

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Insulin ELISA Kit
Product number: YK060
Manufacturer: YANAIHARA INSTITUTE, INC.
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2. COMPOSITION, INFORMATION ON INGREDIENTS

Product Name: Insulin 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 guinea pig anti human insulin antibody			
2)	Standard	100 ng	Recombinant human insulin (Lyophilized)			
3)	Labeled antibody	12 mL	Biotinylated human guinea pig anti human insulin antibody			
4)	SA-HRP solution	12 mL	HRP labeled Streptavidin			
5)	Substrate buffer	25 mL	Phenol	0.2%	108-95-2	C ₆ H ₅ OH
			Chloramphenicol	0.02%	56-75-7	C ₁₁ H ₁₂ CL ₂ N ₂ O ₂
			Hydrogen peroxide	0.015%	7722-84-1	H ₂ O ₂
			Citric acid, monohydrate	0.7%	5949-29-1	C ₆ H ₈ O ₇ · H ₂ O
			Disodium hydrogenphosphate 12-water	2.39%	10039-32-4	Na ₂ HPO ₄ · 12H ₂ O
6)	OPD tablet	2 tablets	o-Phenylenediamine dihydrochloride	10mg	615-28-1	C ₆ H ₈ N ₂ · 2HCL
7)	Stopping solution	12 mL	Sulfuric acid (1M)	5.5%	7664-93-9	H ₂ SO ₄
8)	Buffer solution	25 mL	Phosphate buffer with non specific reaction blocker			
9)	Washing solution (concentrated)	50 mL	Sodium chloride	18%	7647-14-5	NaCl
			Polyoxyethylene sorbitan monolaurate (Tween20)	1%	9005-64-5	C ₂₂ H ₄₂ O ₃
10)	Adhesive foil	3 pieces				

3. HAZARDS IDENTIFICATION

7) Sulfuric acid component causes a severe skin and eyes irritation.

4) Phenol can cause liver, kidney, bladder and cardiac damage.

Pre-existing heart or circulatory disorders may be aggravated by exposure.

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

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 CONTROLS, 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: OSHA Final Limits; TWA= 5 ppm
ACGIH TLV(s); TWA= 5 ppm
ACGIH TLV(s); TWA= 1 ppm
Administrative control level 3.0/0.59Q + 1 mg/m³, Japan Society of Occupational Health(JSOH) 1 mg/m³
OSHA Final Limits; TWA= 1 mg/m³
ACGIH TLV(s); TWA= 1 mg/m³, STEL 3 mg/m³

Personal protection:

Respiratory protection; NIOSH and MSHA approved respirator
Hand protection; Suitable impervious gloves. PVC gloves for component 6).
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)	9)	10)
Appearance	Colorless plate containing white powder in each well	White color, lyophilized powder	Colorless transparent, Liquid	Orange color, Liquid	Colorless transparent, Liquid	White tablet	Colorless transparent, Liquid	Colorless transparent, Liquid	Colorless transparent, Liquid	Colorless transparent Polymer sheet
pH	N.D	N.D	7.5	6.8	5	N.D	N.D	N.D	N.D	N.D
Melting point	N.D	N.D	N.D	N.D	N.D	258	N.D	N.D	N.D	N.D
Boiling point	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D
Flash point	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D
Explosive limits	N.A	N.A	N.A	N.A	N.A	N.A	N.A	N.A	N.A	N.A
Vapor pressure	N.D	N.D	N.D	N.D	N.D	Very small	N.D	N.D	N.D	N.D
Vapor density (air=1)	N.D	N.D	N.D	N.D	N.D	>1	N.D	N.D	N.D	N.D
Specific gravity	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D	N.D
Solubility in water	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble	Insoluble
Decomposition temperature	N.D	N.D	N.D	N.D	N.D	258	N.D	N.D	N.D	N.D

10. STABILITY AND REACTIVITY

Chemical stability:	Product is stable under normal handling.
Shelf life:	Stable up to 15 months after manufacturing.
Hazardous polymerization:	Will not occur.
Conditions to avoid:	Strong light (all components), heat, contact with oxidizing reagents 2), 4), 6) and 9).
Incompatibility with other materials:	oxidizing reagents 2), 4), 6) and 9).
Hazardous decomposition products:	Carbon monoxide, carbon dioxide, nitrogen oxides, halogen compounds and etc. may be formed by combustion 4) and 6). Hydrogen sulfide, Sulfur oxides and etc. May be formed by combustion 7). Carbon monoxide, carbon dioxide and etc. May be formed by combustion (all components except 4), 6) and 7)).

