

**RB – Reaction buffer; Taq – PCR Tag Polymerase; dNTPs – PCR dNTPs; BSA – PCR BSA; 19WTF – EGFR 19 WTF; 19WTR – EGFR 19 WTR; 19 MF – EGFR 19 MF; 19 MR – EGFR 19 MR; 18F – EGFR 18F; 18R – EGFR 18R; 20F – EGFR 20F; 20R – EGFR 20R; 18-IF – EGFR 18-IF; 20-IR – EGFR 20-IR; 21-IR – EGFR 21-IR (components of Ampli1™ EGFR Seq Kit, cumulative MSDS)**

Date of first issue of the safety data sheet: 13<sup>th</sup> November 2012.

Date of revision of the safety data sheet: 13<sup>th</sup> November 2012, revision n° 1.0.

## **1. Identification of the substance or compound**

### *1.1 identification of the substance or compound*

Products name: **RB – Reaction buffer; Taq – PCR Tag Polymerase; dNTPs – PCR dNTPs; BSA – PCR BSA; 19WTF – EGFR 19 WTF; 19WTR – EGFR 19 WTR; 19 MF – EGFR 19 MF; 19 MR – EGFR 19 MR; 18F – EGFR 18F; 18R – EGFR 18R; 20F – EGFR 20F; 20R – EGFR 20R; 18-IF – EGFR 18-IF; 20-IR – EGFR 20-IR; 21-IR – EGFR 21-IR.**

### *1.2 utilisation of the substance or compound*

These products are used as reagent of the EGFR gene mutation detection procedure carried out with Ampli1™ EGFR Seq kit. Use permitted only in the laboratory. For In Vitro use only. For research use only. Not for use in diagnostic procedures.

### *1.3 identification of the company/business responsible for issue on the EU market*

Company name: SILICON BIOSYSTEMS S.p.A.

Address: Via dei Lapidari 12, 40129 Bologna;

Telephone: +39 051-40.71.300;

e-mail: info@siliconbiosystems.com.

### *1.4 Emergency telephone number*

Emergency telephone number: +39 051-40.71.300;

The number is available only from 8.30 a.m. to 5.30 p.m. (GMT +1.00).

## **2. Identification of hazards**

The mixtures are classified as non-hazardous.

Under the normal recommended conditions of use and in the form in which it is presented, the mixtures do not possess properties that are hazardous for human health, for the environment, or from the chemical-physical point of view.

## **3. Composition/information on the ingredients**

### *3.1 hazardous components present in the compound*

The mixtures do not contain any component substances classified as hazardous.

### 3.2 hazard classification of the ingredients

All the component substances of the mixtures are classified as non-hazardous. For the component substances of the mixtures, there are no established limits of concentration or limits of exposure on the work environment. The substances present in mixtures are not classified as persistent, bioaccumulatable or toxic (PBT), or as very persistent or very bioaccumulatable (vPvB).

## 4. First aid measures

### *following inhalation*

There are no known hazards due to inhalation of the products. However, if the user complains of symptoms of discomfort and feels that they are due to the product, it is recommended to remove the affected individual from the polluted atmosphere and take him outside in the fresh air. Delayed effects following exposure are not foreseeable.

### *following contact with the skin or eyes*

In case of contact with the skin, if the affected individual notices irritation at the epidermis level:

- immediately remove contaminated clothing;
- thoroughly wash away the product with plenty of soap and water.

There are no foreseeable delayed effects following exposure.

In case of contact with the eyes, the affected individual could present the following symptoms: tearing, burning, pain, intolerance to or discomfort in sunlight. In such circumstances:

- remove contact lenses if the affected individual wears them;
- wash the product from the eyes, keeping the eyelids open, with plentiful amounts of water as quickly as possible.

Continue bathing the eyes for at least 15 minutes.

If irritation, tearing, pain, swelling of the eyes persists, the affected individual should receive medical attention as soon as possible.

There are no foreseeable delayed effects following exposure.

### *following ingestion*

In case of ingestion, immediately rinse the mouth and subsequently drink plentiful water. Where necessary, consult a doctor.

There are no foreseeable delayed effects following exposure.

