

Reference standard set, Control set

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

1.1. Product identifier

Product name:	Reference standard set, Control set
Catalog number:	ES190 (Standard SK15, optional), ES191 (Standard 1), ES192 (Standard 2), ES193 (Standard 3), ES194 (Standard 4), ES195 (Control 1), ES196 (Control 2)
REACH Registration Number:	A registration number is not available for this substance as the substance or its uses are exempted from registration, according to Article 2 (7) Regulation (EC) No. 1907/2006 [REACH], the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Use of the substance/mixture

Ready-to-use standards and controls for Pancreatic Elastase ELISA.

Uses advised against

None identified.

1.3. Details of the supplier of the safety data sheet

Company name:	BIOSERV Diagnostics GmbH
Street:	Doberaner Str. 151
Place:	D-18057 Rostock Germany
Telephone:	+49 (0) 381 / 3758 2090
Telefax:	+49 (0) 381 / 3758 2099
e-mail:	info@bioserv-diagnostics.com
e-mail (Contact person):	mail@giftnotruf.de
Internet:	http://www.bioserv-diagnostics.com
Responsible Department:	Advisory Center for Intoxication and Embryonic Toxicology, Berlin, Germany

1.4. Emergency telephone number:

+49 (0) 30 / 192 40

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

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Labelling of packages where the contents do not exceed 125 ml

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2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Further Information

Concentrations of dangerous components according to Regulation (EC) No. 1272/2008, as amended by Regulation (EU) 2018/669 are below the concentration limits mentioned in the law.
Contains Sodium Azide (<0.1%) as preservative.

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SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

When in doubt or if symptoms are observed, get medical advice. Provide fresh air.

After contact with skin

Wash with plenty of water.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth thoroughly with water. Get medical advice/attention.

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

No known symptoms to date.

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

Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

None identified.

5.2. Special hazards arising from the substance or mixture

Non-flammable. The product itself does not burn.

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Wash with plenty of water.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling

Do not breathe gas/fumes/vapour/spray. When using do not eat, drink, smoke, sniff.

Advice on protection against fire and explosion

No special measures are necessary.

Further information on handling

Wear personal protection equipment (refer to section 8).

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Do not store together with: Oxidizing agent.

Further information on storage conditions

Observe directions on the label.
storage temperature of 2 °C - 8 °C.

7.3. Specific end use(s)

Use only in accordance to the manual.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. Exposure controls

Protective and hygiene measures

General industrial hygiene practice.

Eye/face protection

Eye protection: not required.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. Chemical protective gloves must meet the requirements of European standard EN 374. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The following materials are suitable for protective gloves (permeation time > 480 min):
NBR (Nitrile rubber); >= 0.11 mm thickness
Take recovery periods for skin regeneration.

Skin protection

Use of protective clothing. When handling with chemical substances, protective clothing with CE-labels including the four control digits must be worn.

Respiratory protection

Respiratory protection not required.

Environmental exposure controls

No special environmental precautions required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless - pale yellow
Odour:	odourless
pH-Value (at 25 °C):	7.2-7.6

Changes in the physical state

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Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	not determined
Flammability	
Solid:	not applicable
Gas:	not applicable
Explosive properties	The product is not: Explosive.
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	not determined
Oxidizing properties	Not oxidising.
Vapour pressure:	not determined
Density:	1.007 g/cm ³
Water solubility:	completely miscible
Solubility in other solvents	not determined
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined

9.2. Other information

Solid content:	not determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non-reactive under normal use conditions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

Stable under recommended storage and handling conditions.

10.5. Incompatible materials

Does not decompose when used for intended uses.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

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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 information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment. There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150102 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); plastic packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%

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ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation
intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)