

Material safety data sheet

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

Date of issue: 2022-05-17 (Rev. 3.3)

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1. Product and company identification

1.1 Product identification

Product name: GynTect®
Basic UDI-DI: 426076785GYNTECTYM

| | | |
|------------------|---------------|---------------|
| Catalogue number | GT003-06 | GT003-10 |
| UDI-DI: | 4260767851017 | 4260767851116 |

Components:

| Components | GT003-06 | GT003-10 |
|----------------------------------|---|--|
| GynTect® Mastermix | 1 x 1.1 ml | 1 x 1.1 ml |
| GynTect® Strips | 12 Strips 6 x for patient samples (green cap) 3 x for positive controls (red cap) 3 x for negative controls (yellow cap) | 12 Strips 10 x for patient samples (green cap) 1 x for positive control (red cap) 1 x for negative control (yellow cap) |
| GynTect® Caps | 12 Caps | 12 Caps |
| GynTect® Positive Control | 1 x 260 µl | 1 x 90 µl |
| GynTect® Water | 1 x 2 ml | 1 x 2 ml |

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

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

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

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1.3 Details of the supplier of the safety data sheet

Supplier: oncgnostics GmbH
Address: Löbstedter Straße 41
07749 Jena
Germany
Phone: +49 (0) 3641 5548500
E-Mail: contact@oncgnostics.com
Technical Support: support@oncgnostics.com

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 |
|------------------------------|--|---|-------------------|
| GynTect® 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 GynTect®-Mastermix: not harmful. H315, H319, H335 P261, P305/P351, P305/P338 | 0.5-1.3 % (wt/wt) |
| | EvaGreen™ | not harmful | 0.3-0.5 x |
| | Tween® 20 CAS No. 9005-64-5 | not harmful | 0.1-0.3 % |
| | ROX | not harmful | 0.03-0.05 x |
| GynTect® Strips | Oligonucleotides | not harmful | - |
| | AccuVue Blue qPCR Dye | not harmful | - |
| GynTect® Positive Control | Bisulfite converted DNA | not harmful | - |
| GynTect® 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 | GynTect® 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 |
| EVA Green | No information available. | LC ₅₀ (fathead minnow) > 750 mg/L | No information available. |

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| | | | |
|----------|---|------------------------------|------------------------------|
| 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. |

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.

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12.2 Persistence and degradability

No information available.

12.3 Bioaccumulation potential

No information available.

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.

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16. Other information

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

None.

16.2 Reason for revision

Valid only for product variant GT003-06 and GT003-10.

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

GynTect® Kit is developed for *in-vitro* diagnostic use and for laboratory application only. Do not use GynTect® at home, as pharmaceutical nor for any other purposes. GynTect® 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. Since oncgnostics cannot control the actual methods, volumes, or conditions of use, oncgnostics shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein.

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