## 5. Fire-fighting measures

### 5.1 suitable extinguishing media

By their chemical nature, the mixtures do not fuel fire. In the event that the mixtures are involved in a fire, extinguish using media suitable to the premises and to the other substances or mixtures present in the premises where the fire occurs.

### 5.2 extinguishing media that must not be used for safety reasons

Do not extinguish using sprays of water.

### 5.3 special hazards of exposure deriving from the substance or the compound, from combustion products or the gasses produced

There are no known special hazards due to the exposure of the mixtures to fire, nor hazards due to the gasses or residues produced by the combustion of the mixtures.

#### *5.4 special protective equipment for fire-fighting personnel*

By their chemical nature, the mixtures do not require special protective equipment for fighting a fire in which it is involved. To choose the most suitable protective equipment, refer to the instructions given for other substances or mixtures that may be present in the premises where the fire occurs.

### **6. Accidental release measures**

#### *6.1 precautions for personnel*

Wear personal protective equipment to prevent contact with the skin.

Eliminate or exclude all sources that could cause a dangerous situation (e.g.: electrocution) or ignite a fire.

#### *6.2 environmental precautions*

Absorb using non-combustible absorbent material.

#### *6.3 clearing methods*

Remove using mechanical means or absorb using non-combustible material and transfer all the materials to a suitable container for subsequent disposal.

### **7. Handling and storage**

#### *7.1 handling*

Avoid the formation of aerosol.

Use only in premises that are well-ventilated or are equipped with localised exhaust systems.

Avoid contact of the mixtures with sources of ignition: open flames, sparks, very hot surfaces.

#### *7.2 storage*

For the correct preservation of the mixtures, store in a cool, well-ventilated place in the containers in which it is supplied, properly sealed.

#### *7.3 particular uses*

For particular uses of the products, refer to the specific information or contact the manufacturer's technical service.

### **8. Personal protection/exposure control**

#### *8.1 exposure limit values*

Not applicable to the mixtures or to the substances they contains.

##### *8.2.1 respiratory protection*

For operational reasons, the best system for handling the mixtures is under an exhaust hood; this method of working is sufficient to protect the operator from the risks related to aspiration of vapours or aerosol of the mixture itself.

##### *8.2.2 hand protection*

Use normal disposable laboratory gloves made of natural latex or lightweight nitrile.

##### *8.2.3 eye protection*

Handling under an exhaust hood provides adequate protection for the eyes, without the need to use other PPE.

#### 8.2.4 skin protection

To protect the skin, use normal laboratory clothing such as lab coats.

#### 8.2.5 control of environmental exposure

It is necessary to observe all national or EU regulations on environmental protection in the use and disposal of the products and its containers.

### 9. Physical and chemical properties

*appearance:* colourless liquids

*odour:* odourless

*pH:* depends on mixtures

*boiling point/interval:* not determined

*melting point/interval:* not determined

*flash point:* not applicable

*flammability (solids, gasses):* not applicable

*auto-flammability:* not applicable

*explosive properties:* not applicable

*comburent properties:* not applicable

*vapour pressure:* not determined

*relative density:* approx. 1000 Kg/m<sup>3</sup>

*solubility in water:* totally miscible

*solubility in fat (fat solvent to be specified):* not determined

*partition coefficient: n-octanol/water:* not determined

*viscosity:* not determined

*vapour density:* not determined

*evaporation velocity:* not determined

*other data:* no other data available

### 10. Stability and reactivity

#### 10.1 conditions to be avoided

Keep far away from heat sources, flames, and electrostatic charges, and avoid direct exposure to direct sunlight.

#### 10.2 materials to be avoided

Avoid contact with very strong acids, to prevent any exothermic reactions.

#### 10.3 hazardous products of decomposition

There no known hazardous substances that can be formed in quantities sufficient to constitute a risk following the decomposition of the product.

### 11. Toxicological information

#### 11.1 exposure by inhalation

No data are available regarding exposure by inhalation of the mixtures or its components. There are no known immediate, delayed, or chronic effects such as sensitising, narcotising, cancerogenous, mutagenous or toxic effects for reproduction due to short or long-term exposure to the mixtures.

### *11.2 exposure by ingestion*

No data are available regarding exposure by ingestion of the mixtures or their components. There are no known immediate, delayed, or chronic effects such as sensitising, narcotising, cancerogenous, mutagenous or toxic effects for reproduction due to short or long-term exposure to the mixtures.

### *11.3 exposure by contact with the skin or eyes*

No data are available regarding exposure by contact with the skin or eyes of the mixtures or their components. There are no known immediate, delayed, or chronic effects such as sensitising, narcotising, cancerogenous, mutagenous or toxic effects for reproduction due to short or long-term exposure to the mixture.

## **12. Ecological information**

### *12.1 general ecological information*

Use according to proper work practices and avoid dispersal of the products in the environment.

### *12.2 ecotoxicity*

No data are available regarding the ecotoxicity of the mixtures and their components.

### *12.3 mobility*

No data are available regarding the mobility of the mixtures and their components.

### *12.4 persistence and degradability*

The mixtures are not persistent and are completely biodegradable in a short time.

### *12.5 bioaccumulation potential*

No data are available regarding the potential of bioaccumulation of the mixtures and their components.

### *12.6 other adverse effects*

The mixtures and their components are not considered to be marine pollutants (WGK = 0).

## **13. Disposal considerations**

Prior to being disposed of or destroyed, the products containers must be cleared and then sent to recycling or recovery of the materials.

The products residues must be disposed of according to the current national and regional regulations.

## **14. Transport information**

### *14.1 special precautions*

The packages of the products must be transported inside suitable insulated polystyrene containers, containing materials for cooling the environment such as bags of ice.

In the event of any suspicion that the product has been delayed in shipping to the user, notify the manufacturer immediately.

Do not place other packages on top of the container used for transporting the mixtures.

### *14.2 classification of transport according to: ADR/RID, IMDG/IMO, ICAO/IATA*

Transport of the mixtures is not regulated.

## 15. Regulatory information

National or European Union regulations regarding the use of the product:

- Italian Legislative Decree 81/08 "Implementation of Art. 1 of Law n°123 of 03 August 2007, regarding protection of health and safety in the workplace (Consolidated law for hygiene and safety in the workplace)";
- Italian Legislative Decree 152/06 "Environmental regulations";
- Decree of the Ministry of Labour and Social Policy of 26<sup>th</sup> February 2004 "Definition of a preliminary list of indicative limits of professional exposure to chemical agents";
- Italian Legislative Decree 65/03 "Implementation of the Directives 1999/45/CE and 2001/60/CE regarding classification, packaging, and labelling of hazardous compounds";
- Regulation 2006/1907/CE "Registration, evaluation, authorisation and restriction of chemical substances (REACH), which establishes a European agency for chemical substances; REACH modifies Directive 45/1999/CE and repeals Council regulation (CEE) n° 793/93 and Commission Regulation (CE) n° 1488/94, as well as Council Directive 76/769/CEE and Commission Directive 91/155/CEE, 93/67/CEE, 93/105/CE and 2000/21/CE";
- Regulation 2008/1272/CE regarding "classification, labelling, and packaging of substances and mixtures" which modifies and repeals Directives 67/548/CEE and 1999/45/CE and that adds modifications to Regulation CE n° 1907/2006 for the part already in force;
- Directive 1967/548/CEE "Concerning the approximation of the laws, regulations, and administrative provisions regarding the classification, packaging, and labelling of hazardous substances";
- Directive 1999/45/CE "Concerning the approximation of the laws, regulations, and administrative provisions regarding the classification, packaging, and labelling of dangerous preparations".

### *Information appearing on the label*

No safety-related information appears on the product label for these mixtures.

## 16. Other information

### *16.1 other important information*

The personnel designated to use the mixtures must be adequately trained in the general methods for the use of chemical products.

The information provided in this safety data sheet has been gathered primarily by consulting the safety data sheets of the component substances of the mixture and by consulting the Database of the European Chemical Bureau (<http://ecb.jrc.it/>) related to such component substances.

### *16.2 information added, eliminated, or modified following the revision of the safety data sheet*

The present edition of the safety data sheet replaces the previous versions in all points.

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The information contained in the present safety data sheet is based on the best information available to the manufacturer.

The references to the risks connected with the use of the product and with its intrinsic characteristics, as well as the legislative regulations and bibliographical sources, are not to be considered exhaustive. The user must evaluate any further risk that may derive from the specific methods and conditions of use of the product.