1. Identification

Product identifier  
OSOM® Ultra Plus Flu A&B Control Kit

Other means of identification  
Product number  
1034

Recommended use  
For external quality control testing.

Recommended restrictions  
For In Vitro Diagnostic use only.

Manufacturer/Importer/Supplier/Distributor information

Corporate Headquarters  
Sekisui Diagnostics, LLC
One Wall Street, Burlington, MA  01803, USA
www.sekisuidiagnostics.com
Phone: 1-800-332-1042
Americas 1-760-476-3962

Emergency telephone number  
Europe, Middle East & Africa +1-760-476-3961
Asia Pacific +1-760-476-3960
Access code 333512

2. Hazard(s) identification

Physical hazards  
Not classified.

Health hazards  
Not classified.

OSHA defined hazards  
Not classified.

Label elements  
Hazard symbol  
None.

Signal word  
None.

Hazard statement  
Exempt (manufactured article).

Precautionary statement  
Prevention  
Not assigned.

Response  
Not assigned.

Storage  
Not assigned.

Disposal  
Not assigned.

Hazard(s) not otherwise classified (HNOC)  
None known.

Supplemental information  
The antigens in this kit have been tested to confirm their inactivity. However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with universal/standard precautions.

3. Composition/information on ingredients

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

4. First-aid measures

Inhalation  
Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact  
Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact  
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion  
Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed  
Direct contact with eyes may cause temporary irritation.
Treat symptomatically.

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special 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
Move containers from fire area if you can do it without risk.

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

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
Sweep or scoop up and remove. For waste disposal, see section 13 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Observe good industrial hygiene practices. Wear appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities
Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits
No exposure limits noted for ingredient(s).

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment
Eye/face protection
Wear safety glasses with side shields (or goggles).

Skin protection
Wear appropriate chemical resistant gloves.

Hand protection

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

Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance
Physical state
Solid.

Form
Coated swab. Dried antigen on control swab.

Color
Not available.

Odor
Not available.
Odor threshold: Not available.

pH: Not available.

Melting point/freezing point: Not available.

Initial boiling point and boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid, gas): Not available.

Upper/lower flammability or explosive limits

- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.

Vapor pressure: Not available.

Vapor density: Not available.

Relative density: Not available.

Solubility(ies)
- Solubility (water): Not available.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Other information
- Explosive properties: Not explosive.
- Oxidizing properties: Not oxidizing.

10. Stability and reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability: Material is stable under normal conditions.

Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.

Conditions to avoid: Contact with incompatible materials.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition products: No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

- Inhalation: No adverse effects due to inhalation are expected.
- Skin contact: No adverse effects due to skin contact are expected.
- Eye contact: Direct contact with eyes may cause temporary irritation.
- Ingestion: Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics: Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

- Acute toxicity: Not expected to be acutely toxic.
- Skin corrosion/irritation: No adverse effects due to skin contact are expected.
- Serious eye damage/eye irritation: Direct contact with eyes may cause temporary irritation.
- Respiratory or skin sensitization: Not a respiratory sensitizer.
This product is not expected to cause skin sensitization.

Skin sensitization

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Germ cell mutagenicity

Carcinogenicity

Not classifiable as to carcinogenicity to humans.

Carcinogenicity

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

IARC Monographs. Overall Evaluation of Carcinogenicity

NTP Report on Carcinogens

Not listed.

NTP Report on Carcinogens

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Reproductive toxicity

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - single exposure

Specific target organ toxicity - repeated exposure

Not classified.

Specific target organ toxicity - repeated exposure

Aspiration hazard

Not an aspiration hazard.

Aspiration hazard

12. Ecological information

Ecotoxicity

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.

Ecotoxicity

Persistence and degradability

No data is available on the degradability of any ingredients in the mixture.

Persistence and degradability

Bioaccumulative potential

No data available.

Bioaccumulative potential

Mobility in soil

No data available.

Mobility in soil

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Other adverse effects

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Disposal instructions

Local disposal regulations

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Local disposal regulations

Hazardous waste code

Waste from residues / unused products

Dispose of in accordance with local 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).

Waste from residues / unused products

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Contaminated packaging

14. Transport information

DOT

Not regulated as dangerous goods.

DOT

IATA

Not regulated as dangerous goods.

IATA

IMDG

Not regulated as dangerous goods.

IMDG

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

US federal regulations

This product is an article pursuant to 29 CFR 1910.1200 and, as such, is not subject to the OSHA Hazard Communication Standard.

US federal regulations

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

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.

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

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)
SARA 304 Emergency release notification
Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not listed.
Toxic Substances Control Act (TSCA) One or more components of the mixture are not on the TSCA 8(b) inventory or are designated “inactive”.
Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.
SARA 311/312 Hazardous chemical
Not listed.
SARA 313 (TRI reporting)
Not regulated.
Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.
Safe Drinking Water Act (SDWA)
Not regulated.
US state regulations
US. Massachusetts RTK - Substance List
Not regulated.
US. New Jersey Worker and Community Right-to-Know Act
Not listed.
US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.
US. Rhode Island RTK
Not regulated.
California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive harm.
16. Other information, including date of preparation or last revision
Issue date 08-April-2020
Revision date -
Version # 01
References ECHA CHEM
Disclaimer The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.