

Version: D.6

FertiPro	Safety Data Sheet according to REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 ID: FP09 I14 R02 Revision date: 02/05/2022
	Data Sheets Reagent 1: pages 1>7 // Data Sheets Reagent 2: pages 8>14
SECTION 1: Identification of	the substance/mixture and of the company/undertaking
1.1. Product identifier	
Product form	: Mixture
Product name	: VitalScreen Reagent 1
Product code	: VITAL_1
GMDN	: 43587
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	: Diagnostic kit for the in vitro determination of sperm vitality
1.2.2. Uses advised against	
No additional information available	
1.3. Details of the supplier of the	na safatu data sheat
FertiPro NV Industriepark Noord 32 8730 Beernem Belgium info@fertipro.com	
1.4. Emergency telephone num	ber
Emergency number	: +3250791805
SECTION 2: Hazards identific	ation
2.1. Classification of the substa	ance or mixture
Classification according to Regulation Skin sensitisation, Category 1 Full text of H statements : see section Adverse physicochemical, human he No additional information available	H317 16
2.2. Label elements	
Labelling according to Regulation (E Hazard pictograms (CLP)	
Signal word (CLP) Hazardous ingredients Hazard statements (CLP) Precautionary statements (CLP)	GHS07 : Warning : Eosin : H317 - May cause an allergic skin reaction. : P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray. P272 - Contaminated work clothing should not be allowed out of the w

1.2

FertiPro NV	
Industriepark Noord 32 8730 Beernem	
Belgium	
info@fertipro.com	
1.4. Emergency telephone number	
Emergency number	: +3250791805
SECTION 2. Horordo identification	
SECTION 2: Hazards identification	
2.1. Classification of the substance or	mixture
Classification according to Regulation (EC)	No. 1272/2008 [CLP]
Skin sensitisation, Category 1	H317
Full text of H statements : see section 16	
Adverse physicochemical, human health an	id environmental effects
No additional information available	
2.2. Label elements	
Labelling according to Regulation (EC) No.	1272/2008 [CLP]
Hazard pictograms (CLP)	
	GHS07
Signal word (CLP)	: Warning
Hazardous ingredients	: Eosin
Hazard statements (CLP)	: H317 - May cause an allergic skin reaction.
Precautionary statements (CLP)	: P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray.
	P272 - Contaminated work clothing should not be allowed out of the workplace.
	P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing
	protection/
	P302+P352 - IF ON SKIN: Wash with plenty of water/
	P321 - Specific treatment (see supplemental first aid instruction on this label).
	P333+P313 - If skin irritation or rash occurs: get medical advice/attention.
	P362+P364 - Take off contaminated clothing and wash it before reuse.
	P501 - Dispose of contents/container to
2.3. Other hazards	
Containe no PPT/vPvP substances > 0.1%	

Contains no PBT/vPvB substances ≥ 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.

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SECTION 3: Composition/information on ingredients

Substance 3.1. 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
eosin	(CAS No) 17372-87-1 (EC no) 241-409-6	1 - 5	Eye Irrit. 2, H319 Skin Sens. 1, H317
sodium chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	0,1 - 1	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

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 a (show the label where possible).	dvice
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, follow warm water rinse. Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Specific treatment (see supplemental first aid instruction on this label). Wa contaminated clothing before reuse.	
First-aid measures after eye contact : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medica attention if pain, blinking or redness persist.	I
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 : May cause an allergic skin reaction.	
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 smoke.	o not
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.	

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6.3. Methods and material for co	ontainment 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/perso	nal protection.
SECTION 7: Handling and sto	rage
7.1. Precautions for safe handling	ng
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 vapour. Avoid breathing dust/fume/gas/mist/vapours/spray.
Hygiene measures	: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.
7.2. Conditions for safe storage	, including any incompatibilities
Storage conditions	: Keep only in the original container in acool well ventilated place away from direct (sun)light. Kee 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 - 25 °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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Personal protective equipment:

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

type of protection must be selected according to the concentration and volume of the dangerous

The selected protective gloves have to meet the specifications of Regulation EU 2016/425 and

Face shield and safety glasses. Use equipment for eye protection tested and approved under

: 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

- : Avoid all unnecessary exposure. Wear fire/flame resistant/retardant clothing.
- Personal protective equipment symbol(s):

substance at the specific workplace.

laboratory practices. Wash and dry hands.



the standard EN374.

Skin protection:

Hand protection

Eye/Face protection

appropriate government standards such as NIOSH (US) or EN 166 (EU).

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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).
Thermal hazards	: No additional information available
Environmental exposure controls	: 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	: Red.	
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	
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	
рН	: No data available	
Viscosity, kinematic	: No data available	
Solubility	: highly soluble in water.	
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 (max. 5 days) at elevated temperature (≤37°C). Stable for 24 months after date of manufacture.

10.3.	Possibility of hazardous reactions
Not estab	lished.
10.4.	Conditions to avoid
Direct (su	n)light. Extremely high or low temperatures. Open fire.
10.5.	Incompatible materials
Strong ac	ids. Strong bases.
10.6.	Hazardous decomposition products
Smoke. C	arbon monoxide. Carbon dioxide.

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SECTION 11: Toxicological informatio

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11.1. Information on hazard classes as def	ned in Regulation (EC) No 1272/2008
Acute toxicity (oral, dermal, inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Specific target organ toxicity (STOT) (single exposure)	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Specific target organ toxicity (STOT) (repeated exposure)	: Not classified
Additional information	: Based on available data, the classification criteria are not met.
Sodium azide (26628-22-8)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure
Aspiration hazard	: Not classified
Additional information	: 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 available	
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	: Not classified
(acute)	
Hazardous to the aquatic environment, long-term (chronic)	: Not classified
12.2. Persistence and degradability	
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VitalScreen Reagent 1 Persistence and degradability	Not established.
Sodium Chloride (7647-14-5)	Nat astablished
Persistence and degradability	Not established.
12.3. Bioaccumulative potential	
VitalScreen Reagent 1	
Bioaccumulative potential	Not established.
Sodium Chloride (7647-14-5)	
Bioaccumulative potential	Not established.
12.4. Mobility in soil	
No additional information available	
12.5. Results of PBT and vPvB assessmen	l de la companya de l
No additional information available	
12.6. Endocrine disrupting properties	
No additional information available	

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12.7. Other adverse effects Avoid release to the environment	
SECTION 13: Disposal consider 13.1. Waste treatment methods Waste disposal recommendations	ations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials SECTION 14: Transport informa	: Avoid release to the environment.
In accordance with ADR / RID / IMDG / IA	
14.1.UN numberNot regulated for transport14.2.UN proper shipping name	
Proper Shipping Name (ADR) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) Proper Shipping Name (ADN) Proper Shipping Name (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
14.3.Transport hazard class(es)ADR: Transport hazard class(es)IMDG: Transport hazard class(es)IATA: Transport hazard class(es)ADN: Transport hazard class(es)RID: Transport hazard class(es)	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
14.4.Packing groupPacking group (ADR)Packing group (IMDG)Packing group (IATA)Packing group (ADN)Packing group (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
14.5.Environmental hazardsDangerous for the environmentMarine pollutantOther information14.6.Special precautions for user	: No : No : No supplementary information available

Overland transport / Transport by sea / Air transport/ Inland waterway transport/ Rail transport No data available

14.7. Maritime transport in bulk according to IMO instruments Not applicable

SECTION 15: Regulatory information

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

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.

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15.1.2. National regulatio	0	
France		
Occupational diseases		
Code D	Description	
RG 78 D	iseases caused by so	odium chloride in salt mines and their dependencies
Germany		
Water hazard class (WGK)		: WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1)
Hazardous Incident Ordinanc	e (12. BlmSchV)	: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)
Netherlands		
SZW-list of carcinogenic subs		: None of the components are listed
SZW-list of mutagenic substa		: None of the components are listed
NON-exhaustive list of reproc	luctive toxins -	: None of the components are listed
Breastfeeding		
NON-exhaustive list of reproc		
NON-exhaustive list of reproc	luctive toxins -	: None of the components are listed
Development		
Denmark		
Danish National Regulations		: Young people below the age of 18 years are not allowed to use the product
		Pregnant/breastfeeding women working with the product must not be in direct contact wit
Quuite aulau d		the product
Switzerland		· LK 10/12 Liquida
Storage class (LK) : LK 10/12 – Liquids		. EK 10/12 – Elquius
Storage class (LK) 15.2. Chemical safety a No chemical safety assessme SECTION 16: Other in	ent has been carried o	put
15.2. Chemical safety a No chemical safety assessme	ent has been carried or formation	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
15.2. Chemical safety a No chemical safety assessme SECTION 16: Other in Data sources	ent has been carried or formation :	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.
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 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other in Data sources Other information Classification according to Skin Sens. 1 	ent has been carried or formation : : Regulation (EC) No.	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. None.
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other in Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase 	ent has been carried or formation : Regulation (EC) No.	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. None. 1272/2008 [CLP]: H317
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other in Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 1 (Dermal) 	ent has been carried or formation : Regulation (EC) No. ses:	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other in Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrass Acute Tox. 1 (Dermal) Acute Tox. 2 (Inhalation) 	ent has been carried or formation : Regulation (EC) No.	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other in Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 1 (Dermal) Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) 	ent has been carried or formation : Regulation (EC) No.	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other information Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 1 (Dermal) Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) Aquatic Acute 1 	ent has been carried or formation : Regulation (EC) No. ses:	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2 Hazardous to the aquatic environment — Acute Hazard, Category 1
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other information Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 1 (Dermal) Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) Aquatic Acute 1 Aquatic Chronic 1 	ent has been carried or formation : Regulation (EC) No.	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2 Hazardous to the aquatic environment — Acute Hazard, Category 1
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other information Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 1 (Dermal) Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) Aquatic Acute 1 Aquatic Chronic 1 Eye Irrit. 2 	ent has been carried or formation : Regulation (EC) No. ses:	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2 Acute toxicity (oral), Category 2 Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1 Serious eye damage/eye irritation, Category 2
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 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other information Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 2 (Inhalation) Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) Aquatic Acute 1 Aquatic Chronic 1 Eye Irrit. 2 Skin Sens. 1 STOT RE 2 	ent has been carried or formation : Regulation (EC) No. : : : : : : : : : : : : : : : : : : :	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. None. 1272/2008 [CLP]: H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2 Base of the aquatic environment — Acute Hazard, Category 1 Base of the aquatic environment — Chronic Hazard, Category 1 Base of the aquatic environment — Chronic Hazard, Category 1 Skin sensitisation, Category 1 Specific target organ t
 15.2. Chemical safety a No chemical safety assessment SECTION 16: Other introduced Data sources Other information Classification according to Skin Sens. 1 Full text of H- and EUH-phrase Acute Tox. 2 (Inhalation) Acute Tox. 2 (Oral) Aquatic Acute 1 Aquatic Chronic 1 Eye Irrit. 2 Skin Sens. 1 STOT RE 2 H300 	ent has been carried or formation : Regulation (EC) No. ses:	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. None. 1972/2008 [CLP]: H317 H317 Acute toxicity (dermal), Category 1 Acute toxicity (inhal.), Category 2 Acute toxicity (oral), Category 2 Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1 Serious eye damage/eye irritation, Category 2 Skin sensitisation, Category 1 Specific target organ toxicity — Repeated exposure, Category 2 Fatal if swallowed
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Safety Data Sheet (SDS), EU

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



VitalScreen Reagent 1 / VitalScreen Reagent 2 Safety Data Sheet according to REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 ID: FP09 I14 R02 Revision date: 02/05/2022 Ve

Version: D.6

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SECTION 1: Identification of the	substance/mixture and of the company/undertaking
1.1. Product identifier	
Product form	: Mixture
Product name	: VitalScreen Reagent 2
Product code	: VITAL_2
GMDN	: 43587
1.2. Relevant identified uses of the	e 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	: Diagnostic kit for the in vitro determination of sperm vitality
1.2.2. Uses advised against	
1.2.2. Uses advised against No additional information available	
1.3. Details of the supplier of the s FertiPro NV	afety data sneet
Industriepark Noord 32	
8730 Beernem	
Belgium info@fertipro.com	
1.4. Emergency telephone number	
Emergency number	: +3250791805
SECTION 2: Hazards identificati	on
2.1. Classification of the substance	e or mixture
Classification according to Regulation ((EC) No. 1272/2008 [CLP]
Not classified	
Adverse physicochemical, human healt	h 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 ≥ 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
nigrosin	(CAS No) 8005-03-6	5 - 10	Not classified
sodium chloride	(CAS No) 7647-14-5 (EC no) 231-598-3	1 - 5	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

Full text of H-phrases: see section 16

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SECTION 4: First aid measures **Description of first aid measures** 4.1. 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. : Remove contact lenses, if possible. Rinse immediately with plenty of water. Obtain medical First-aid measures after eye contact attention if pain, blinking or redness persist. : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. First-aid measures after ingestion 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 **Extinguishing media** 5.1. : Foam. Dry powder. Carbon dioxide. Water spray. Sand. Suitable extinguishing media : Do not use a heavy water stream. Unsuitable extinguishing media 52 Special hazards arising from the substance or mixture No additional information available 5.3. Advice for firefighters : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any **Firefighting instructions** 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. : Ventilate area. Emergency procedures 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 : Soak up spills as soon as possible. Collect spillage. Store away from other materials. Methods for cleaning up 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 : Keep only in the original container in a well ventilated place away from direct (sun)light. Keep Storage conditions container closed when not in use. Do not freeze. Do not use after expiry date. Strong bases. Strong acids. Incompatible products Incompatible materials : Sources of ignition. Direct (sun)light. Heat sources. : 2 - 25 °C Storage temperature 7.3. Specific end use(s)

See instructions for use delivered with the device.

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SECTION 8: Exposure controls/personal protection		
8.1.	Control parameters	

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Skin protection:

Hand protection

Eye/Face protection

No additional information available

8.2. Exposure controls

<u> </u>	Personal protective equipment symbol(s):
Personal protective equipment:	: Avoid all unnecessary exposure. Wear fire/flame resistant/retardant clothing.
Appropriate engineering controls:	: Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.



	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 the specifications of Regulation EU 2016/425 and the standard EN374.

- : 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).
- 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).

 Thermal hazards
 : No additional information available

 Environmental exposure controls
 : 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	: Red.
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
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
рН	: No data available

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Viscosity, kinematic	: No data available
Solubility	: highly soluble in water.
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 (max. 5 days) at elevated	temperature (≤37°C). 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 tempera	tures. 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 (oral, dermal, inhalation)	: Not classified	
Skin corrosion/irritation	: Not classified	
Additional information	: Based on available data, the classification criteria are not met	
Serious eye damage/irritation Additional information	: Not classified	
Respiratory or skin sensitisation	 Based on available data, the classification criteria are not met. May cause an allergic skin reaction. 	
Germ cell mutagenicity	: Not classified	
Additional information	: Based on available data, the classification criteria are not met.	
Carcinogenicity	: Not classified	
Additional information	: Based on available data, the classification criteria are not met.	
Reproductive toxicity	: Not classified	
Additional information	: Based on available data, the classification criteria are not met.	
Specific target organ toxicity (STOT) (single exposure)	: Not classified	
Additional information	: Based on available data, the classification criteria are not met.	
Specific target organ toxicity (STOT) (repeated exposure)	: Not classified	
Additional information	: Based on available data, the classification criteria are not met.	
Sodium azide (26628-22-8)		
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure	
Aspiration hazard	: Not classified	

