

Material safety data sheet

According to directive (EC) 1907/2006 (REACH)



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1. Product and company identification

1.1 Product identification

Product name: ScreenYu Gyn®
Catalogue number: SG001-46
Basic UDI-DI: 426076785SCREENYUGYNP6
UDI-DI: 4260767852212

Components:

ScreenYu Gyn® Mastermix	1 x 0,55 ml
ScreenYu Gyn® Strips	6 Strips For up to 46 patient samples and controls
ScreenYu Gyn® Caps	6 Caps
ScreenYu Gyn® Positive Control	1 x 90 µl
ScreenYu Gyn® Water	1 x 2 ml

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

ScreenYu Gyn® Kit is developed for *in-vitro* diagnostic use and for laboratory application only. Do not use ScreenYu Gyn® at home, as pharmaceutical nor for any other purposes. ScreenYu Gyn® is developed for specially trained personnel only.

ScreenYu Gyn® is a diagnostic kit for the qualitative detection of epigenetic markers in bisulfite-converted DNA from cervical samples.

1.3 Details of the supplier of the safety data sheet

Supplier: Epitype GmbH
Address (headquarters): Moritzburger Weg 67
01109 Dresden
Germany
Address (manufacturing site): Löbstedter Straße 41
07749 Jena
Germany
Phone: +49 (0) 3641 5548500
E-Mail: contact@epitype.de
Technical Support: support@epitype.de

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1.4 Emergency phone

Germany: Poison information centre of Mecklenburg-Vorpommern, Saxony-Anhalt, Saxony and Thuringia (GGIZ); Phone: +49 (0) 361 730730

Other countries: „Poisons Information Service“

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to directive (EC) No. 1272/2008: not harmful to health according to directive (EC) 1272/2001 (CLP)

Classification according to directive No. 67/548/EEC and 1999/45/EC: not harmful

For very large quantities: may cause irritation of the skin, eyes, and breathing.

Potential health effects:

Eyes: may cause irritation of the eyes.

Skin: may cause irritation of the skin.

Swallow: may be harmful to health if swallow large quantities.

Breathing: may cause irritation if large quantities are spilled or if aerosols are formed.

2.2 Label elements

None.

2.3 Other harms

None.

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3. Composition / information on ingredients

3.1 Description of ingredients

Ingredient	Chemical	Classification according to regulation (EC) no. 1272/2008, Annex VII (substances)	Concentration
ScreenYu Gyn® Mastermix	Glycerin EC No. 200-289-5 CAS No. 56-81-5	not harmful	0.5-1.3 % (wt/wt)
	Tris(hydroxymethyl) aminomethan EC No. 201-064-4 CAS No. 77-86-1	In liquid form and in the concentration present in the ScreenYu Gyn®-Mastermix: not harmful. H315, H319, H335 P261, P305/P351, P305/P338	0.5-1.3 % (wt/wt)
	Tween® 20 CAS No. 9005-64-5	not harmful	0.1-0.3 %
ScreenYu Gyn® Strips	Oligonucleotides	not harmful	-
ScreenYu Gyn® Positive Control	Bisulfite converted DNA	not harmful	-
ScreenYu Gyn® Water	Water EC No. 231-791-2 CAS No. 7732-18-5	not harmful	100 %

As long as a reagent in general is considered as not harmful it means that this reagent is considered as not harmful according to EU law. This does not mean that this reagent does not have any harmful effects. Please note further recommendations and safety precautions to ensure the handling to be as safe as possible.

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4. First-Aid measures

4.1 Description of the First-Aid measure

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Remove contaminated clothing, and wash skin with plenty of water for at least 15 minutes. Consult a physician if skin irritation stays.

In case of eye contact

Immediately rinse eyes for at least 5 minutes under running water, holding the eyelid open. Remove contact lenses if present and rinse eyes again. Consult a physician if irritation of the eyes stays.

If swallowed

Rinse mouth with water and drink a glass of water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. Fire-fighting measures

5.1 Extinguishing media

Dry chemical, spray water, carbon dioxide (CO₂), foam.

Adapt extinguishing measures to suit the environment.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Fire-fighting instructions

Fire fighters should wear full-face, self-contained breathing apparatus and impervious protective clothing.

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6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Do not breathe gas/fumes/vapour. See section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains / groundwater / soil.

6.3 Methods and materials for containment and cleaning up

Soak up spilled substances with inert absorbent material. Keep in suitable, closed containers for disposal.

Dispose contaminated materials according to section 13.

6.4 Reference to other sections

Information for safe handling see section 7.

See section 8 for information on personal safety equipment.

See section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Avoid inhalation of vapour or mist. Avoid contact with eyes and skin. Wear approved safety goggles. Wear protective gloves and appropriate clothing to prevent skin contact. Observe good industrial hygiene practices.

7.2 Precautions for safe storage, including any incompatibilities

Store in the dark at 2 °C to 8°C in closed original container. Keep away from food, drink and animal feeding stuff.

Avoid longer light exposure.

8. Exposure controls and personal protection

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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8.2 Limitation and monitoring of exposure

8.2.1 Appropriate engineering controls

Provide adequate ventilation, esp. in closed rooms and minimize the risk of inhalation of vapours and mists.
General industrial hygiene practice.

8.2.2 Personal protective equipment

Eye / face protection



Wear safety glasses with side-shields conforming EN 166 (EU) or NIOSH (US).

