



Material Safety Data Sheet

Version 3.0
Last revised: July 2022

SECTION 1: IDENTIFICATION OF THE SUBSTANCES/MIXTURES AND OF THE COMPANY

1.1 Product identifier

Product name	:	SensiScreen® FFPE KIT qPCR Assay
Reference number	:	1154, 1846
Basic UDI-DI	:	5713915SS013VA

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

SensiScreen® FFPE KIT qPCR Assay is a semi-quantitative real-time Polymerase Chain Reaction (PCR) assay intended for the semi-quantitative detection of specific somatic KIT proto-oncogene (KIT) gene mutations in human DNA purified from solid biopsies such as Formalin-Fixed Paraffin-Embedded (FFPE) tissue. The assay is used with real-time PCR systems and samples can be prepared using automated platforms or in manual workflows. SensiScreen® FFPE KIT qPCR Assay is an *in vitro* diagnostic medical device intended to detect, identify, and quantify the KIT somatic mutational status as an aid in selecting the proper treatment of cancer. SensiScreen® FFPE KIT qPCR Assay is intended for use by healthcare professionals or qualified laboratory personnel instructed and trained in the techniques of real-time PCR as well as proficient in handling biological samples. Medical interventions based on results from this product requires medical authorization.

1.3 Details of the supplier of the safety data sheet

Address	:	PentaBase A/S Petersmindevej 1A DK-5000 Odense C www.pentabase.com
Phone	:	+45 36 96 94 96
E-mail address	:	info@pentabase.com

1.4 Emergency telephone number

Emergency Phone	:	112 (EU) Contact physician
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SECTION 2. HAZARDS IDENTIFICATIONS

2.1 Classification of the substance or mixture

The product is classified as not hazardous according to regulation (EC) No. 1272/2008.

2.2 Label elements

The product is classified as not hazardous according to regulation (EC) No. 1272/2008.

2.3 Other hazards

No special hazards to be mentioned.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

The product is a non-radioactive, non-hazardous mixture composed of oligonucleotides (with non-radioactive modifications) suspended in water/buffer (pH 7.0).

SECTION 4. FIRST AID-MEASURES

4.1 General information

Consult a physician. Show this MSDS to the doctor in attendance.

Inhalation

If inhaled, move to fresh air. If breathing becomes difficult contact a physician.

Skin contact

Wash of immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Rinse mouth thoroughly with water. Consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

5.1 Conditions of flammability

Not flammable or combustible.

5.2 Suitable Extinguishing Media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas



5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective suit if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, or gas. Ensure adequate ventilation.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose. Keep in suitable, closed container for disposal.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

No special measures required. Smoking, eating, and drinking should be prohibited in the application area. Protect from contamination by using laminar flow cabin.

7.2 Conditions for safe storage

Keep tightly closed. Store reagents as indicated in Instructions for Use and the product label. Protect products from light.

SECTION 8. EXPOSURE AND CONTROL/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Hand protection

Wear protective gloves to prevent skin contact.

Eye protection

Not required

Skin and body protection

Wear laboratory coat.

Respiratory protection

None under normal use conditions.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.3 Environmental exposure controls

The product should not be allowed to enter drains, water courses or the soil.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form

Liquid

Colour

Clear to light red solution

Water solubility

Soluble

Odour

No data available

Melting point/freezing point

No data available

Boiling point

No data available

Flash point

No data available

Flammability (soil, gaseous)

No data available

Evaporation rate

No data available

**Explosive properties**

No data available

Density

No data available

SECTION 10. STABILITY AND REACTIVITY**10.1 Chemical stability**

Stable under recommended storage conditions.

10.2 Possibility of hazardous reactions

Reacts with acids, alkalis, and oxidizing agents.

10.3 Conditions to avoid

No data available

10.4 Materials to avoid

None based on information supplied.

SECTION 11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

There is no data available

Inhalation

There is no data available

Skin contact

There is no data available

Eye contact

There is no data available

Ingestion

There is no data available

Reproductive toxicity

There is no data available

Specific target organ toxicity

There is no data available

SECTION 12. ECOLOGICAL INFORMATION**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods****Disposal recommendations for the product**

Dispose of in accordance with local regulations. Contact a licensed professional waste disposal service for advice.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION**13.2 UN proper shipping name**

Not classified as dangerous goods in the meaning of transport regulation but requires ice elements or dry ice (UN 1845) for shipments.

Hazard class

No data available

**Subsidiary class**

No data available

Packing group

No data available

UN-NO

No data available

IATA

Not regulated as dangerous goods

ADR

Not regulated as dangerous goods

IMDG

Not regulated as dangerous goods

SECTION 15. REGULATORY INFORMATION**15.1 Restrictions on Use**

None

15.2 Chemical safety assessment

No information available

15.3 National regulations

No information available

SECTION 16. OTHER INFORMATION

The information provided in this MSDS is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.