and acronyms:	
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
CAS	Chemical Abstracts Service (division of the American Chemical Society)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
IOELV	Indicative Occupational Exposure Limit Value
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
N.O.S.	Not Otherwise Specified
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
Pow (log)	n-octanol/water partition coefficient
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Data sources

: ECHA (European Chemicals Agency). Supplier's safety documents. Classification according to Regulation (EC) No. 1272/2008 [CLP].

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Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable