MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: ***Flu A, Flu B & RSV* Real Time PCR**
Composition: Reaction mix tubes + Rehydration Buffer.

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

Relevant identified uses:

- *REACTION MIX TUBES*: *Flu A, Flu B & RSV* Real Time PCR Detection Kit designed for specific identification of Influenza type A (Flu A), type B (Flu B) and/or Human Respiratory Syncytial Virus (RSV A and B) in respiratory samples from patients with signs and symptoms of respiratory infection.
- *REHYDRATION BUFFER*: Solution for reconstituting the stabilized product. This buffer is only provided with the product which has to be used (*Flu A, Flu B & RSV* Real Time PCR).

Uses advised against: No information available.

1.3. Company/undertaking identification

Manufacturer: **CerTest Biotec**
Pol. Industrial Río Gállego II
Calle J, Nº 1
50840, San Mateo de Gállego
Zaragoza (SPAIN)
Telephone number: +34 976520354
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1.4. Emergency telephone number: 112 (EU) / +34 976520354

SECTION 2: HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture: Non-hazardous preparation (Regulation 1272/2008/EC).

2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]: Non-hazardous.

2.1.2. Classification according to Directive 1999/45/EC: Non-hazardous.

2.1.3 Additional information: See SECTION 16.

2.2 Label elements

Signal Word: **None**

2.3 Other hazards: No hazards know*.*

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances:

No information available.

3.2 Mixtures

Mixture description:
Rehydratation buffer: Saline solution.
Reaction mix: a mix of enzymes, primers-probes, buffer, dNTPs, $MgCl_2$, stabilizers and internal control in stabilized format

3.2.1 Hazardous components: No information available.

***Note*:** The concentration of the used substances in order to manufacture the product are not hazardous for health. (Regulation (EC) No 1272/2008 [CLP]).

The device consists in a conical tube containing the reaction mix in stabilized format.

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

- **Following eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.
- **Following skin contact:** Wash off immediately with soap and plenty of water. Consult a physician.
- **Following ingestion:** Clean mouth with water and drink afterwards plenty of water. Consult a physician.

- **Following inhalation:** Ensure sufficient ventilation of workplace. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed: No information available**.**

4.3 Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

- **Suitable Extinguishing Media:** Water or CO_2. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- **Extinguishing media which must not be used for safety reasons:** No information available.

5.2 Special hazards arising from the substance or mixture:-No information available.

5.3 Advice for firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures: Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation.

6.2 Environmental precautions: Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up: Soak up with inert absorbent material. Clean contaminated surface thoroughly.

6.4 Reference to other sections: If appropriate Sections 8 and 13 shall be referred to.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling: Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves. Specimens should be handled as potentially infectious materials.

7.2 Conditions for safe storage, including any incompatibilities: The kits can be shipped and stored at 2-40ºC until expiration date stated in the label. Avoid storage near to heat sources and keep away from sunlight.

7.3 Specific end use(s): No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters: Any specific protection and prevention measures should not be taken during use of the product.
Exposure limits: No information available.

8.2 Exposure controls: All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

8.2.1 Appropriate engineering controls: No relevant for this material.

8.2.2 Personal protective equipment: Handle with disposable gloves (EN 374). Wear appropriate protective safety eyewear and clothing, such as a lab coat and a mask.

8.2.3 Environmental Exposure Controls: No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance/Physical State	Conical tubes: Light coloured powder cake in stabilized format packaged. Rehydration buffer: Transparent liquids packaged in conical tubes.

<u>The following table only applies to Rehydration buffer:</u>

Odor	Not determined	**Explosion Limits**	Not applicable
pH	Not determined	**Vapor Density**	Not determined
Boiling Point	Not determined	**Relative density**	Not determined
Flash Point	Not applicable	**Solubility**	Soluble
Vapor Pressure	Not determined	**Flammability**	Not applicable
Melting Point	Not determined	**Viscosity**	Not determined
Autoignition Temperature	Not determined	**Explosive Properties**	Not explosive
Partition Coefficient (n-octanol/water)	Not determined	**Oxidizing Properties**	Not determined

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity: No hazardous reactivity known.

10.2 Chemical stability: Under correct storage, (see section 7 for more information) the product is stable. No known hazardous reactions.

10.3 Possibility of hazardous reactions: Not applicable.

10.4 Conditions to avoid: Direct contact with a flame. Stored temperatures outside the range of 2-40 ° C. Avoid storing in places with high humidity and keep away from sunlight.

10.5 Incompatible materials: The samples should be treated following our instructions for use provided in our kits.

10.6 Hazardous decomposition products: No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- **Acute toxicity:** Product does not present an acute toxicity hazard based on known or supplied information.
- **Skin corrosion/irritation:** Based upon the available data, the classification criteria are not met.
- **Serious eye damage/irritation:** Based upon the available data, the classification criteria are not met.
- **Respiratory or skin sensitisation:** Based upon the available data, the classification criteria are not met.
- **Germ cell mutagenicity:** Based upon the available data, the classification criteria are not met.
- **Carcinogenicity:** A4-Not classifiable as a Human Carcinogen.
- **Reproductive toxicity:** Based upon the available data, the classification criteria are not met.
- **Summary of evaluation of the CMR properties:** Based upon the available data, the classification criteria are not met.
- **STOT-single exposure:** Based upon the available data, the classification criteria are not met.
- **STOT-repeated exposure:** Based upon the available data, the classification criteria are not met.
- **Aspiration hazard:** Based upon the available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: Based upon the available data, the classification criteria are not met. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

12.2 Persistence and degradability: Based upon the available data, the classification criteria are not met.

12.3 Bioaccumulative potential: Based upon the available data, the classification criteria are not met.

12.4 Mobility in soil: Based upon the available data, the classification criteria are not met.

12.5 Results of PBT and vPvB assessment: No data available for assessment.

12.6 Other adverse effects: Based upon the available data, the classification criteria are not met.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

- **Waste from Residues:** After testing, the product must be disposed of compliance with the respective local, state or national regulations.
- **Non-contaminated packaging:** The containers can be recycled.

SECTION 14: TRANSPORT INFORMATION

- **Maritime transport (IMDG/IMO):** Not dangerous preparations not required transport regulations.
- **Land transport (ADR):** Not dangerous preparations not required transport regulations.
- **Air Transport (IATA):** Not dangerous preparations not required transport regulations.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for *in vitro* diagnosis, so they must meet the criteria described in Directive 98/79/CE, do not carry the CE marking for marketing outside the EU.

The product is a mixture which is not subject to Regulation (EC) No 1005/2009, (EC) No 850/2004.

National Regulations: Please ask your national/regional authorities.

15.2 Chemical Safety Assessment: A Chemical Safety Assessment/Report has not been conducted.

SECTION 16: OTHER INFORMATION

- **Recommendations:** Consult instructions for use prior to product use. Professional use only for *in vitro* diagnosis.
- **References (previous version):** RD 255/2003, of February 28, approving the Regulation on classification, packaging and labeling of dangerous preparations, which incorporates into Spanish law Directive 1999/45/CE, Directive 2001/60/CE and partly Directive 2001/58/CE. Directive 91/155/CE.
- **Changes:** Update in accordance with Regulation (EC) No 1272/2008 and EU No 2015/830 (changes to all sections).

- **Abbreviations and acronyms:**
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative

- **Key literature references and sources for data:** see instruction for use, Safety Data sheet and ECHA.
- **Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:** Annex I section 3 and 4; Annex VI Table 3.1 of Regulation (EC) No 1272/2008 was used for the purpose of classification.
- **Training advice:** No special training is required.
- **Contact**

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