

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

Date SDS established : August 8, 2016

Revision number : 1

1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product and components identifier

Catalogue Number	Product Name
WI-4396,WI-43480	AiD™ anti-HIV 1+2 ELISA
WI-44S96,WI-443S480	AiD™ HIV Ag/Ab ELISA ^{Plus}
WB-1296,WB-12480	AiD™ HBsAg ELISA
WC-31S96,WC-31S480	AiD™ anti-HCV ELISA ^{Plus}
WA-1196	HAV- IgM ELISA
WT-5296	Anti-TP (Syphilis) ELISA
WT-1196	TB-IGRA
WE-7196	HEV- IgM ELISA
WE-7296	HEV- IgG ELISA
WE-7596	HEV- Ag ELISA ^{Plus}
WJ-1010	HAV- IgM RAPID TEST
WJ-1910, WJ-1950	Rotavirus - Ag RAPID TEST
WJ-1610, WJ-1650, WJ-1610E, WJ-1650E	Anti-TP (Syphilis) RAPID TEST
WE-1510	HEV- IgM RAPID TEST

Components	Component of (kit)
Positive Controls	All kits
Background Tube	IGRA
Testing Culture Tube	
Positive tubes	
Negative Control	All kits
HRP-Conjugate	All kits
Sample Diluent	HBsAg, HCV, HEV-Ag, HEV-IgG,HEV-IgM, ELISAs
Standard Diluent	IGRA
Specimen diluent	Rotavirus, HEV-IgM, HAV-IgM, Syphilis Rapid Tests
Wash Buffer	All kits
Chromogen A	
Chromogen B	
Stop Solution	
Biotin-Conjugate	HCV ELISA and HIV Ag/Ab ELISA

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test



- 1.2 Relevant identified uses of the substance or mixture and uses advised against:
In vitro diagnostic use
- 1.3 Details of the supplier of the safety data sheet: e-mail address : wtexport@ystwt.com
- 1.4 Emergency telephone number: Call your local emergency centre: +86-10-59528888

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Positive Control Negative Control Background Tube Testing Culture Tube Positive Tube HRP-Conjugate Sample Diluent / Standard Diluent Chromogen A Biotin-Conjugate	Skin Sens. Cat. 1; H317
Chromogen B	Repr. Cat. 1B; H360D

2.2 Label elements

Positive Control Negative Control Background Tube Testing Culture Tube Positive Tube HRP-Conjugate Sample / Standard Diluent Chromogen A Biotin-Conjugate	 Warning H317 P280 P333+P313 P363
Chromogen B	 Danger H360D P201 P280 P308+P313

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

2.3 Other hazards

Chromogen B contains N,N-Dimethylformamide, which is listed on the Candidate List of Substances of Very High Concern for Authorisation (REACH Article 59).

Positive Control, Negative Control, Background Tube, Testing Culture Tube, Positive Tube, HRP-Conjugate, Specimen Diluent contain material of animal origin.

Positive Control and Negative Control contain material of human origin.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Component name	Hazardous ingredient	ID nrs.	Classification	Conc.
Positive Control Negative Control Background Tube Testing Culture Tube Positive Tubes HRP-Conjugate Sample / Standard Diluent Chromogen A Biotin-Conjugate	Mixture* (3:1) CMIT/MIT = 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one	Index: 613-167-00-5 CAS: 55965-84-9	Acute Tox. Cat.3; H301 Acute Tox. Cat.3; H311 Skin Corr. Cat.1B; H314 Skin Sens. 1 ; H317 Acute Tox. Cat.3; H331 Aquatic Acute Cat.1; H400 Aquatic Chronic Cat.1; H410	0.005%
Chromogen B	DMF = N,N-dimethylformamide	Index: 616-001-00-x CAS: 68-12-2 EC: 200-679-5 REACH registration: 01-2119475605-32-XXXX	Acute Tox. Cat.4; H312 Eye Irrit. Cat.2; H319 Acute Tox. Cat.4; H332 Repr. Cat.1B; H360D	0.5%

This CMIT/MIT mixture is a component at 5% of Proclin-300.

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2 Special hazards arising from the substance or mixture:

Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas

5.3 Advice for firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition.

Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

For personal protection see section 8.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Discharge into the environment must be avoided.

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

- 6.3 Methods and material for containment and cleaning up:
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

- 6.4 Reference to other sections
For disposal see section 13.

