MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name Rapidtesta FLU NEO (Extraction Reagent Buffer)

Revision date 01-27-2012

 Version #
 01

 CAS #
 Mixture

 Kit number
 485749

Product useAn in vitro diagnostic immunochromotographic assay intended for the qualitative detection of

influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in

symptomatic patients. It is intended to aid in the rapid differentiatal diagnosis of influenza A and/or

B viral infections.

Manufacturer/Supplier Sekisui Diagnostics, LLC

6659 Top Gun Street San Diego, CA 92121 USA www.sekisuidiagnostics.com

Phone: 858-452-3198

Emergency Americas 1-760-476-3962

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

2. Hazards Identification

Physical state Liquid.

Appearance Clear liquid.

Emergency overview Physical and health hazard information on reagent mixtures have not been determined.

OSHA regulatory status This product is not hazardous according to OSHA 29CFR 1910.1200.

Potential health effects

Routes of exposure Inhalation. Ingestion. Skin contact. Eye contact. Eyes Splashes may irritate and cause redness.

Skin Prolonged skin contact may cause redness, irritation and dry skin.

Inhalation Vapors and mist may irritate throat and respiratory system and cause coughing.

Ingestion May cause discomfort if swallowed.

Chronic effects No data available.

Signs and symptoms Ingestion may cause irritation and malaise.

Potential environmental effects The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First Aid Measures

First aid procedures

Eye contact In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding

the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get

medical attention if irritation develops and persists.

InhalationMove to fresh air. Call a physician if symptoms develop or persist.IngestionIf material is ingested, immediately contact a poison control center.Notes to physicianProvide general supportive measures and treat symptomatically.

5. Fire Fighting Measures

Flammable properties This product is not flammable.

Extinguishing media

Suitable extinguishing

media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

None known.

Protection of firefighters

Specific hazards arising from the chemical

When heated to decomposition, may produce hydrazoic acid fumes.

Protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion

products

Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide.

6. Accidental Release Measures

Personal precautions Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during

clean-up. Do not touch damaged containers or spilled material unless wearing appropriate

protective clothing.

Environmental precautions Methods for containment

Do not allow to enter drains, sewers or watercourses. Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all

applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient

ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Exposure guidelines

Follow standard monitoring procedures.

Engineering controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

Personal protective equipment

Eye / face protection

Wear approved safety glasses or goggles.

Skin protection

Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection

Under normal conditions, respirator is not normally required.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Clear liquid. Clear. Color

Odor Not available. Not available. Odor threshold

Liquid. Physical state Liquid. **Form** 7.6 рH

Not available. **Melting point** Freezing point Not available. **Boiling point** Not available. Flash point Not available. **Evaporation rate** Not available. Flammability limits in air, upper, Not available.

% by volume

Flammability limits in air, lower, Not available.

% by volume

Not available. Vapor pressure Not available. Vapor density Not available. Specific gravity Soluble. Solubility (water) **Partition coefficient** Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature**

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions.

Conditions to avoid Protect against direct sunlight. Incompatible materials Strong oxidizing agents. Acids.

Hazardous decomposition

products

None.

Possibility of hazardous

reactions

Not expected to occur.

11. Toxicological Information

May cause discomfort if swallowed. **Acute effects**

Local effects May cause eye irritation on direct contact.

Sensitization No data available. No data available. **Chronic effects** Carcinogenicity Not classified.

No epidemiological data is available for this product. **Epidemiology**

Not classified. Mutagenicity Not classified. Reproductive effects

Symptoms and target

organs

May cause eye irritation on direct contact.

No other specific acute or chronic health impact noted. **Further information**

12. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. **Environmental effects**

Aquatic toxicity Not classified.

Persistence and No data is available on the degradability of this product.

degradability

Bioaccumulation / No data available.

Accumulation

Not available.

Partition coefficient

(n-octanol/water)

Mobility in environmental

media

The product is soluble in water.

13. Disposal Considerations

Disposal instructions Dispose in accordance with all applicable regulations.

Waste from residues / unused

products

Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

All components are on the U.S. EPA TSCA Inventory List.

This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug

Administration.

TSCA Section 12(b) Export Notification(40 CFR 707, Subpt. D)

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

> Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CRF 355, Appendix A)

No

Section 311/312 (40 CFR

United States & Puerto Rico

370)

No

Drug Enforcement

Administration (DEA) (21 CFR

1308.11-15)

Not controlled

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS

contains all the information required by the CPR.

WHMIS status Non-controlled

Inventory status

Country(s) or region Inventory name On inventory (yes/no)*

Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard

Toxic Substances Control Act (TSCA) Inventory

(NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 0

> Flammability: 0 Physical hazard: 0

NFPA ratings Health: 0

> Flammability: 0 Instability: 0

Rapidtesta FLU NEO (Extraction Reagent Buffer) 906533 Version #: 01 Revision date: 01-27-2012 Print date: 01-27-2012

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Issue date

01-27-2012