Additional information

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11.2. Information on other hazards			
11.2.1. Endocrine disrupting properties			
No additional information available			
11.2.2. Other information			
	· Pasad an availably	data the algorithmation oritoria are not mot	
Potential adverse human health effects and symptoms	. Dased on available	e data, the classification criteria are not met	
SECTION 12: Ecological information	on		
12.1. Toxicity			
Hazardous to the aquatic environment, short-t (acute)	term : Not classified		
Hazardous to the aquatic environment, long-te (chronic)	erm : Not classified		
12.2. Persistence and degradability			
VitalScreen Reagent 2			
Persistence and degradability	Not established.		
Sodium Chloride (7647-14-5)			
Persistence and degradability	Not established.		
12.3. Bioaccumulative potential			
VitalScreen Reagent 2			
Bioaccumulative potential	Not established.		
Sodium Chloride (7647-14-5) Bioaccumulative potential	Not established.		
	Not established.		
12.4. Mobility in soil			
No additional information available			
12.5. Results of PBT and vPvB assessed	nent		
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 considerati	ons		
13.1. Waste treatment methods			
Waste disposal recommendations	: Dispose in a safe man	ner in accordance with local/national regulations.	
Ecology - waste materials	: Avoid release to the er	-	
SECTION 14: Transport informatio			
In accordance with ADR / RID / IMDG / IATA /	ADN		
14.1. UN number			
UN-No. (ADR)	: Not applicable		
UN-No. (IMDG)	: Not applicable		
	: Not applicable		
UN-No. (ADN) UN-No. (RID)	: Not applicable : Not applicable		
14.2. UN proper shipping name			
Proper Shipping Name (ADR)	: Not applicable		
Proper Shipping Name (IMDG)	: Not applicable		
Proper Shipping Name (IATA)	: Not applicable		
Proper Shipping Name (ADN)	: Not applicable		
Proper Shipping Name (RID)	: Not applicable		
14.3. Transport hazard class(es)			
ADR			
Transport hazard class(es) (ADR)	: Not applicable		
02/05/2022	EN (English)	ID: FP09 I14 R02	12/14

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IMDG Transport hazard class(es) (IMDG)	: Not applicable
IATA Transport hazard class(es) (IATA)	: Not applicable
ADN Transport hazard class(es) (ADN)	: Not applicable
RID Transport hazard class(es) (RID)	: Not applicable
14.4.Packing groupPacking group (ADR)Packing group (IMDG)Packing group (IATA)Packing group (ADN)Packing group (RID)	 Not applicable Not applicable Not applicable Not applicable Not applicable
14.5.Environmental hazardsDangerous for the environmentMarine pollutantOther information	: No : No : No supplementary information available

14.6. Special precautions for user

Overland transport No data available Transport by sea No data available Air transport

No data available

Inland waterway transport

No data available Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

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.

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National regulations 15.1.2. France **Occupational diseases** Code Description RG 78 Diseases caused by sodium chloride in salt mines and their dependencies Germany : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1) Water hazard class (WGK) 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 : Pregnant/breastfeeding women working with the product must not be in direct contact with **Danish National Regulations** the product Switzerland : LK 6.1 - Toxic materials Storage class (LK) 15.2. **Chemical safety assessment** No chemical safety assessment has been carried out **SECTION 16: Other information** REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE Data sources 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- and EUH-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 Aquatic Acute 1 Hazardous to the aquatic environment - Acute Hazard, Category 1 Hazardous to the aquatic environment - Chronic Hazard, Category 1 Aquatic Chronic 1 STOT RE 2 Specific target organ toxicity — Repeated exposure, Category 2 H300 Fatal if swallowed H310 Fatal in contact with skin. H330 Fatal if inhaled. 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

Safety Data Sheet (SDS), EU

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