7 HANDLING AND STORAGE

- 7.1 Precautions for safe handling:
Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.
For precautions see section 2.2.
- 7.2 Conditions for safe storage, including any incompatibilities:
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
- 7.3 Specific end use(s):
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters
Components with workplace control parameters

N,N-Dimethylformamide

Value	Control parameter	Basis	remarks
STEL	10 ppm 30 mg/m ³	UK. EH40 WEL	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.
TWA	5 ppm 15 mg/m ³		
STEL	10 ppm 30 mg/m ³	2009/161/EU amending 2000/39/EC	Identifies the possibility of significant uptake through the skin Indicative
TWA	5 ppm 15 mg/m ³		

- 8.2 Exposure Controls
Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

Personal protective equipment

Eye/face protection

Tightly fitting safety goggles. Faceshield (8-inch minimum).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Positive Control, Negative Control, HRP-Conjugate, Sample / Standard Diluent, Specimen diluent, Wash Buffer, Chromogen A, Chromogen B, Stop Solution and Biotin-Conjugate: all liquid components with very small volume - between 1 and 50 ml

9.2 Other Information

None.

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

10 STABILITY AND REACTIVITY

- 10.1 Reactivity:
No data available
- 10.2 Chemical stability:
Stable under recommended storage conditions
- 10.3 Possibility of hazardous reactions:
No data available
- 10.4 Conditions to avoid:
Heat, flames and sparks.
- 10.5 Incompatible Materials
Strong oxidizing agents, Reducing agents, Amines, Mercaptans
- 10.6 Hazardous decomposition products
Other decomposition products - No data available
In the event of fire: see section 5

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

5% CMIT/MIT in ProClin 300

Acute toxicity

LD50 Oral - Rat - 862 mg/kg
LD50 Dermal - Rabbit - 2,800 mg/kg

Skin corrosion/irritation

Skin - Rabbit
Result: Corrosive

Serious eye damage/eye irritation

Eyes - Rabbit
Result: Corrosive to eyes

Respiratory or skin sensitisation

Guinea pig
Result: May cause sensitisation by skin contact.

Germ cell mutagenicity

No data available

DMF

LD50 Oral - Rat - 2,800 mg/kg
LC50 Inhalation - Rat - 4 h - 9 - 15 mg/l
LD50 Dermal - Rabbit - 1,500 mg/kg

Skin - Human
Result: Mild skin irritation - 24 h

Eyes - Rabbit
Result: Moderate eye irritation

No data available

Mouse lymphocyte
Mutation in mammalian somatic cells.

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

IARC: 3 - Group 3: Not classifiable as to its carcinogenicity to humans (N,N-Dimethylformamide)

Reproductive toxicity

No data available

May cause congenital malformation in the fetus.

Specific target organ toxicity - single exposure

No data available

No data available

Specific target organ toxicity - repeated exposure

No data available

No data available

Aspiration hazard

No data available

No data available

Additional Information

RTECS: Not available

RTECS: Not available

burning sensation, Cough, wheezing, laryngitis, Shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin,

Warning: intolerance for alcohol can occur up to 4 days after dimethylformamide exposure.

N,Ndimethylformamide is considered to be a potent liver toxin., Vomiting, Diarrhoea, Abdominal pain,

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

5% CMIT/MIT in ProClin 300: No data available

DMF :

Toxicity to fish

LC50 - Oncorhynchus mykiss (rainbow trout) - 9,000 - 13,000 mg/l - 96 h

LC50 - Lepomis macrochirus (Bluegill) - 6,700 - 7,500 mg/l - 96 h

LC50 - Pimephales promelas (fathead minnow) - 10,400 - 10,800 mg/l - 96 h

LC50 - Oncorhynchus mykiss (rainbow trout) - 9,800 mg/l - 96 h

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

LC50 - *Lepomis macrochirus* (Bluegill) - 6,300 mg/l - 96 h

LC50 - *Pimephales promelas* (fathead minnow) - 10,600 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 - *Daphnia magna* (Water flea) - 9,600 - 13,100 mg/l - 48 h

EC50 - *Daphnia magna* (Water flea) - 15,700 mg/l - 48 h

Toxicity to algae

LC50 - *Desmodesmus subspicatus* (green algae) - > 500 mg/l - 96 h

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life with long lasting effects.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

14 TRANSPORT INFORMATION

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

-
- 14.1 UN number
Not applicable.
- 14.2 UN Proper shipping name
Not applicable.
- 14.3 Transport hazard class(es)
Not applicable.
- 14.4 Packing group
Not applicable.
- 14.5 Environmental hazards
No.
- 14.6 Special precautions for user
Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable.

15 REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.
DMF: REACH – Listed on Candidate List of Substances of Very High Concern for Authorisation (Article 59).
Toxic for reproduction (article 57c)
- 15.2 Chemical Safety Assessment
For this product a chemical safety assessment was not carried out

16 OTHER INFORMATION

Hazard statements and Precautionary statements referred elsewhere in the safety data sheet:

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
P201	Obtain special instructions before use.

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Global Product Name: Wantai ELISA and Rapid Test

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308-313	IF exposed or concerned: Get medical advice/attention.
P333-313	If skin irritation or rash occurs: Get medical advice/ attention.
P363	Wash contaminated clothing before reuse.

Further information

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

Changes to previous version of the SDS :