

SAFETY DATA SHEET**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**

Product name Coagpia APTT-N APTT Reagent
Manufacturer/Supplier SEKISUI MEDICAL CO., LTD. Tsukuba Plant
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Recommended uses and restrictions on use: For in vitro diagnostic use.

SECTION 2: HAZARDS IDENTIFICATION**GHS classification :**

SKIN SENSITIZER	Category 1
GERM CELL MUTAGENICITY	Category 1B
TOXIC TO REPRODUCTION	Category 1

Items without a category description are those not classified, not applicable or classification not possible into GHS category.

Hazard Symbol**Signal word**

Danger

Hazard statements

H317 : May cause an allergic skin reaction
H340 : May cause genetic defects
H360 : May danger fertility or the unborn child

Precautionary Statements-(Prevention)

P201 : Obtain special instructions before use.
P202 : Do not handle until a safety precautions have been read and understood.
P261 : Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P280 : Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statements-(Response)

P302 + P352 : If on skin: Wash with plenty of soap and water.
P333 + P313 : If skin irritation or rash occurs: get medical advice/attention.
P362 + P364 : Take off contaminated clothing and wash it before reuse.

P308 + P313 : If exposed or concerned: get medical advice/attention.

Precautionary Statements-(Storage)

P405 : Store locked up.

Precautionary Statements-(Disposal)

P501 : Dispose of contents/container to a located point (in accordance with local/regional/international regulation).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**Single Substance or Mixture**

Mixture

Chemical name	Weight-%	ENCS	CAS No.
Phenol	0.1	3-481	108-95-2
ProClin 300	<0.1	5-5235 9-378	55965-84-9
Copper (II) Sulfate Pentahydrate	<0.01	1-300	7758-99-8

SECTION 4: FIRST AID MEASURES**Inhalation**

Remove to fresh air. If you feel unwell, call a POISON CENTER or doctor/physician.

Skin contact

Wash off immediately with soap and plenty of water. Get medical attention if irritation develops and persists.

Remove contaminated clothes and wash them before reuse.

Eye contact

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Immediate medical attention is required.

Ingestion

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without medical advice.

Acute effect and delayed effect

Acute effect: May cause an allergic skin reaction,

Delayed effect: May cause genetic defects, May danger fertility or the unborn child

Protection of first-aiders

Use personal protective equipment as required.

SECTION 5: FIRE FIGHTING MEASURES**Suitable extinguishing media**

Use powder, carbon dioxide, dry sand, or other extinguishing media depending on the type of fire in the surrounding area.

Unsuitable extinguishing media

Pouring straight streams of water

Specific hazards arising from the product

Container may burst due to fire. Irritant, corrosive or toxic gases may be generated due to the fire.

Special extinguishing method

Remove the containers if it is not dangerous. Even after extinguishment, cool the containers sufficiently with large quantities of water.

Protection of fire-fighter

Perform fire fighting from the windward. Use personal protective equipment as required.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

For indoor, provide adequate ventilation process until the end of working. Deny unnecessary entry other than the people involved by, for example, using a rope. While working, wear appropriate protective equipments to avoid adhering it on skin, or inhaling the gas. Work from windward, and retract the people downwind. Let the workers wear appropriate protective gear (see the “8. EXPOSURE CONTROLS/PERSONAL PROTECTION” section) to prevent contact with eyes and skin and inhalation.

Environmental precautions

To be careful not discharge to the environment without being properly handled waste contaminated. See the “12. ECOLOGICAL INFORMATION” section for additional information.

Methods and materials for containment and methods and materials for cleaning up

Absorb dry sand, earth, sawdust and the waste rug. Collect empty container that can be sealed. Stop the leakage, if it is not dangerous.

Recovery , neutralization

Remove the contaminated objects and wipe off the rest using waste rug.

Secondary disaster prevention measures

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevent inflow into sewers, drains, basements, or closed places.

SECTION 7: HANDLING AND STORAGE**Handling****Technical measures**

Carry out the engineering control (see the “8. EXPOSURE CONTRL/PERSONAL PROTECTION” section) and use personal equipment as required.

