

Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Human s-IgA(Saliva) ELISA Kit
Product number: YK280
Manufacturer: YANAIHARA INSTITUTE, INC.
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2. HAZARDS IDENTIFICATION

GHS classification

Classification of the substance or mixture 3), 5)

Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 1A, 2
Serious eye damage/eye irritation	Category 1, 2A
Specific target organ toxicity (single exposure)	Category 1
Category 1 respiratory system, cardiovascular system, kidneys, nervous system	
Specific target organ toxicity (repeated exposure)	Category 1
Category 1 respiratory system, cardiovascular system, liver, digestive system, blood system, kidneys, pancreas, thymus, central nervous system	
Germ cell mutagenicity	Category 1B
Reproductive Toxicity	Category 1B

Pictograms



Signal word Danger

Hazard statements

H314 - Causes severe skin burns and eye damage
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H332 - Harmful if inhaled
H340 - May cause genetic defects
H360 - May damage fertility or the unborn child
H370 - Causes damage to the following organs: respiratory system
H372 - Causes damage to the following organs through prolonged or repeated exposure:

respiratory system

Precautionary statements-(Prevention)

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required
- Contaminated work clothing should not be allowed out of the workplace
- Wear protective gloves/protective clothing/eye protection/face protection
- Do not breathe dust/fume/gas/mist/vapors/spray
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product
- Use only outdoors or in a well-ventilated area

Precautionary statements-(Response)

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Call a POISON CENTER or doctor/physician if you feel unwell
- IF ON SKIN: Wash with plenty of soap and water
- IF exposed or concerned: Get medical advice/attention
- Wash contaminated clothing before reuse
- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- If skin irritation or rash occurs: Get medical advice/attention
- IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

Precautionary statements-(Storage)

- Store locked up.
- Store in a well-ventilated place. Keep container tightly closed.

Precautionary statements-(Disposal)

- Dispose of contents/container to an approved waste disposal plant

Others

Other hazards Not available

Other reagents may be harmful if inhaled and ingested. May cause eye and skin irritation.

3. COMPOSITION, INFORMATION ON INGREDIENTS¹⁾

Product Name
 Human s-IgA (Saliva) ELISA Kit

CAS Number
 None

Kit components:

No.	Component	Quantity	Chemical name	Wt%	CAS No.	Chemical Formula
1)	Antibody coated plate	1 plate	Plate coated with mouse anti human s-IgA monoclonal antibody ①			
2)	Standard	10 μ g	Purified human s-IgA②			
3)	HRP-labeled antibody solution	12 mL	HRP labeled goat anti human IgA (α chain) antibody ③			
4)	Enzyme substrate solution	12 mL	Phenol ④	0.096%	108-95-2	C6H5OH
			chloramphenicol ⑤	0.02%	56-75-7	C11H12CL2N2O2
			3,3',5,5'-Tetramethylbenzidine ⑥	No information	54827-17-7	C16H20N2
5)	Stopping solution	12 mL	Sulfuric acid (1M) ⑦	9.69%	7664-93-9	H2SO4
6)	Buffer solution (concentrated 2x)	25 mL	Buffer containing a reaction accelerator ⑧			
7)	Washing solution (concentrated)	50 mL	Sodium chloride ⑨	18%	7647-14-5	NaCl
8)	Adhesive foil	3 pieces	Polyoxyethylene sorbitan monolaurate (Tween20) ⑩	1%	9005-64-5	C22H42O3

4. FIRST AID MEASURES

Inhalation: Immediately remove victim to fresh air. Consult a physician if necessary.

Eye contact: Immediately flush eyes with flooding amounts of running water for at least 15 minutes. Consult a physician if necessary.

Skin contact: Immediately remove contaminated clothes and shoes, flush skin with plenty of water or shower. Wash contaminated clothing and shoes. Consult a physician if necessary.

Ingestion: Immediately seek medical attention.

5. FIRE FIGHTING MEASURES

Flammable properties: Nonflammable

Extinguishing media: Foam, Carbon dioxide, dry chemical powder, soil, water

Fire fighting instructions: May emit toxic fumes under fire conditions. Wear full fire fighting protective equipment including self-contained breathing apparatus. Do not contact to the components when extinguish fire.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Remove all ignition sources and ventilate. Wear suitable protective equipment. Avoid contact with skin and eyes. Keep off except persons concerned.

Environmental precautions: Prevent spills from entering sewers, watercourses or low area, and prevent from affecting environment.

