

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product Name HHV-6 IgG Antibody ELISA Kit
Catalog Number 15-401-000

1.2 Relevant identified uses of the substance or mixture and uses advised against

SU24 Scientific research and development

1.3 Details of the supplier of the safety data sheet

Manufacturing Supplier Advanced Biotechnologies, Inc
1545 Progress Way
Eldersburg, MD 21784
Telephone (410) 792-9779

1.4 Emergency telephone number

24 Hour Emergency Number ChemTel, Inc 1-800-255-3924

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture**Classification according to Regulation (EC) No 1272/2008**

This product is classified as hazardous according to the Regulation (EC) No 1272/2008 and subsequent amendments.

This product is classified as hazardous according to the Globally Harmonized System (GHS).

This product is classified as hazardous according to OSHA GHS regulations within the U.S.

Skin Irritant (Category 2)

Eye Irritant (Category 2A)

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

Hazard-determining component of labelling Stop Solution - 1N Sulfuric Acid (0.5M)

Hazard Pictograms**Signal Word**

Warning

Hazard statements

H315+H320: Causes skin and eye irritation

Precautionary Statements

P264: Wash hands, forearms, and other exposed areas thoroughly after handling.

P280: Wear protective gloves.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P321: Specific treatment (See Section 4)

P332+P313: If skin irritation occurs: Get medical advice/attention.

P362: Take off contaminated clothing and wash before reuse.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

2.3 Other hazards**Hazards Not Otherwise Classified (HNOC) or covered by GHS**

There are no other hazards not otherwise classified that have been identified. The human plasma controls in this kit have been tested as negative for HBsAg, HIV-1 antigen, and for antibodies to HIV-1, HIV-2 and HCV. However, no test system can ensure the absence of viral antigens. Therefore, handle all human plasma components as potentially biohazardous. Use proper personal protective equipment, appropriate biosafety level laboratory according to the Biosafety in Microbiological and Biomedical Laboratories manual. The local, regional, national and international regulations should be observed when disposing these components.

Safety Data Sheet

Results of PBT and vPvB assessment

PBT	Not applicable
vPvB	Not applicable

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Only ingredient present at a concentration considered hazardous is sulfuric acid (1-3%). For thimerosal (0.01%-0.2%), the hazard classification criteria are not met based on the ATE data. ATE > 2000 mg/kg. For all other chemicals, there are no known health hazards present in concentrations \geq 1% and there are no known carcinogens present in concentrations \geq 0.1%.

Components with Classification		Present in Component	Concentration/Amount
CAS: 7664-93-9 EC No: 231-639-5	1N Sulfuric Acid (0.5M) Synonyms: Sulphuric Acid	Stop Solution	2.72%
CAS: 54-64-8 EC: 200-210-4	Thimerosal	20X Wash Buffer	0.2%
CAS: 54-64-8 EC: 200-210-4	Thimerosal	Specimen Diluent Conjugate Component A Conjugate Component B Positive Control Plasma Negative Control Plasma	0.01%

Additional Kit Components	
CAS: 9005-64-5 EC: 500-018-3	Sorbitan monolaurate, ethoxylated Synonyms: Tween 20
CAS: 10049-21-5 EC: 231-834-5	Dipotassium hydrogenorthophosphate Synonyms: Sodium Phosphate, Monobasic
CAS: 7758-11-4 EC: 231-834-5	Dipotassium hydrogenorthophosphate Synonyms: Potassium Phosphate, Dibasic
CAS: 54827-17-7 EC: 259-364-6	3,3',5,5'-Tetramethylbenzidine (TMB)
CAS: 7558-79-4 EC No: 231-448-7	Sodium Phosphate, Dibasic Synonyms: Disodium hydrogenorthophosphate
CAS: 7778-77-0 EC No: 231-913-4	Potassium Phosphate, Monobasic Synonyms: Potassium dihydrogenorthophosphate
CAS: 7647-14-5 EC No: 231-598-3	Sodium Chloride
CAS: 7447-40-7 EC No: 231-211-8	Potassium Chloride
CAS: N/A EC No: N/A	Positive Control Plasma (Human Plasma)
CAS: N/A EC No: N/A	Negative Control Plasma (Human Plasma)
CAS: N/A EC No: N/A	HHV-6 Antigen Coated ELISA Plate

Safety Data Sheet

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation	Supply fresh air; consult doctor in case of complaints.
After skin contact	Immediately wash with water and soap and rinse thoroughly.
After eye contact	Rinse immediately with plenty of water and seek medical advice.
After swallowing	If swallowed, seek medical advice immediately and show the container/label/SDS.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

To minimize contact, wear a laboratory coat, nitrile or latex gloves, and protective glasses.
Avoid breathing vapors, mist or gas.

