

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 1**
 Product code : EPI_PLUS_1
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	90 - 99	Not classified
Sodium dodecyl sulfate	(CAS No) 151-21-3 (EC no) 205-788-1	0.1 - 1	Flam. Sol. 2, H228 Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Chronic 3, H412
Sodium Dihydrogen Phosphate Dihydrate	(CAS No) 13472-35-0	0.1 - 1	Not classified
Disodium Phosphate Dihydrate	(CAS No) 10028-24-7	0.1 - 1	Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool, well ventilated place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct (sun)light.
Storage temperature	: 2 - 8 °C

7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless

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Odour	: Odourless
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: Non flammable
Explosive limits	: No data available
Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: 6.70 – 6.90
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days. Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

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Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

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Persistence and degradability : Not established.

Sodium dodecyl sulfate (151-21-3)

Persistence and degradability : May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

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Bioaccumulative potential : Not established.

Sodium dodecyl sulfate (151-21-3)

Bioaccumulative potential : Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / AND) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

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Other information : No supplementary information available

14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed

SZW-list of mutagenic substances : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Breastfeeding

NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Development

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified

Full text of H-phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2

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Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Sol. 2	Flammable solids, Category 2
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
H228	Flammable solid
H300	Fatal if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H330	Fatal if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 2**
 Product code : EPI_PLUS_2
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dimethyl sulphoxide (DMSO)	(CAS No) 67-68-5	50 - 70	Not classified
4-Nitrophenyl-alpha-D-glucopyranoside	(CAS No) 3767-28-0	30 - 50	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
 First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
 First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.

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First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool place away from direct (sun)light.
Keep container closed when not in use.
Do not freeze.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct (sun)light. Heat sources.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless
Odour	: Sulphurous
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: Non flammable
Explosive limits	: No data available
Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available

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Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days. Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

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Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

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Persistence and degradability : Not established.

12.3. Bioaccumulative potential

EpiScreen Plus Reagent 2

Bioaccumulative potential : Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

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Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed
SZW-list of mutagenic substances : None of the components are listed
NON-exhaustive list of reproductive toxins - Breastfeeding : None of the components are listed
NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed
NON-exhaustive list of reproductive toxins - Development : None of the components are listed

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified	
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SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 3**
 Product code : EPI_PLUS_3
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	70 - 90	Not classified
D-(+)-Glucose	(CAS No) 50-99-7 (EC no) 200-075-1	10 - 20	Not classified
Sodium dodecyl sulfate	(CAS No) 151-21-3 (EC no) 205-788-1	0.1 - 1	Flam. Sol. 2, H228 Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Chronic 3, H412
Sodium Dihydrogen Phosphate Dihydrate	(CAS No) 13472-35-0	0.1 - 1	Not classified
Disodium Phosphate Dihydrate	(CAS No) 10028-24-7	0.1 - 1	Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct (sun)light. Heat sources.
Storage temperature	: 2 - 8 °C

7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

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Colour	: Colourless
Odour	: Odourless
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: Non flammable
Explosive limits	: No data available
Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: 6.55-6.75
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days . Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified

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Aspiration hazard : Not classified
Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

EpiScreen Plus Reagent 3

Persistence and degradability : Not established.

Sodium dodecyl sulfate (151-21-3)

Persistence and degradability : May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

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Bioaccumulative potential : Not established.

Sodium dodecyl sulfate (151-21-3)

Bioaccumulative potential : Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

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14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed

SZW-list of mutagenic substances : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Breastfeeding

NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Development

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified

Full text of H-phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1

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Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Sol. 2	Flammable solids, Category 2
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
H228	Flammable solid
H300	Fatal if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H330	Fatal if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 4**
 Product code : EPI_PLUS_4
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	≥ 99	Not classified
Sodium hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	< 0.1	Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Sodium hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	(0.5 \leq C < 2) Eye Irrit. 2, H319 (0.5 \leq C < 2) Skin Irrit. 2, H315 (2 \leq C < 5) Skin Corr. 1B, H314 (5 \leq C < 100) Skin Corr. 1A, H314

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Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool place away from direct (sun)light.
Keep container closed when not in use.
Do not freeze.
Do not use after expiry date.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct (sun)light. Heat sources.