Methods for Clean up: In case of spill of liquid material, take up or cover spilled material with ashes or other incombustible absorbents, and put in a container to be sealed. After completely picked up, dispose. In case of spill of solid or powder material, prevent causing dust, sweep and collect, and put in a container to be sealed. Wash the spill site with water.

7. HANDLING AND STORAGE

- Handling:** Obtain a package insert before use.
Read all the cautions for safety in the package insert before use.
Avoid strong light.
Avoid contact, inhalation and swallow.
Use only in open air or ventilated area.
Prevent from entering eyes.
Ventilate the area to keep concentration in air below exposure limits.
Avoid inhalation of mist, vapor and spray of material.
Avoid contact with eyes, skin and clothing.
Do not smoke and eat while using this kit.
Wash hands thoroughly after handling.
Prevent from entering environment.
Handle materials with suitable protection.
Use suitable equipments.
Do not pipette by mouth.
Do not leak, overflow and scatter.
Do not fall down and damage.
- Storage:** Store away from sunlight in a cool and dark place at 36-47°F (2-8°C).

8. EXPOSURE CONTOROLS, PERSONAL PROTECTION

Engineering measures: General ventilation and/or local exhaust ventilation as well as process isolation is necessary to minimize employee exposure and maintain exposure limits below exposure limits. Equip eye flushing facilities and shower rooms near operating place where this kit is handled or stored.

Control parameter:

④ OSHA Final Limits;	TWA= 5 ppm
JSOH (Japan);	TWA= 5 ppm OEL
	TWA= 19mg/m3 OEL skin
ACGIH TLV(s);	TWA= 5 ppm skin
⑦ OSHA Final Limits;	TWA= 1 mg/m3
JSOH (Japan);	TWA= 1 mg/m3
ACGIH TLV(s);	TWA= 0.2 mg/m3

Personal protection:

Respiratory protection;	NIOSH and MSHA approved respirator.
Hand protection;	Suitable impervious gloves.
Eye protection;	Suitable safety glasses (goggles).
Skin protection;	Suitable protective clothing.

Others: Wash hands thoroughly after handling materials.

9. PHYSICAL AND CHEMICAL PROPERTIES

Component	1)	2)	3)	4)	5)	6)	7)	8)
Appearance	Colorless plate	White color, lyophilized powder	Orange color, Liquid	Colorless to pale yellow liquid	Colorless transparent, Liquid	Colorless transparent, Liquid	Colorless transparent, Liquid	Colorless transparent Polymer sheet
pH	N/A	N/A	6.8-6.9	3.3-3.8	<1.0	D/N/A	D/N/A	N/A
Melting point	N/A	D/N/A	N/A	N/A	N/A	N/A	N/A	N/A
Boiling point	N/A	N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	N/A
Flash point	N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	N/A
Explosive limits	N/A	D/N/A	D/N/A	Not explosive	D/N/A	D/N/A	D/N/A	N/A
Vapor pressure	N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	N/A
Vapor density (air=1)	N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	N/A
Specifics gravity	D/N/A	D/N/A	D/N/A	1.01	D/N/A	D/N/A	D/N/A	D/N/A
Solubility in water	Insoluble	Soluble	Mixable	Mixable	Mixable	Mixable	Mixable	Insoluble
Decomposition temperature	N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	D/N/A	N/A

N/A: Not applicable
 D/N/A: data not available

10. STABILITY AND REACTIVITY

Chemical stability: Product is stable under normal handling.
Shelf life: Stable up to 24 months after manufacturing.
Hazardous polymerization: Will not occur.
Conditions to avoid: Extremes of temperature and direct sunlight, heat, flames and sparks, static electricity, spark, moisture
Incompatibility with other materials: Alkaline substances, metals, strong oxidizing agents
Hazardous decomposition products: Sulfur oxides(SOx), Carbon monoxide(CO), carbon dioxide(CO2), Nitrogen oxides(NOx)

11. TOXICOLOGICAL INFORMATION

Information as the mixture is not available.