11. TOXICOLOGICAL INFORMATION

Information as the mixture is not available.

- Acute toxicity : 4) Phenol (oral, rat); LD50=340mg/kg ³⁾
Chloramphenicol (oral, rat); LD50=2500mg/kg ²⁾
ATE=319.8
Category 4
Hazard statement; Harmful if swallowed
- 5) Hydrogen peroxide (oral, rat); LD50=311mg/kg ⁴⁾
Disodium hydrogenphosphate 12-water (oral, rat); LD50=17000mg/kg ³⁾
Citric acid (oral, rat); LD50=3000mg/kg ²⁾
ATE=284985
Not classified
- 6) o-phenylenediamine-dihydrochloride (oral, rat); LD50=290mg/kg ²⁾
Category 3
Hazard statement; Toxic if swallowed
- 9) Tween 20 (oral, rat); LD50=37000mg/kg ²⁾
Sodium chloride (oral, rat); LD50=3000mg/kg ²⁾
Not classified
- 4) Phenol (dermal, rat); LD50=670mg/kg ⁴⁾
Information on other ingredients not available
Category 3
Hazard statement; Toxic in contact with skin
- 5) Hydrogen peroxide (dermal, rat); LD50=4060mg/kg ⁴⁾, Content=0.015%
Information on Disodium hydrogenphosphate 12-water not available
Citrate acid (dermal, rabbit); LD50=1260mg/kg ²⁾
Not classified
- 7) Sulfuric acid (inhalation, rat); LD50=347ppm (4hour equivalent: 0.347mg/L) ⁵⁾
Category 2
Hazard statement; Fatal if inhaled

Skin corrosion/irritation:

- 4) Phenol (skin, rabbit and human); Corrosive ¹⁵⁾, Content=0.2%
Chloramphenicol; Information not available
Not classified
- 5) Disodium hydrogenphosphate 12-water (skin, rabbit); 500mg/24H. Mild ²⁾
Citric acid (skin, rabbit); 500mg/24H, Weak ²⁾
Hydrogen peroxide (skin); R-phase(s)=R35 (causes severe burns),
Content=0.015%
Not classified
- 7) Sulfuric acid (skin); pH<1
Category 1A-1C
Hazard statement; Causes severe skin burns and eye damage
- 9) Tween 20 (skin, human); 15mg/3days, Mild ²⁾
Sodium chloride (skin, rabbit); 500mg/24H, Mild ²⁾
Category 3
Hazard statement; Skin irritant

Serious eye damage/irritation:

- 4) Phenol (eye, rabbit); When phenol, in glycerin dilutions down to 10% or 5% aqueous solutions, was applied to the rabbit eyes, severe damage (complete destruction to opaque corneas) ⁷⁾ was seen. Content=0.2%
Chloramphenicol; Information not available.
Not categorized
- 5) Disodium hydrogenphosphate 12-water (eye, rabbit); 500mg/24H, Mild ²⁾
Citric acid (eye, rabbit); 0.75mg/24H, Severe ²⁾
Hydrogen peroxide (eye, animal); Severe. Corrosive ⁴⁾¹⁷⁾. Content=0.015%.
Not classified
- 7) Sulfuric acid (eye, human); In case of human accident, serious damage was seen ⁷⁾.
Sulfuric acid (eye, rabbit); Medium irritation for 5% solution and severe irritation for 10% solution ⁸⁾. pH<2.
Category 1
Hazard statement; Causes severe skin burns and eye damage
- 9) Tween 20 (eye); R-phase(s)=R36 (Irritating to eyes) ²⁾
Sodium chloride (eye, rabbit); 10mg/24H, Medium
100mg/24H, Medium ²⁾
Category 2B
Hazard statement; Causes eye irritation

Respiratory or skin sensitization:

Respiratory sensitization

- 4) Phenol and chloramphenicol; Information not available

Skin sensitization

- 4) Phenol (skin, guinea pig); Negative in Mugnussen and Kligman skin sensitization test ¹⁵⁾.