6.2 Environmental precautions

Disinfect material before disposal.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material. Disinfect area with 3% hydrogen peroxide followed by 70% isopropyl alcohol.

6.4 Reference to other sections

See Section 7 for Safe Handling. See Section 8 for Exposure Controls. See Section 13 for Disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

This product should be handled in accordance with Good Laboratory Practices and any applicable local guidelines.
Wear appropriate protective equipment (see Section 8). Practice good work hygiene.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature 2-8°C in well-sealed receptacle.

Safety Data Sheet

7.3 Specific end use(s)

Advanced Biotechnologies Inc’s indirect ELISA for Human Herpesvirus-6 IgG antibody detects HHV-6 IgG specific antibodies in human serum or plasma. The test is intended as an aid in the detection of reactivation/reinfection or persistent infection with HHV-6 and can provide serological evidence of previous HHV-6 infection.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

Sulfuric Acid	OSHA PEL	TWA 1mg/m ³
	NIOSH REL	TWA 1mg/m ³
	ACGIH TLV	0.2 mg/m ³ (Thoracic fraction)
Thimerosal (Organomercury)	OSHA PEL	TWA 0.01mg/m ³ Ceiling 0.04mg/m ³
	Cal/OSHA PEL	TWA 0.01mg/m ³ STEL 0.03 mg/m ³ Ceiling 0.04 mg/m ³
	NIOSH REL	TWA 0.01mg/m ³ STEL 0.03mg/m ³ (skin)
	ACGIH TLV	TWA 0.01mg/m ³ STEL 0.03mg/m ³
Sucrose	OSHA PEL	TWA 15mg/m ³ (total) TWA 5mg/m ³ (respirable fraction)
	NIOSH REL	TWA 10mg/m ³ (total) TWA 5mg/m ³ (respirable fraction)

8.2 Exposure controls

Personal protective equipment

General protective/hygienic measures The usual precautionary measures are to be adhered to when handling chemicals and biological material.

Ventilation Work in a biological safety cabinet to reduce the possibility of exposure.

Respiratory protection Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard, if a risk assessment indicates this is necessary.

Protection of hands Protective gloves (i.e. nitrile or equivalent).

Eye protection Safety glasses or safety goggles, as appropriate.

Body protection Protective work clothing and laboratory coats.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance	Form: Liquid Color: Clear, transparent
Odor	Odorless
Odor Threshold	Not determined
pH	Stop Solution: pH ≤ 2 TMB: pH 3.3 – 3.8 Other components: pH 6 - 8
Change in condition	Melting point/Melting range: Not determined Boiling point/Boiling range: Not determined
Flash point	Not applicable
Evaporation rate	Not determined
Flammability (solid, gaseous)	Does not apply, substance is a liquid.
Auto/Self-ignition temperature	Not determined
Decomposition temperature	Not determined
Self-igniting	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
Vapor pressure/density	Not determined
Density	Not determined
Viscosity	Not determined
Solubility in/Miscibility with Water	Soluble

9.2 Other information

No further relevant information available.