Acute toxicity : 3) Phenol (oral, rat); LD50=375mg/kg
 (dermal rabbit) LD50=670mg/kg
 Chloramphenicol (oral, rat); LD50=2500mg/kg
 ATE=319.8
 Hazard statement; Harmful if swallowed.
 4) Not classified
 5) Sulfuric acid (inhalation, rat); 2H LC50=510mg/m3
 (oral, rat) LD50=2140mg/kg
 Category 4
 Hazard statement; Harmful if inhaled.
 Content=9.69%
 7) Tween 20 (oral, rat); LD50=37000mg/kg
 Sodium chloride (oral, rat); LD50=3000mg/kg

Not classified

Skin corrosion/irritation:

- 3) Phenol; Based on the NITE GHS classification results.
Category 2
Hazard statement: Causes skin irritation.
Content=0.096%
Chloramphenicol; Information not available.
Not classified
- 4) Not classified
- 5) Sulfuric acid; Based on the NITE GHS classification.
Category 1A
Hazard statement: Causes severe skin burns and eye damage.
Content=9.69%
- 7) Tween 20 (skin, human); 15mg/3days, Mild
Sodium chloride (skin, rabbit); 500mg/24H, Mild
Category 3
Hazard statement: Skin irritant

Serious eye damage/irritation:

- 3) Phenol; Based on the NITE GHS classification results.
Category 2A
Hazard statement: Causes serious eye irritation
Content=0.096%
Chloramphenicol; Information not available.
Not categorized
- 4) Not classified
- 5) Sulfuric acid; Based on the NITE GHS classification results.
Category 1
Hazard statement: Causes serious eye damage.
Content=9.69%
- 7) Tween 20 (eye); R-phase(s) =R36 (Irritating to eyes)
Sodium chloride (eye, rabbit); 100mg/24H, Medium
Category 2B
Hazard statement: Causes eye irritation.

Respiratory or skin sensitization:

Respiratory sensitization

- 3) Phenol; Based on the NITE GHS classification results.
Chloramphenicol; Information not available.
- 4) Not classified
- 5) Sulfuric acid; No data available.

Skin sensitization

- 3) Phenol; Based on the NITE GHS classification results.
Chloramphenicol (skin); Causes allergic skin reaction. Content=0.02%
Not classified

- 4) Not classified
- 5) Sulfuric acid; No data available.

Germ cell mutagenicity:

- 3) Phenol; Based on the NITE GHS classification results.
Category 1B
Hazard statement; May cause genetic defects.
Content=0.096%
Chloramphenicol; Information not available.
- 4) Not classified
- 5) Sulfuric acid; No data available.

Carcinogenicity:

- 3) Phenol; IARC 3 (1999) (substances which cannot be classified to human carcinogens), ACGIH: A4 (2005), IRIS: D (2002)
Chloramphenicol; IARC group 2A (substances which may be carcinogenic to human), Content=0.02%
Not classified
- 4) Not classified
- 5) Sulfuric acid; Occupational exposure to Mist of inorganic strong acids including sulfuric acid is classified to group 1 in IARC (to have carcinogenicity for human), group A2 in ACGIH (suspected human carcinogens) and group K in NTP (known to have carcinogenicity for human). With respect for the evaluation by IARC and current evaluation by NTP, it should be classified to category 1, however since sulfuric acid itself is classified to Category 4 in DFGOT and is not classified to carcinogen by any other organization, component 5) cannot be classified.

Reproductive toxicity:

- 3) Phenol; Based on the NITE GHS classification results.
Category 1B
Hazard statement; May damage fertility or the unborn child.
Content=0.096%
Chloramphenicol; Information not available.
- 4) Not classified
- 5) Sulfuric acid; No data available.

Specific target organ systemic toxicity/Single exposure:

- 3) Phenol; Based on the NITE GHS classification results.
Category 1 respiratory system, cardiovascular system, kidney and nervous system
Hazard statement; Causes damage to following organs: respiratory system, cardiovascular system, kidneys, nervous system.
Content=0.096%

Chloramphenicol; Information not available.

- 4) Not classified
- 5) Sulfuric acid; Based on the NITE GHS classification results.
Category 1 respiratory system
Hazard statement; Causes damage to the following organs: respiratory system.
Content=9.69%

Specific target organ systemic toxicity/Repeated exposure:

- 3) Phenol; Based on the NITE GHS classification results.
Category 1 cardiovascular system, liver, digestive system, blood system, kidney, pancreas, thymus, central nervous system
Hazard statement; Causes damage to the following organs through prolonged or repeated exposure: cardiovascular system, liver, digestive system, blood system, kidneys, pancreas, thymus, central nervous system.
Content=0.096%
- Chloramphenicol; Information not available.

- 4) Not classified
- 5) Sulfuric acid; Based on the NITE GHS classification results.
Category 1 respiratory system
Hazard statement; Causes damage to respiratory system with long term or repeated exposure: respiratory system.
Content=9.69%

12. ECOLOGICAL INFORMATION

Information as the mixture is not available.

