Safety Data Sheet

According with Regulation (EC) No 1907/2006

QUALITY MANAGEMENT **Version 2.5, DATE:2021-04-05**

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking	
Trade name	Rapid Response™ COVID-19 Antigen Rapid Test Device
Catalog number	COV-19C25
Chemical Family/Use of the substance preparation	In vitro diagnostic rapid test, it is intended to aid in the rapid differential diagnosis of SARS-CoV-2 viral nucleoprotein antigens from human nasopharyngeal secretions and nasal secretions.
Formula	Proprietary mixture
Shipping name	Not applicable
Dot hazard classification	Not applicable
Manufacturer	BTNX Inc. 570 Hood Road, Unit 23, Markham, ON, Canada T: 905-944-9565
Contact	info@btnx.com
Emergency telephone	Phone: +1905-944-9565 Fax: +1905-944-0406 Phone number is available during office hours as follows: Mon – Fri 8 :30 AM – 5:30 PM
SECTION 2: Hazards Identification	
Classification of the substance or mixture	**Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Label elements	**Labelling according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation
Other Hazards	No particular hazards if test is used according to the instructions. The product contains chemicals and materials of animal origin. Although the risk of infection is rated as extremely unlikely, a direct contact should be avoided.
SECTION 3: Composition/Information on Ingredients	
This product is a mixture In vitro diagnostics medical device. **Kit Components:** Test devices: Strips inside the housing contain small amounts of chemicals (proteins, surfactants, biological buffers, salts, carbohydrates, polymers, latex particles and preservative (sodium azide)) and small amounts of antibodies or antigens as active ingredients of the detection reaction, conjugated to latex particles or immobilised on the test line regions. The backing plate of each test strip is made of polyethylene. The membrane is nitrocellulose. The strip further contains adsorbent pads (cellulose), polyester and glass fiber. Extraction buffer Buffer components: Biological buffer, salts and surfactants. Preservatives: Sodium azide. Coated Aluminium Foil for single pouched test devices Individually packed swabs: The sterilized swab is not manufactured by BTNX Inc. The supplier of	

sterilized swab is Jiangsu Changfeng Medical Industry Co., Ltd. The EU representative is Llins Service & Consulting GmbH. The notified body is TÜV Rheinland LGA Products GmbH. Desiccant (SiO_2) Package insert (paper) Extraction tube Nozzle with filter Tube stand	
Hazardous Components: The product has no hazardous component according to the CLP regulation ((EC) No 1272/2008). Although the substance sodium azide (CAS 26628-22-8) is rated as hazardous, they do not need to be declared as hazardous components in this formulation because of the extremely low concentration on the test strip and in the buffer solution (CAS 26628-22-8: <0.1%).	
Chemical Names and Synonyms	Not applicable
Chemical Family	Not applicable
Formula	Not applicable
Shipping Name	Not applicable
Hazard Classification	Not applicable
SECTION 4: First-aid Measures	
If used according to the instructions the described scenarios are extremely unlikely.	
After skin contact	The buffer solution and possibly other kit components may cause slight irritations upon contact. Remove contaminated clothing. Wash affected area with plenty of water. If irritation or signs of toxicity occur, seek medical attention.
After eye contact	The buffer solution and possibly other kit components may cause slight irritations upon contact. Remove from source of exposure. Wash with copious amounts of water (for appr. 15 min) with eyelid held open. If irritation or signs of irritation, pain or toxicity occur, seek medical attention.
After ingestion	If buffer solution, kit or test components have been ingested, rinse mouth with water provided the person is conscious. If irritation or signs of toxicity occur, seek medical attention.
After inhalation	Inhalation of any components of the kit is extremely unlikely. If a component is inhaled and causes discomfort, remove exposed person from source of exposure and take outside to fresh air. If breathing is difficult, irritation or signs of toxicity occur, seek medical attention.
SECTION 5: Firefighting Measures	
Flash point	Not applicable
Flammable limits	Not applicable
Autoignition temperature	Not applicable
Extinguishing media	Suitable extinguishing media: Dry chemical, CO_2, water spray or alcohol-resistant foam. Unsuitable extinguishing media: Not known. If possible, run-off water should be prevented from entering bodies of water or other environmentally sensitive areas.
Special fire combustion products	None