Precautions

Do not rough handling containers, such as upsetting, falling, giving a shock, and dragging. Prevent leakage, overflow, and scattering. Not generate steam and dust in vain. Seal the container after use. Wash hands after handling. In places other than those specified, should not be smoking or eating or drinking.

Safety handling precautions

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Avoidance of contact

Refer to the “10. STABILITY and REACTIVITY” section

Storage**Technical measures**

Prohibit the use of frozen product, because accurate results may not obtained due to qualitative change.

Safe storage conditions

Store away from sunlight in a cool place (2-10°C).

Incompatible substances

Refer to the “10. STABILITY and REACTIVITY” section

Safe packing material

Keep in the product original container.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION**Exposure limits**

Chemical name	ISHL Working Environmental Evaluation Standards-Administrative Control level	JSOH	ACGIH TLV-TWA
Phenol (CAS : 108-95-2)	N/A	5ppm	5ppm

Engineering control

In case of indoor workplace, use a local exhaust system. Provide the safety shower facility, and hand- and

eye--wash facility. And display their position clearly.

Personal protective equipment

Respiratory protection	Protective mask
Hand protection	Protection gloves
Eye protection	Protective eyeglasses or chemical safety goggles
Skin and body protection	Wear suitable protective clothing, protective boots.

General hygiene considerations

Do not eat, drink or smoke when using this product

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	liquid
Color	Pale yellow to pale green
Odor	No data available
pH	No data available
Melting point/freezing point	No data available
Boiling point, initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limit	No data available
Vapor pressure	No data available
Vapor density	No data available
Specific Gravity/Relative density	No data available
Solubility	No data available
n-Octanol/water partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity (coefficient of viscosity)	No data available
Dynamic viscosity	No data available

SECTION 10: STABILITY AND REACTIVITY

Stability

Stable under usual handling conditions.

Hazardous reactions

No information available

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

No information available

Hazardous decomposition products

No information available

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY: ORAL	Phenol (CAS : 108-95-2); LD ₅₀ : 512mg/kg (Rat, EHC 161 (1964)) ProClin 300 (CAS : 55965-84-9); LD ₅₀ : 53mg/kg (Rat, ChemIDPlus) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); LD ₅₀ : 300mg/kg (Rat, EHC 200 (1998)) <u>Product : Not classified</u>
ACUTE TOXICITY: SKIN	Phenol (CAS : 108-95-2); LD ₅₀ : 670mg/kg (Rat, EHC 161 (1964)) <u>Product : Not classified</u>

ACUTE TOXICITY: INHALATION	Phenol (CAS : 108-95-2); LC ₅₀ : 0.316mg/L (NLM) <u>Product : Not classified</u>
SKIN CORROSION/ IRRITATION	Phenol (CAS : 108-95-2); Category 1A-1C (RTECS (CD-ROM)) <u>Product : Not classified</u>
SERIOUS EYE DAMAGE/ EYE IRRITATION	Phenol (CAS : 108-95-2); Category 1 (RTECS (CD-ROM)) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 1 (CERI Hazard Data sheet, 2001-59 (2002)) <u>Product : Not classified</u>
RESPIRATORY SENSITIZATION	<u>Product : Classification not possible</u>
SKIN SENSITIZATION	ProClin 300 (CAS : 55965-84-9); Category 1 (EC CLP, C ₅₀ ≥0.0015%) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 1 (EHC 200 (1998)) <u>Product : Category 1</u>
GERM CELL MUTAGENICITY	Phenol (CAS : 108-95-2); Category 1B (EC CLP) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 2 (ATSDR (2004), EHC 200 (1998)) <u>Product : Category 1B</u>
CARCINOGENICITY	<u>Product : Classification not possible</u>
TOXIC TO REPRODUCTION	Phenol (CAS : 108-95-2); Category 1B (EC CLP) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 2 (ATSDR (2004), EHC 200 (1998)), CERI Hazard Data sheet, 2001-59 (2002)) <u>Product : Category 1</u>
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)	Phenol (CAS : 108-95-2); Category 1 (respiratory organs, cardiovascular system, kidney, nervous system) (EHC 161 (1994), CERI Hazard assessment report No.32 (2005), ATSDR (1998)) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 1 (nervous system, liver, blood circulatory system, kidney), Category 3 (respiratory tract irritation) (CERI Hazard Data sheet, 2001-59 (2002)), ICSC (J) (2001)) <u>Product : Not classified</u>
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)	Phenol (CAS : 108-95-2); Category 1 (cardiovascular system, liver, digestive tract, blood circulatory system, kidney, spleen, thymus, central nervous system) (EHC 161 (1994), CERI Hazard assessment report No.32 (2005), ATSDR (1998)) Copper (II) Sulfate Pentahydrate (CAS : 7758-99-8); Category 2 (respiratory organs, blood circulatory system) ATSDR (2004)) <u>Product : Not classified</u>
ASPIRATION HAZARD	<u>Product : Classification not possible</u>