Aquatic environmental toxicity/Acute phase:

- 3) Phenol; Ceriodaphnia: EC50=3.1mg/L/48h (EU-RAR, 2002)
Algae/aquatic plants (*Pseudokirchneriella subcapitata*)
96H EC50=46.42 mg/L
Fish (*Pimephales promelas*) 96H LC50=11.9-50.5mg/L
Crustacea (*Daphnia magna*), 48H EC50=4.24-10.7 mg/L
Chloramphenicol; 96H LC50=15-42 μ g/L
Component 3) is not classified.
- 4) No information available.
- 5) Sulfuric acid; In fish (Bluegill), 96H LC50=16-28mg/L
Daphnia magna 24H EC50=29mg/L
Hazard statement; Harmful to aquatic life.

Aquatic environmental toxicity/Chronical phase:

- 3) Phenol; Based on the NITE GHS classification results
Chloramphenicol; Has rapid degradability.
Component 3) is not classified.
- 5) Sulfuric acid; Based on the NITE GHS classification results.

13. DISPOSAL CONSIDERATIONS

Dispose of all waste material including containers in accordance with all applicable laws and local environmental regulations.

14. TRANSPORT INFORMATION

As a mixture, the substance is subjected to no limitations.

15. REGULATORY INFORMATION

International Inventories

EINECS/ELINCS	Listed
TSCA	Listed

Japanese regulations

Fire Service Act; Not applicable

Poisonous and Deleterious Substances Control Law; Not applicable

Industrial Safety and Health Act;

Group 3 Specified Chemical Substance, (Ordinance on Prevention of Hazards Due to Specified Chemical Substances Art.2 Para.1, Item 6)
Harmful Substances Whose Names Are to be Indicated on the Label (Law Art.57, Para.1, Enforcement Order Art.18)
Notifiable Substances (Law Art.57-2, Enforcement Order Art.18-2 No.613, 474)

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.;

Priority Assessment Chemical Substances (Law Article 2, Para.5)

Regulations for the carriage and storage of dangerous goods in ship;

Corrosive Substances(Ordinance Art.3, Ministry of Transportation Ordinance Regarding Transport by Ship and Storage)

Civil Aeronautics Law;

Corrosive Substances (Ordinance Art.194, MITL Notification for Air Transportation of Explosives etc.)

Marine Pollution Prevention Law Pollutant Release and Transfer Register Law;

Class 1

Class 1 - No. 349

Air pollution Control Law; Specified substance

EU Directive 1999/45/EC; classification, packaging and labeling of dangerous Preparations

SYMBOL : C (as component 5)

R-phrases : 35 (as component 5)

S-phrases : 26-45 (as component 5)

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
In case of accident or if you feel unwell, seek medical advice immediately.

EC index No. : ④=604-001-00-2, ⑥=259-364-6, ⑦=016-020-00-8

Other ingredients=Not listed.

Follow all the regulations in your country.

16. OTHER INFORMATION

Reference

- 1) Internal data of Yanaihara Institute, Inc.
- 2) Chemwathch MSDS
- 3) RTECS (2006)
- 4) EU RAR (2003)
- 5) SIDS (2001)
- 6) Environmental Risk Assessment of Chemicals Vol.3 (Ministry of environment, Japan) (2004)
- 7) ATSDR (1998)
- 8) SIDS (2001)
- 9) DFDS (2001)
- 10) EU- RAR (2002)
- 11) SIDS (2003)
- 12) CERI-NITE Hazard Assessment Report (2005)
- 13) NTP DB (Access on Dec., 2005)
- 14) Narotsky and Kavlock (1995)
- 15) EHC 161 (1994)
- 16) MSDS by Wako Pure Chemical Industries, Ltd.
- 17) ECETOC JACC (1993)
- 18) ACGIH (2001)
- 19) NITE Biodegradation and Bioconcentration of the Existing Chemical Substances
- 20) PHYSPROP Database (2005)
- 21) IUCLID (2000)
- 22) HSDB (2006)
- 23) JSOH Recommendation of Occupational Exposure Limits (1993)
- 24) IARC (1992)
- 25) ACGIH (2004)

Key literature references and sources for data etc.:

NITE: National Institute of Technology and Evaluation (JAPAN) <http://www.safe.nite.go.jp/japan/db.html>
IATA dangerous Goods Regulations RTECS: Registry of Toxic Effects of Chemical Substances Japan
Industrial Safety and Health Association GHS Model SDS Dictionary of Synthetic Organic Chemistry,
SSOCJ, Koudansha Scientific Co.Ltd. Chemical Dictionary, Kyouritsu Publishing Co., Ltd. etc.

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