Protective equipment for firefighter	As in any fire, wear self-contained breathing apparatus and full protective gear.
SECTION 6: Accidental Release Measures	
Personal safety precaution	Remove unprotected persons from source of exposure. Avoid contact with skin and eyes. Use universal precautions during clean-up procedures.
Spill and leak procedures	Large spills or leak of this kit are unlikely. Personnel who have received basic chemical safety trains can generally handle small-scale releases. Wear protective garment (safety glasses, gloves, lab coat). Take up spills with absorbent paper; if necessary clean with disinfectant afterwards and dispose of in accordance with the local regulations (see section 13). Clean affected area with water afterwards.
Environmental precautions	No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Generally, a release to the environment should be avoided.
SECTION 7: Handling and Storage	
Precaution to be taken in handling and storage	Store at 2-30℃
Requirements to be met by storage conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Other precautions/special hazards	No information available.
SECTION 8: Exposure Controls/Personal Protection	
The product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.	
Exposure limits	No information available.
Derived no effect level (DNEL)	No information available.
Predicted no effect concentration (PNEC)	No information available.
Skin and body protection	Laboratory clothes
Eye protection	Protective Lab Glasses are recommended
Hand protection	Impervious Gloves (nitrile, rubber, latex or equivalent)
Respiratory protection	Mask
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.
Environmental exposure controls	No special environmental controls are required. Disposal of test according to section 13.
SECTION 9: Physical and Chemical Properties	
Physical State	Solid material Buffer solution: liquid
Color	White
Odor	Odorless
Flash point	Not determined
Flammability	Not determined

pH-value at 20°C	Not applicable for solid materials Buffer solution: ≈ 7
Melting/freezing point	Solid materials: Plastics decomposition at ~300°C Buffer solution: ≈ 0°C (do not freeze)
Vapor pressure (20°C)	Not applicable for solid components Buffer solution: ~23hPa (similar to water)
Vapor density	Not applicable.
Specific Gravity	No information available.
Water solubility	No information available.
Solubility in other solvents VALUE	No information available.
SECTION 10: Stability and Reactivity	
Reactivity	Not known
Chemical stability	The product is stable. Hazardous degradation products are not known, if the storage conditions are observed. Plastic components: Hazardous decomposition products during burning possible.
Conditions to avoid	Extreme of temperature and direct sunlight.
Incompatible materials	Acids.
Hazardous decomposition products	None under normal use conditions.
SECTION 11: Toxicological Information	
Product information	Product does not present an acute toxicity hazard based on known or supplied information.
Serious eye damage/irritation	No information available.
Skin corrosion/irritation	No information available.
Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information. Sodium azide (pure substance): Oral LD50 (rat): 27mg/kg; dermal LD50 (rabbit): 20mg/kg
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
Summary of evaluation of the CMR properties	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.
SECTION 12: Ecological Information	

Ecotoxicity effects	No information available. No adverse effects on the environment are expected. However, for sodium azide, following applies: Harmful to aquatic life with long lasting effects. In the present amounts (<0.1%) hazardous influences on the environment are to be unlikely as the concentrations of hazardous components are below the threshold values that would require labeling.
Persistence and degradability	Generally plastic materials are not biodegradable and should not be dumped into the environment.
Bio accumulative potential	The potential of kit components to accumulate in animal or plant systems is considered to be very limited.
Mobility in soil	No information available.
Results of PBT and vPvB assessment	No sufficient information available for assessment. To our knowledge this preparation contains no amounts of substances regarded as persistent, bioaccumulative and toxic (PBT) or substances that are considered to be very persistent and very bioaccumulative (vPvB) that need to be declared.
Other adverse effects	No information available.
SECTION 13: Disposal Considerations	
Waste from residues/unused products	No specifications required. In all cases disposal of tests should be in compliance with federal and local regulations. The potentially infectious character of the sample material should be taken into consideration before disposal. Observe regulations for proper disposal of such materials. Frequently tests can be disposed of with the regular garbage. If in doubt, we recommend contacting the relevant authorities and/or an approved waste-disposal company for information to ensure compliance.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for disposal. Non-contaminated packaging materials can be recycled.
SECTION 14: Transport Information	
Identification	Not applicable.
Transport(ICAO/IATA)	According to the 61st edition 2020 of IATA Dangerous Goods Regulation, the products are not dangerous, poisonous, harmful, corrosive flammable or explosive. They are not spiritual medicines, not anesthetic or narcotic, and cannot be used to make bio-chemical weapons. They are in sealed packages and conform to applicable export requirements. The products are safe for transportation and not regulated by IATA DGR/IMDG.
SECTION 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.
Chemical safety assessment	For this product, a chemical safety assessment has not been carried out.

SECTION 16: Other Information

The given information is based on the current state of knowledge but does not guaranty product performances under cannot be used as basis for legal disputes.

For further information please contact BTNX.

MSDS-I092