Material Safety Data Sheet

Vitassay Healthcare S.L.U.
Parque Tecnológico Walqa
Ctra. N-330 Km. 566
22197 Huesca (Spain)
info@vitassay.com

To whom it may concern,

"VITASSAY HEALTHCARE S.L.U." (VAT Nº B-22401343), a company duly incorporated under the laws of Spain, specialized in the Research, Development and Manufacturing of "In vitro" products for the Clinical Diagnostic, located at Parque Tecnológico WALQA Ctra. N330, Km 566, 22197-Cuarte (Huesca, SPAIN).

Hereby declares the following:

In accordance with Regulation (EC) No 1907/2006 (REACH)[1], Rapid Test Kits do not require Material Safety Data Sheets on account of their classification as non-hazardous to health and the environment because it does not contain substances and/or mixtures which meet the hazard classification criteria available in Regulation (EC) No 1272/2008 (CLP)[2], or which are in concentrations higher than the value established in the mentioned regulation for their declaration.

All the Rapid Test Kits***** manufactured by Vitassay Healthcare contain Sodium azide (CAS No. 26628-22-8) as a preservative. Due to its concentration <0.1%, the preparation is not classified as dangerous on the basis of health and/or environment effects. The concentration is lower than the generic cut-off values listed in table 1.1 of Annex I to Regulation (EC) No 1272/2008 and the substance does not have a limit of Community exposure in the workplace, neither are classified as PBT/vPvB, neither are they on the candidate list.

- **Precautions for safe handling:** Good Laboratory Practices. Wear Protective clothing, use disposable gloves, goggles and mask. Do not eat, drink or smoke or apply cosmetic products in the working area. Once you finish the test wash your hands. Avoid contact and contamination.
- **Conditions for safe storage including any incompatibilities:** The kits can be shipped and stored at 2-30ºC in a dry place until expiration date stated in the label. All the kit components are for only one use and should remain in its primary packaging until use. Do not freeze.
- **Specific end use(s):** Use only the diluent provided for sample dilution and other components provided in the kit.
- **Ecological information:** The product should be discarded in a proper biohazard container after testing. These containers should be discarded in accordance with local or national laws or regulations. The product contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very

bioaccumulative (vPvB). This product doesn't contain components with environmental endocrine disrupting properties.

The European Union criteria harmonized in CLP adapt and consider the Globally Harmonized System of classification and Labelling of Chemicals (GHS)[3].

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Emergency telephone number:

European Union Emergency number: 112 (EU) (available 24 hours).

Number of the manufacturer (Vitassay Healthcare S.L.): +34 974 001 193 (available 7-15h).

Huesca, Spain, December 20th 2022

Javier Garfella
Technical manager
VITASSAY HEALTHCARE S.L.U.

(*) ***Except for the Strep A products that MSDS[4] is required.***

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1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

3. GHS, Globally Harmonized System of Classification and Labelling of Chemicals nineth revised edition available at:
https://unece.org/transport/standards/transport/dangerous-goods/ghs-rev9-2021.

4. The MSDS will be done according to the commission regulation (EU) 2020/878 of 18 June 2020 amending the Annex II "Requirements for the compilation of safety data sheets" to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).