



# 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® Liquid PIK3CA qPCR Assay  
Reference number : 5585, 5591, 5586, 5600, 5601, 5592, 5587, 5590  
Basic UDI-DI : 5713915SS010V4

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

SensiScreen® Liquid PIK3CA qPCR Assay is a semi-quantitative real-time Polymerase Chain Reaction (PCR) assay intended for the detection, identification, and relative quantification of specific somatic mutations in the human phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha (PIK3CA) gene in cell-free DNA (cfDNA) purified from liquid biopsies including blood and plasma. The assay is used with real-time PCR systems and samples can be prepared using automated platforms or in manual workflows. The assay is an *in vitro* diagnostic medical device intended to aid in the detection, identification, monitoring of disease progression, and re-appearance based on PIK3CA mutation status. The test result correlates with the amount of PIK3CA mutant cfDNA. Result can be used to determine changes in PIK3CA mutation quantity levels in patients over time such as during cancer interventions and as an aid in selecting proper treatment of cancer. SensiScreen® Liquid PIK3CA qPCR Assay is intended to be used 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

## 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.

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## 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.

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## 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.

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## 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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

#### Form

Liquid

#### Colour

Light pink 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

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**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.

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**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

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**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

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**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.

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**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

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**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

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**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.