Safety Data Sheet

SECTION 10: Stability and reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical stability	Stable under normal conditions of use.
10.3 Possibility of hazardous reactions	All components are stable with no known reactivity, with the exception of Stop Solution, which may have an exothermic reaction with strong bases and reducing agents.
10.4 Conditions to avoid	Store away from reactive materials.
10.5 Incompatible materials	No further relevant information available.
10.6 Hazardous decomposition products	No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects	
Acute toxicity	Sulfuric Acid – Human Inhibitor Concentration 20mmol/L/24hour
LD/LC50 values relevant for classification	ATE > 2000 mg/kg
Primary irritant effect	
Skin corrosion/irritation	Sulfuric Acid – Severe Irritant, Rabbit (250µg or 5mg/30s rinse)
Serious eye damage/irritation	Sulfuric Acid – Severe Irritant, Rabbit (250µg or 5mg/30s rinse)
Respiratory or skin sensitization	Sulfuric Acid – Acute Inhalation Toxicity, (Rat 255 mg/m ³ , 4Hr)
CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Sulfuric Acid – Suspected human carcinogen
Reproductive toxicity	Sulfuric Acid – Developmental Abnormalities, Rabbit (20mg/m ³ /7Hr)
STOT-single exposure	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity	
Aquatic toxicity	Sulfuric Acid - The substance is harmful to aquatic organisms.
12.2 Persistence and degradability	No further relevant information available.
12.3 Bioaccumulative potential	No further relevant information available.
12.4 Mobility in soil	No further relevant information available.
General notes	Avoid release to the environment.
12.5 Results of PBT and vPvB assessment	
PBT	None of the substances present are considered PBT.
vPvB	None of the substances present are considered vPvB.
12.6 Other adverse effects	No further relevant information available.

Safety Data Sheet

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

The user of this product has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state, and federal laws and regulations regarding treatment, storage, and disposal for hazardous and nonhazardous wastes.

Uncleaned packaging recommendation

Disposal must be made according to official regulations.

Recommended cleansing agents

Disinfection with 3% hydrogen peroxide followed by 70% isopropyl alcohol.

SECTION 14: Transport information

14.1 UN number

DOT, ADR, IMDG, IATA

UN2796

14.2 UN proper shipping name

DOT, ADR, IMDG, IATA

Sulfuric acid with 51% or less acid

14.3 Transport hazard class(es)

DOT, ADR, IMDG, IATA Class

Class 8, Corrosive Materials

14.4 Packing group

DOT, ADR, IMDG, IATA

Packing Group II

14.5 Environmental hazards

Marine Pollutant

Mixture Not Classified Marine Pollutant

14.6 Special precautions for user

Not Applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not Applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Unites States (USA)

SARA Section 355 (extremely hazardous substances)

Sulfuric Acid is listed, but present below the CERCLA RQ.

SARA Section 313 (Specific toxic chemical listings)

Sodium Phosphate, Dibasic and Sulfuric Acid listed, but are present below the CERCLA RQ.

Mercury compounds (thimerosal) listed.

TSCA (Toxic Substances Control Act)

All chemicals are listed.

Proposition 65 (California)

Mercury compounds (thimerosal) listed.

Sulfuric Acid listed.

Chemicals known to cause Cancer

Mercury compounds (thimerosal) listed.

Chemicals known to cause rep. toxicity for females

Mercury compounds (thimerosal) listed.

Chemicals known to cause developmental toxicity

Mercury compounds (thimerosal) listed.

Carcinogenic Categories

EPA

Mercury compounds (thimerosal) listed.

IARC

Mercury compounds (thimerosal) listed

Sulfuric Acid listed.

NIOSH-Ca

Mercury compounds (thimerosal) listed.

Sulfuric Acid listed.

Sucrose listed.

Canada - Canadian Domestic Substances List (DSL)

All chemicals are listed.

Other regulations, limitations and prohibitive regulations

Seveso III Directive (2012/18/EU)

None of the ingredients are listed.

Substances of very high concern (SVHC)

None of the ingredients are listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Safety Data Sheet

SECTION 16: Other information

Disclaimer

The above information is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide. Advanced Biotechnologies, Inc. shall not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DOT: US Department of Transportation

EPA: Environmental Protection Agency

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IARC: International Agency for Research on Cancer

IMDG: International Maritime Code for Dangerous Goods

LC50/LD50: Lethal concentration, 50 percent/Lethal dose, 50 percent

OSHA: Occupational Safety and Health Administration

PBT/vPvB: Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative

PEL/REL: Permissible Exposure Limit/Recommended Exposure Limit

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006)

SARA: Superfund Amendments and Reauthorization Act

STOT: Specific Target Organ Toxicity

SVHC: Candidate List of Substances of Very High Concern

TWA: Time Weighted Average

WEEL: Workplace Environmental Exposure Levels

Date of Preparation

The effective date in the header of this document is the date of preparation and/or last revision.