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Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless
Odour	: Odourless
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability (solid, gas)	: Non flammable
Explosive limits	: No data available

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Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: > 12
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days). Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

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11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

EpiScreen Plus Reagent 4

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

EpiScreen Plus Reagent 4

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

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Safety Data Sheet

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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed

SZW-list of mutagenic substances : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Breastfeeding

NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed

NON-exhaustive list of reproductive toxins - : None of the components are listed

Development

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified	
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Full text of H-phrases:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 5**
 Product code : EPI_PLUS_5
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	≥ 99	Not classified
Sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
4-nitrophenol, p-nitrophenol	(CAS No) 100-02-7 (EC no) 202-811-7 (EC index no) 609-015-00-2	< 0.1	Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Oral), H302 STOT RE 2, H373

Full text of H-phrases: see section 16

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.
First-aid measures after eye contact	: Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Remove ignition sources. Use special care to avoid electric charges. No open fire. Do not smoke.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool place away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct (sun)light. Heat sources.
Storage temperature	: 2 - 8 °C

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7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellow
Odour	: Odourless
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: Non flammable
Explosive limits	: No data available

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Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days. Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

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11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

EpiScreen Plus Reagent 5

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

EpiScreen Plus Reagent 5

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

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Safety Data Sheet

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Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.
Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.
Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed
SZW-list of mutagenic substances : None of the components are listed
NON-exhaustive list of reproductive toxins - : None of the components are listed
Breastfeeding
NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed
NON-exhaustive list of reproductive toxins - : None of the components are listed
Development

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified

Full text of H-phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
H312	Harmful in contact with skin
H330	Fatal if inhaled
H332	Harmful if inhaled
H373	May cause damage to organs through prolonged or repeated exposure

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H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product form : Mixture
 Product name : **EpiScreen Plus Reagent 6**
 Product code : EPI_PLUS_6
 GMDN : 64102

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
 Use of the substance/mixture : In Vitro Diagnostic Device (IVD) for the semi-quantitative measurement of neutral alpha-glucosidase in human semen (plasma).

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FertiPro NV
 Industriepark Noord 32
 8730 Beernem
 Belgium
 info@fertipro.com

1.4. Emergency telephone number

Emergency number : +3250791805

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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 is 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.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ultrapure water	(CAS No) 7732-18-5 (EC no) 231-791-2	≥ 99	Not classified
Sodium dodecyl sulfate	(CAS No) 151-21-3 (EC no) 205-788-1	0.1 - 1	Flam. Sol. 2, H228 Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Chronic 3, H412
Sodium hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	< 0.1	Skin Corr. 1A, H314

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Specific concentration limits:

Name	Product identifier	Specific concentration limits
Sodium hydroxide	(CAS No) 1310-73-2 (EC no) 215-185-5 (EC index no) 011-002-00-6	(0,5 ≤ C < 2) Skin Irrit. 2, H315 (0,5 ≤ C < 2) Eye Irrit. 2, H319 (2 ≤ C < 5) Skin Corr. 1B, H314 (C ≤ 5 < 100) Skin Corr. 1A, H314

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash affected clothing before reuse.
- First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Use special care to avoid static electric charges. No open fire. Do not smoke.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool away from direct (sun)light. Keep container closed when not in use. Do not freeze. Do not use after expiry date.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct (sun)light. Heat sources.
Storage temperature	: 2 - 8 °C

7.3. Specific end use(s)

See instructions for use delivered with the device.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

8.2.2.2. Skin protection

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.

Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.

8.2.2.3. Respiratory protection

Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Do not pipette liquid using a mouth pipette.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

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Colour	: Colourless.
Odour	: Odourless.
Odour threshold	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flammability	: Non flammable
Explosive limits	: No data available
Lower explosion limit	: No data available
Upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: > 12
Viscosity, kinematic	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Kow)	: No data available
Vapour pressure	: No data available
Vapour pressure at 50 °C	: No data available
Density	: No data available
Relative density	: No data available
Relative vapour density at 20 °C	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable after transport at elevated temperature ($\leq 37^{\circ}\text{C}$) for max. 5 days . Stable for 24 months after date of manufacture.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct (sun)light. Extremely high or low temperatures. Open fire.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Smoke. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified

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Aspiration hazard : Not classified
Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

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Persistence and degradability	Not established.
Sodium dodecyl sulfate (151-21-3)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

EpiScreen Plus Reagent 6	
Bioaccumulative potential	Not established.
Sodium dodecyl sulfate (151-21-3)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR / RID / IMDG / IATA / ADN) : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) (ADR / RID / IMDG / IATA / AND) : Not applicable

14.4. Packing group

Packing group (ADR / RID / IMDG / IATA / AND) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

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Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport / Transport by sea / Air transport / Inland waterway transport / Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-list of carcinogenic substances : None of the components are listed

SZW-list of mutagenic substances : None of the components are listed

NON-exhaustive list of reproductive toxins -

Breastfeeding

NON-exhaustive list of reproductive toxins - Fertility : None of the components are listed

NON-exhaustive list of reproductive toxins -

Development

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

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

Not classified

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2

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Flam. Sol. 2	Flammable solids, Category 2
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H228	Flammable solid
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H412	Harmful to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product