

Valid date of Jan. 22, 2021

1. Product and Company Identification
Product name : Asan Easy Test Flu/COVID-19 Ag

Product number : AM3491-K

Application of the Product: Clinical Laboratory Application (Diagnostic Kit)

Manufacturer/Supplier : ASAN PHARMACEUTICAL CO., LTD

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2. Composition/Information on Ingredients
[Flu/COVID-19 Ag Combo test device]

	CAS#	Concentration	Exposure Limits
a. Gold conjugates: Mouse monoclonal anti-influenza A antibody-gold conjugate	N/A	0.4±0.08µg	N/A
b. Gold conjugates: Mouse monoclonal anti-influenza B antibody-gold conjugate	N/A	0.4±0.08µg	N/A
c. Gold conjugates: Mouse monoclonal anti-COVID-19 nucleoprotein antibody-gold conjugate	N/A	0.25±0.05µg	N/A
d. Nus tag gold conjugated	N/A	0.08±0.016µg	N/A
e. Test line 1: Mouse monoclonal anti-influenza A antibody	N/A	1.0±0.2µg	N/A
f. Test line 2: Mouse monoclonal anti-influenza B antibody	N/A	1.0±0.2µg	N/A
g. Test line: Mouse monoclonal anti-COVID-19 Ag nucleoprotein antibody	N/A	0.78±0.15µg	N/A
h. Control line: Mouse monoclonal anti-nus tag antibody	N/A	0.93±0.186µg	N/A

(N/A ; not applicable, because of being provided as solid-phase on individual test device)

Sample diluent (0.35ml/vial) Aqueous buffer solution for sample dilution

	CAS#	Concentration	Exposure Limits
a. Carbonate	497-19-8	0.35±0.07ml	N/A
b. Triton X-100	9002-93-1	1.5±0.3mg	N/A
b. Sodium azide	26628-22-8	0.1%	N/A

3. Hazards Identification

Physical State and Appearance : Dangerous solid or liquid substances present in > 1%.
 : Test strip membrane - in white and colored plastic device.
 : Sample diluents - Clear, liquid

Emergency : No specific hazard.

Routes of Entry : Absorbed through skin. Inhalation. Ingestion.

Skin Contact	:	Irritation of the product in case of skin contact: Not available. Sensitization of the product: Not available.
Aggravating conditions	:	Repeated or prolonged exposure is not known to aggravate medical condition.
Potential Chronic Health Effects	:	<u>Carcinogenic effects</u> : Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)]. <u>Mutagenic effects</u> : Not available. <u>Teratogenic effects</u> : Not available.
Overexposure /Signs/Symptoms	:	Not available
See Toxicological Information (section 11)		

4. First Aid Measures

Inhalation	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion	:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin Contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
Eye Contact	:	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water at least 15 minutes. Cold water may be used. Get medical attention.

5. Fire-Fighting Measures

Extinguishing Media

Suitable	:	Not applicable. Use an extinguishing agent suitable for surrounding fires.
Flammability of the Product	:	Non-flammable.
Autoignition Temperature	:	Not applicable.
Flash Points	:	Not applicable.
Flammable Limits	:	Not applicable.
Fire Hazards in Presence of Various Substances	:	Not applicable.
Explosion Hazards in Presence of Various Substances	:	Not considered as a product presenting risks of explosion.
Special Remarks on Fire Hazards	:	Not available.

6. Accidental Release Measures

Environmental Precautions and Clean-up Methods	:	Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary
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system.

Small Spill and Leak : Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7. Handling and Storage

Handling : Avoid breathing vapors or spray mists.

Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. Exposure controls and Personal protection

Engineering measures : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protective equipment

Skin and Body : Lab coat.

Hands : Gloves.

Eyes : Safety glasses.

Feet : Not applicable

Personal Protection in Case of a Large Spill : Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Consult local authorities for acceptable exposure limits.

9. Physical and Chemical Properties

Physical state : Test strip membrane - in white.
Sample diluents - Clear, liquid

Color : Colorless.

Odor : Not available.

Odor Threshold : Not available.

Taste : Not available.

Molecular Weight : Not applicable.

Molecular Formula : Not applicable.

pH :: Neutral

Boiling Point : The lowest known values is 100°C (212°F)(water)

Melting Point : May start to solidify at 0°C (32°F) based on data for: water.

Critical Temperature : The lowest known value is 374.3°C(705.7°F)(water).

Vapor Pressure : The highest known value is 3.2 kPa (23.8 mmHg) (at 20°C)

Volatility : 0%(w/w). (water). Weighted average: 0%(w/w).

VOC : -90°C(%).

Evaporation rate : 0.36 (water) compared to (n-butyl acetate= 1).

Specific Gravity : Not available.

Solubility : Easily soluble in cold water, hot water, methanol, acetone.

Ionicity (in Water) : Amphoteric. (water).

Dispersion Properties : See solubility in water, methanol, acetone.

Physical Chemical Comments : Not available.

10. Stability and Reactivity

Stability : The product is stable.
Hazardous Decomposition Products : Not applicable.
Hazardous Polymerization : Will not occur.
Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.

11. Toxicological information

Chronic Effects on Humans : Carcinogenic effects: Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)].

Other Toxic Effects on Human : No specific information is available in our database regarding the other toxic effects of this material for humans.

Special Remarks on Toxicity to Animals : Not available.

special Remarks on Chronic Effects on Humans : Not available.

Special Remarks on Other Toxic Effects on Humans : Not available.

12. Ecological information

BOD and COD : Not available.
Biodegradable/OECD : Not available.
Mobility : Not available.
Products of Degradation : Not available.
Toxicity of the products of Biodegradation : Not available.
Special Remarks on the Products of Biodegradation : Not available.

13. Disposal considerations

Methods of disposal; Waste of residues; Contaminated packaging : Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Waste Stream : Not available.

Consult your local or regional authorities.

14. Transport information

DOT regulations :
Hazard class : - None hazard

Land Transport ADR/RID (cross-border)
ADR. RID class : -
Maritime transport IMDG :
IMDG Class : - None hazard
Marine pollutant : No
Air transport ICAO-TI and IATA-DGR : None hazard
ICAO/IATA Class : - None hazard

15. Regulations

Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity:

None of the ingredients is listed

Carcinogen categories

EPA (Environmental Protection Agency):

None of the ingredients is listed

IARC (International Agency for Research on Cancer):

None of the ingredients is listed

NTP (National Toxicology Program) :

None of the ingredients is listed

TLV(Threshold Limit Value established by ACGIH) :

None of the ingredients is listed

MAK(German Maximum Workplace Concentration) :

None of the ingredients is listed

NIOSH-Ca(National Institute for Occupational Safety and Health) :

None of the ingredients is listed

OSHA-Ca(Occupational Safety & Health Administration) :

None of the ingredients is listed

Hazard-determining components of labelling :

sodium azide

Risk phrases:

Harmful if swallowed

safety phrases:

This material and its container must be disposed of in a safe way.

Wear suitable protective clothing.

If swallowed, seek medical advice immediately and show this container or label.

National regulations:

Water hazard class: Generally not hazardous for water.

16. Other information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guideline of ASAN PHARMACEUTICAL CO., LTD. shall not be held liable for any damage resulting from handling or from contact with above product. Final determination of suitability of any material is the sole responsibility of user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that are the only hazards that exist.