Phenol (skin, Mouse); Negative in MEST test ¹²⁾.
Phenol (skin, human volunteer); Negative ¹²⁾
Chloramphenicol (skin); Causes allergic skin reaction ²⁾. Content=0.02%
Not classified

Germ cell mutagenicity:

- 4) Phenol; Information on heritable germ cell mutagenicity tests not available
Phenol; Positive in somatic cell mutagenicity tests (chromosome aberration test)
¹¹⁾¹²⁾.
Chloramphenicol; Information not available.
Category 1B
Hazard statement; May cause genetic defects

Carcinogenicity:

- 4) Phenol; IARC group 3 (substances which can not be classified to human carcinogens)
Chloramphenicol; IARC group 2A (substances which may be carcinogenic to human) ¹⁶⁾, Content=0.02%
Not classified
5) Hydrogen peroxide; IARC group 3 (substances which can not be classified to human carcinogens). ACGIH group A3 (confirmed as animal carcinogen and relation to human is not unknown)
Other ingredients; Not classified.
6) o-phenylenediamine dihydrochloride; EU group 3 (substances which cause suspicion of human carcinogenicity)
Category 2
Hazard statement; Suspected of causing cancer
7) Sulfuric acid; Occupational exposure to Mist of inorganic strong acids including sulfuric acid are classified to group 1 in IARC (to have carcinogenicity for human ²⁴⁾), group A2 in ACGIH (suspected human carcinogens) and group K in NTP (known to have carcinogenicity for human) ²⁵⁾. 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 ⁹⁾ and is not classified to carcinogen by any other organization, component 8) can not be classified.

Reproductive toxicity:

- 4) Phenol (animal); In dose not to be seen general toxicity for parental animals, decrease in number of newborn was seen ¹²⁾¹⁴⁾.
Chloramphenicol; Information not available.
Category 1B
Hazard statement; May damage fertility or the unborn child
5) Hydrogen peroxide; In vitro experiment, effects to human sperm was seen. In animals, although no descriptions for general toxicity for parental animals, there are descriptions of effects to sperm

motility, female estrous cycle, decrease in number of maternal animals to give birth and decrease in body weight of newborn animals ¹⁷⁾. Content=0.015%

Other ingredients; Information not available.

Component 5) can not be classified.

Specific target organ systemic toxicity/Single exposure:

4) Phenol (human); There are reports effects to human listed below.

[Effects to heart and blood vessel]

[Effects to nervous system like, excess respiratory rate, difficulty in breathing, dysrhythmia, cardiovascular shock, severe metabolic acidosis, methemoglobinemia, acute renal failure, renal disorder, dark urine and spasm] ¹¹⁾

[Heart dysrhythmia] ¹⁵⁾

[Arrhythmia and bradycardia] ⁷⁾ etc.

Phenol (animal); There was a report of [Strong suppression of pupillary reflex] ¹²⁾. Every effect in animal is seen within the guidance value ranges of Category 1.

Since these reports, respiratory organs, cardiovascular system, kidney and nervous system seem to be the target organs.

Chloramphenicol; Information not available.

Category 1 (Respiratory organs, cardiovascular system, kidney and nervous system)

Hazard statement; Causes damage to respiratory organs, cardiovascular system, kidney and nervous system.

5) Hydrogen peroxide; Irritation in nose, throat and respiratory duct for human and animals ¹⁰⁾¹⁸⁾. Congestion in lung and trachea, lung edema, pulmonary emphysema, epithelium necrosis of trachea in animal within the guidance value ranges of Category 1 were described ¹⁰⁾. In human, headache, dizziness, tremor, spasm, benumbedness, faint and brain infarction were described ¹⁸⁾.

Content=0.015%

Other ingredients; Information not available.

Component 5) can not be classified.

7) Sulfuric acid (human); Respiratory irritation symptoms like cough and shortness of breath are known in low dose inhalation ⁹⁾. Persistent effects like hypofunction of lung and fibrosis, and emphysema as well as cough, shortness of breath and hemoptysis in high dose inhalation ⁷⁾.

Sulfuric acid (guinea pig); Pulmonary bleeding and malfunction of lung in inhalation exposure for 8 hours ⁷⁾.

Category 1 (Respiratory organs)

Hazard statement; Causes damage to respiratory organs.

Specific target organ systemic toxicity/Repeated exposure:

- 4) Phenol (human); There are reports of effects to human listed below.
[Increase in mortality rate caused by cardiovascular diseases] ¹²⁾
[Neonatal hyper bilirubinemia] ¹⁵⁾
[Nausea, vomition, diarrhea, abdominal pain, hemolytic anemia, methemoglobinemia, glomerulus denaturation, renal tubulonecrosis, papillary cell bleeding] ⁷⁾ and etc.