Hand protection



Wear protective gloves. Use skin protection. Breakthrough times, permeation rates and degradation characteristics of the material must be taken into consideration.

Use protective gloves conforming the specifications of the EC directive 89/686/EEC and the resultant standard EN 374.

Material of gloves: nitrile rubber

Layer thickness (mm): ≥ 0.11 mm

Breakthrough time (min.): Level ≥ 6

The breakthrough time has to be determined and can be asked from the manufacturer.

Personal protection



Wear protective clothing such as laboratory coats to protect against chemicals. Depending on the type of chemical and its concentration, the protective clothing has to be chosen.

Respiratory protection

Respiratory protection is not needed if product is used according to instructions for use. If necessary, refer to 29 CFR 1910.134, CSA Z94.4-93 or EN 149 (EU).

Hygiene measures

Avoid contact with the skin, eyes and clothing. Immediately change contaminated clothing. Thoroughly wash hands at the end of work. Keep away from food, drink and animal feeding stuffs.

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8.2.3 Environment exposure control measures

Do not let product enter drainage.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Properties	ScreenYu Gyn® Mastermix
Appearance	liquid
Colour	clear
Odour	odourless
Odour threshold	No information available.
pH	8.7 (± 0.1)
Melting point / freezing point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporate rate	No information available.
Flammability (solid, gaseous)	No information available.
Explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Solubility in water	No information available.
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Oxidizing properties	No information available.

9.2 Other data

No information available.

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10. Stability and reactivity

10.1 Reactivity

Sensitive to light and heat.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions.

Exposition to high temperatures may produce hazardous decomposition products.

10.4 Conditions to avoid

Heat, flames, sparks and light.

10.5 Materials to avoid

Oxidizing agents and acids.

10.6 Hazardous decomposition products

At elevated temperatures, acrolein, carbon oxides, nitrogen oxides.

In case of fire: see section 5.

11. Toxicological information

11.1 Information on toxicological effects

Toxicity data on mixture of substances in this product are not available. The following statements concerning the toxicological potential refer to raw materials.

Acute toxicity

Components	Oral	Dermal	Inhalation
Tris(hydroxymethyl)aminomethan	LD ₅₀ (rat) = 5900 mg/kg	No information available.	No information available.
Glycerin	LD ₅₀ (rat) = 12600 mg/kg	LD ₅₀ (rabbit) > 1000 mg/kg	LD ₅₀ (rat) = 570 mg/m ³
Tween 20	LD ₅₀ (rat) = 38900 mg/kg	No information available.	No information available.
Water	LD ₅₀ (rat) > 90 mL/kg	No information available.	No information available.

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Potential health effects

Eyes May cause eye irritation in sensitive people.

Skin May cause skin irritation in sensitive people.

Inhalation May be harmful if inhaled.

Ingestion May be harmful if swallowed.

Chronic toxicity

Germ cell mutagenicity No information available.

Carcinogenetic effects No information available.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity No information available.

Specific target organ toxicity – single exposure No information available.

Specific target organ toxicity – repeated exposure No information available.

Additional information

None.

12. Ecological information

Quantitative data on ecotoxicity of mixture of substances in this product is not available. The following statements concerning the ecotoxicity potential refer to raw materials.

12.1 Toxicity

Ecotoxicity

The components of the product are classified as non-hazardous to the environment.

Aquatic toxicity

Glycerin LC₅₀ (Goldfish) = 5000 mg/L

Tween 20 LC₅₀ (other fish) = 350 mg/L (24h)

No information available for other components of the product.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulation potential

No information available.

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12.4 Mobility in soil

The product is water soluble and may spread in water systems.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

13. Disposal considerations

Dispose of waste in accordance with local state or national regulation for proper disposal.

14. Transport information

Not dangerous as defined by the transport regulations.

ADR/RID-Code, IMDG-Code, ICAO-TI, IATA-DGR.: none

Marine pollutant: none

15. Regulatory information

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

This MSDS fulfils the requirements of the directive (EC) No. 1907/2006

National regulations

Water hazard class: low hazardous to water (WGK 1)

Further relevant regulations

None.

15.2 Chemical safety assessment

None.

16. Other information

16.1 Classification and labelling according to directive (EC) 67/548/EEC or 1999/45/EC

None.

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16.2 Reason for revision

Section 1.3: Change of manufacturer and of address and contact details to Epitype GmbH.

16.3 Wording of the listed risk phrases (H and P statements), warnings and safety recommendations of those referred to in sections 2 to 15

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P305/P351	If in eyes: Rinse cautiously with water for several minutes.
P305/P338	Remove contact lenses if present and easy to do – continue rinsing.

16.4 Training for employees

General safety instructions.

16.5 Recommended usage limitations

ScreenYu Gyn® Kit is developed for *in-vitro* diagnostic use and for laboratory application only. Do not use ScreenYu Gyn® at home, as pharmaceutical nor for any other purposes. ScreenYu Gyn® is developed for specially trained personnel only.

16.6 Further information

The information above was acquired by diligent search and/or investigations and the recommendations are based on prudent application of professional judgement. The information shall not be taken as being all inclusive and is to be used as a guide only. All materials and mixtures may present unknown hazards and should be used with caution. As Epitype GmbH cannot control the methods, quantities or conditions of use, the company accepts no liability for any damage or loss resulting that may arise from the use of, or contact with, the product as described herein.

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