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity	Phenol (CAS : 108-95-2): Ceriodaphnia LC ₅₀ : 3.1 mg/L/48h (EU=RAR (2002)) ProClin 300 (CAS : 55965-84-9): Brachydanio rerio LC ₅₀ : 0.27 mg/L/96h (e-ChemPortal; HSNO) Copper (II) Sulfate Pentahydrate (CAS: 7758-99-8): Daphnia magna LC ₅₀ : 7µg/L/48h (EHC200, 1998) <u>ACUTE HAZARDS TO THE AQUATIC ENVIRONMENT: Not classified</u> <u>CHRONIC HAZARDS TO THE AQUATIC ENVIRONMENT: Not classified</u>
Persistence and degradability	No information available
Bioaccumulative potential	No information available
Mobility in soil	No information available

SECTION 13: DISPOSAL CONSIDERATION**Waste from residue**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated container and contaminated packing

Disposal should be in accordance with applicable regional, national and local laws and regulations.

SECTION 14: TRANSPORT INFORMATION

International Regulations	
Maritime Regulatory Information	in accordance with IMO regulations
Aviation regulatory information	in accordance with ICAO/IATA regulation
UN No.	Not applicable
Proper Shipping Name	Not applicable
Class	Not applicable
Packing Group	Not applicable
Marine Pollutant	Not applicable
Pictogram	Not applicable
Japanese Regulations	
Class	Not applicable
UN No.	Not applicable
Proper Shipping Name	Not applicable
Packing Group	Not applicable
Land transportation: Fire Service Act	Not applicable
Maritime transport: Ship Safety Act	Not applicable
Air transport: Civil Aeronautics Law	Not applicable
Special precautions for user	In compliance with the "7. HANDLING AND STORAGE" section. Before transportation, confirm the absence of breakage, corrosion, leakage, etc. in the containers. Place the containers on board in a manner that will cause no tumbling, falling, and damage and take reliable measures against container collapsing on board.

SECTION 15: REGULATORY INFORMATION

Industrial Safety and Health Act: Notifiable Substances (Enforcement Order Art. 18-2 Attached Table No.9)	Phenol (CAS : 108-95-2); No.474, Threshold ≥ 0.1 weight %
Poisonous and Deleterious Substances Control Act	Not applicable
Pollutant Release and Transfer Register Law	Not applicable
Pharmaceutical and Medical Device Act	In vitro diagnostic
Fire Service Act	Not applicable
Ship Safety Act	Not applicable
Civil Aeronautics Law	Not applicable

SECTION 16: OTHER INFORMATION

Literature and references	1. GHS (Rev.4 and Rev.5) 2. JIS Z 7252-2014 3. JIS Z 7253-2012 4. National Institute of Technology and Evaluation: http://www.safe.nite.go.jp/ghs/list.html 5. Ministry of Health, Labour and Welfare Workplace Safety Site http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_FND.aspx
Revision history of SDS	1st: 01/07/2013 2nd: 01/06/2016 3rd: 24/06/2016
Revision version	3
<p>The information of this product safety data sheet is based on the present state of our knowledge. It does not include all information. If new information is obtained, it may be added or the original information may be corrected. The information is applicable to the product with regard to appropriate safety precautions and does not represent any guarantee of the properties of the product. It is requested that the user be responsible for ensuring conditions for safe use.</p>	

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