Phenol (animal); There are reports of effects to animals listed below.
[Significant decrease of red blood cell count, protein cast and renal tubulonecrosis in kidney, papillary bleeding, atrophy/necrosis of spleen/thymus, vacuolization of hepatocyte, severe effects to central nervous system, liver disorder] ¹²⁾
Every effect in animal is seen within the guidance value ranges of Category 1.

Since these reports, cardiovascular system, liver, digestive tracts, vascular system, kidney, spleen, thymus and central nervous system seem to be the target organs.

Chloramphenicol; Information not available.

Category 1 (Cardiovascular system, liver, digestive tracts, vascular system, kidney, spleen, thymus and central nervous system)

Hazard statement; Causes damage to cardiovascular system, liver, digestive tracts, vascular system, kidney, spleen, thymus and central nervous system with long term or repeated exposure.

- 5) Hydrogen peroxide (human); Irritative to lung ¹⁷⁾.

Hydrogen peroxide (dog); Fibrous tissue nidus in lung appeared frequently and mixture of atelectasis and emphysema fields were recognized within the dose of the guidance value ranges of Category 1 in the inhalation test of vapor¹¹⁾.

Hydrogen peroxide (oral, rat); Effects to white blood cell count and hematocrit value, and hemolysis were seen within the dose of the guidance value ranges of Category 2 ⁴⁾.

Content=0.015%

Other ingredients; Information not available.

Component 6) can not be classified

Hazard statement; Causes irritation to respiratory organs.

- 7) Sulfuric acid (inhalation, rat); Cell proliferation in larynx mucosa was recognized within the dose of the guidance value ranges of Category 1 in the inhalation exposure test for 28 days ⁵⁾.

Sulfuric acid (inhalation, guinea pig); Disorders of respiratory tract and lung like nasal septum edema, emphysema,

atelectasis, bronchiole hyperemia, edema, bleeding, thrombus were recognized within the dose of the guidance value ranges of Category 1 in the repeated inhalation test for 14-139 days ⁷⁾.

Sulfuric acid (inhalation, monkey); Histological changes like Hyperplasia of the cells and hypertrophy of the wall in bronchiole were recognized within the dose of the guidance value ranges of Category 1 (0.048mg/L, 23.5Hr/Day) in the inhalation exposure test for 78 weeks in crab-eating macaque ⁷⁾.

Category 1

Hazard statement; Causes damage to respiratory system with long term or repeated exposure.

12. ECOLOGICAL INFORMATION

Information as the mixture is not available.

Aquatic environmental toxicity/Acute phase:

4) Phenol; In crustaceans (Ceriodaphnia quadrangula), 48H LC50=3.1mg/L ¹⁰⁾
(Category 2)

Chloramphenicol; 96H LC50=15-42 µg/L ²⁾ (Category 1)

Component 5) is not classified since estimated value of acute aquatic environmental toxicity with the simple adding method, 22%<25%.

5) Hydrogen peroxide; In crustaceans (Ceriodaphnia quadrangula), 48H
LC50=2.4mg/L ⁴⁾

Disodium hydrogenphosphate 12-water; Information not available.

Citric acid; In algae, 72H LC50=80mg/L ²⁾

Component 6) is not classified since estimated value of acute aquatic environmental toxicity with the simple adding method, 0.85%<25%.

7) Sulfuric acid; In fish (Bluegill), 96H LC50=16-28mg/L ¹¹⁾

Category 3

Hazard statement; Harmful to aquatic life

Aquatic environmental toxicity/Chronical phase:

4) Phenol; Phenol has rapid degradability (85% by BOD) ¹⁹⁾ and is estimated to have small bioaccumulative potential (logKow=1.46) ²⁰⁾

Chloramphenicol; Has rapid degradability ²⁾

Component 4) is not classified.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

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

SYMBOL : C as component 7)

R-phrases : 35 as component 7)

S-phrases : 26-45 as component 7)

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. : =604-001-00-2, =008-003-00-9, =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) Chemwatch 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) CERl·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)

The above information is believed to be correct to be the best of our knowledge and information, but does not purport to be all inclusive and should be used as only a guide. This product is intended to be used by expert persons having chemical knowledge and skill, at their own discretion and risk. Yanaihara institute shall not be held liable for any damages resulting from handling or contact with the above product. Users should determine the suitability of the information for their particular purpose.