

Fertility Score Safety Data Sheet according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 ID: FP09 106 R02 Revision date: 05/01/2022

Version:E.3

SECT	ON 1: Identification of the su	bstance/mixture and of the company/undertaking
1.1.	Product identifier	
Product	name	: Fertility Score
GMDN		: 61072
1.2.	Relevant identified uses of the sub	stance or mixture and uses advised against
1.2.1.	Relevant identified uses	
Industria	al/Professional use spec	: For in vitro diagnostic use only
Use of t	he substance/mixture	: Home fertility test
1.2.2.	Uses advised against	
No addi	tional information available	
1.3.	Details of the supplier of the safety	/ data sheet
8730 Be Belgium info@fe	epark Noord 32 eernem rtipro.com	
1.4.	Emergency telephone number	
Emerge	ncy number	: +3250791805
SECT	ON 2: Hazards identification	
2.1.	Classification of the substance or	mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified		
	e physicochemical, human health an tional information available	d environmental effects
2.2.	Label elements	
Labelling according to Regulation (EC) No. 1272/2008 [CLP] No labelling applicable		
2.3.	Other hazards	

Other hazards 2.3.

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
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
Resazurin sodium salt	(CAS No) 62758-13-8	< 0,1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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	: Allow affected person to breathe fresh air. 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.
First-aid measures after eye contact	: 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 ef	
Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
4.3. Indication of any immediate med No additional information available	ical attention and special treatment needed
SECTION 5: Firefighting measures	3
5.1. Extinguishing media	
Suitable extinguishing media	: Water spray. Foam. Dry Powder. Carbon Dioxide. 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 the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
SECTION 6: Accidental release me	easures
6.1. Personal precautions, protective	equipment and emergency procedures
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	
	otify authorities if liquid enters sewers or public waters.
6.3. Methods and material for contain	ment and cleaning up
Methods for cleaning up	: Collect spillage. Soak up spills as soon as possible. Store away from other materials.
6.4. Reference to other sections	
See Heading 8. Exposure controls and person	nal 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 or vapour.
7.2. Conditions for safe storage, inclu	Iding any incompatibilities
Storage conditions	: Do not freeze before use. Keep only in the original container in a cool, well ventilated place awa from (sun)light. Keep container closed when not in use. Do not use after exprive date.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct (sun)light.
Storage temperature	: ≤ 30 °C
7.3. Specific end use(s)	
See instructions for use delivered with the dev	vice.
SECTION 8: Exposure controls/pe	rsonal protection
8.1. Control parameters	
8.1.1 National occupational exposure and	biological limit values
No additional information available	

No additional information available

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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

8.2.1. Appropriate engineering controls

No additional information available

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

Eye protection: Chemical goggles or safety glasses

8.2.2.2. Skin protection

Hand protection: Wear protective gloves.

8.2.2.3. Respiratory protection

Respiratory protection: Wear appropriate mask

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.

SECTION 9: Physical and chemical properties		
9.1. Information on basic physical and chemical properties		
Physical state	: Liquid	
Colour	: Dark blue.	
Odour	: Odourless.	
Odour threshold	: Not available	
Melting point	: Not available	
Freezing point	: Not available	
Boiling point	: Not available	
Flammability	: Non flammable	
Explosive limits	: Not available	
Lower explosion limit	: Not available	
Upper explosion limit	: Not available	
Flash point	: Not available	
Auto-ignition temperature	: Not available	
Decomposition temperature	: Not available	
рН	: 7,20 – 8,00	

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Viscosity, kinematic	: Not 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

SECT	ION 10: Stability and reactivity	
10.1.	Reactivity	
No additional information available		
10.2.	Chemical stability	
Not est	ablished.	
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	
Carbon	monovide, Carbon diovide, Furne	

Carbon monoxide. Carbon dioxide. Fume.

SECTION 11: Toxicological information Information on hazard classes as defined in Regulation (EC) No 1272/2008 11.1. 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 : Not classified Additional information Based on available data, the classification criteria are not met 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 : Based on available data, the classification criteria are not met Additional information Specific target organ toxicity (STOT) - single : Not classified exposure Additional information : Based on available data, the classification criteria are not met Resazurin sodium salt (62758-13-8) STOT-single exposure _H_335_EU. Specific target organ toxicity (STOT) - repeated : Not classified exposure Additional information : Based on available data, the classification criteria are not met Sodium Azide (26628-22-8) STOT-repeated exposure _H_373_EU.

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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	: Based on available data, the classification criteria are not met
symptoms	
SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term	: Not classified
(acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	
v ,	
Fertility Score Persistence and degradability	Not established.
Sodium Chloride (7647-14-5)	Net established
Persistence and degradability	Not established.
12.3. Bioaccumulative potential	
Fertility Score	Mart - stables d
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 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 42: Dispessel considerations	
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 / ADM	N
14.1. UN number	
	Not applicable
UN-No. (IMDG)	Not applicable
UN-No. (IATA)	Not applicable
UN-No. (ADN) :	Not applicable
UN-No. (RID) :	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)	
	Not applicable
Transport hazard class(es) (IMDG)	Not applicable
Transport hazard class(es) (IATA)	Not applicable

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Transport hazard class(es) (ADN) Transport hazard class(es) (RID)	: Not applicable : Not applicable
14.4. Packing group	
Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: 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 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.

15.1.2. National regulations

SZW-lijst van mutagene stoffen

France		
Occupational diseases		
Code	Description	
RG 78	Diseases caused by sodium chloride in salt mines and their dependencies	
Germany Water hazard class (WGK) Hazardous Incident Ordina		

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

: None of the components are listed

ng : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

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NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	: None of the components are listed
Denmark	
Denindik	
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.		
Full text of R-, 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		
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1		
Eye Irrit. 2	Serious eye damage/eye irritation, 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		
H300	Fatal if swallowed		
H310	Fatal in contact with skin.		
H315	Causes skin irritation		
H319	Causes serious eye irritation		
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		

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