According to 91/155 EC DHT ELISA Kit (IB59116)

Version: 2.0 Effective: December 3, 2007 Page 1 of 9

1. Data on Components

Regarding components in the kit, the following products are defined as hazardous chemicals according to the Directive 67/548/EEC.

Accordingly, Material Safety Data Sheets for the following chemicals are enclosed:

2-Methyl-2H-isothiazol-3-one: At a final concentration from 0.001-0.05% is used as a preservative in the following components of the kit: *Calibrators and Control, HRP Conjugate Concentrate, Assay Buffer and Wash Buffer Concentrate.* **Sulfuric Acid**: At a final concentration of 5% (v/v) is used in the *Stopping Solution.* **TMB Substrate**

2. General Information

The information contained in this document is believed to be correct, however, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. IBL-America shall not be liable for any damages resulting from handling or from contact with the above products.

Section 1- Identification of Substance

Calibra HRP-0 Assay	ELISA Kit (IB59116) Lators and Control Conjugate Concentrate Buffer Buffer Concentrate				
8201 (Minne Tel/Fa E-mail	Immuno-Biological Laboratories, Inc. (IBL-America) 8201 Central Avenue NE, Suite P Minneapolis, MN 55432 Tel/Fax: (888) 523-1246 / (763) 780-2988 E-mail: info@ibl-america.com Internet: www.ibl-america.com				
Section 2	2 - Data on Compor	nents			
Chemical Characterization: Preparation Description: Mixture of substances listed below with non	hazardous additions				
Hazardous Ingredients	%	CAS Number	EC Number		
2-Methyl-2H-isothiazol-3-one	0.001-0.05%	2682-20-4	220-239-6	-	
		С; R34-F	243		
Section	3 - Hazard Identifica	ation			
Hazard Description: C Corrosive Information concerning to particular hazards to man skin contact. Classification System: The classification is according to data. Section General Information: No special measures required. After Inhalation: Supply fresh air; consult doctor in case After Skin Contact: Wash off with soap and plenty of wa After Eye Contact: Rinse opened eye for several minute After Ingestion: If symptoms persist consult doctor.	the latest editions of the 4 - First Aid Measu of complaints. ter.	EU-lists, and extende		-	

Version: 2.0 Effective: December 3, 2007 Page 2 of 9

Section 5 - Fire Fighting Measures	
Suitable Extinguishing Agents: CO ₂ powder or water spray. Fight larger fires with water spray or alcohol resistant Protective Equipment: No special measures required.	foam.
Section 6 - Accidental Release Measures	
Person-Related Safety Precautions: Not required. Measures for Environmental Protection: Dilute with plenty of water. Do not allow to enter sewers / surface or grou Measures for Cleaning/Collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal bin Additional Information: No dangerous substances are released.	
Section 7 - Handling and Storage	
Handling: Information for Safe Handling: Avoid contact with skin and eyes. Information for Fire and Explosion Protection: No special measures required.	
Storage: Requirements to be met by Storerooms and Receptacles: No special requirements. Information About Storage in One Common Storage Facility: Not required. Further Information About Storage Conditions: None.	
Storage Class: Class According to Regulation on Flammable Liquids: Void.	
Section 8 - Exposure Controls and Personal Protection Gear	
Additional Information About Design of Technical Facilities: No further data; see item 7. Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any rele materials with critical values that have to be monitored at the workplace. Additional Information: The lists valid during the making were used as the basis.	evant quantities of
Personal Protective Equipment: General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handli Respiratory Protection: Not required. Protection of Hands: Protective gloves. Eye Protection: Goggles recommended during refilling.	ng chemicals.
Section 9 - Physical and Chemical Properties	
Form: Liquid Colour: Colourless Odour: Odourless Change in Condition Melting Point/Melting Range: Undetermined Boiling Point/Boiling Range: Undetermined Flash Point: Not applicable Self-Igniting: Product is not self-igniting. Danger of Explosion: Product does not present an explosion hazard Density: Undetermined Solubility in/Miscibility With: Water: Fully miscible	

According to 91/155 EC DHT ELISA Kit (IB59116)

Version: 2.0 Effective: December 3, 2007 Page 3 of 9

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect: On the Skin: No irritant effect.

On the Eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Section 12 - Ecological Information

General Notes: Generally not hazardous for water.

Section 13 - Disposal Considerations

Product:

Recommendation: Smaller quantities can be disposed of with household water.

Uncleaned Packaging:

Recommended Cleansing Agents: Water, if necessary together with cleansing agents. Section 14 - Transport Information

Special Shipping Information: Does not constitute a hazard.

Section 15 - Regulations

Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives.

Section 16 - Other Information

Text of R phrases listed in section 2:

R 34 - Causes burns.

R 43 – May cause sensitization by skin contact.

This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Prepared By: QA Department (QMR)

Version: 2.0 Effective: December 3, 2007 Page 4 of 9

Section 1- Ident	ification of Su	ubstance
Product Identification:		
DHT ELISA Stopping Sc	Kit (IB59116) Solution	
Supplier Information:		
Immuno-Bic 8201 Centra Minneapolis Tel/Fax: (88 E-mail: info	ological Laboratorie al Avenue NE, Suit 5, MN 55432 8) 523-1246 / (76 @ibl-america.com w.ibl-america.com	63) 780-2988
Section 2 - D	ata on Compo	onents
Chemical Characterization: Preparation		
Description: Mixture of substances listed below with nonhazar		
Hazardous Ingredients	%	CAS Number EC Number
Sulfuric Acid	5%	7664-93-9 N/A
		C; R35
Section 3 - H	azard Identifi	cation
		cation
Hazard Description: C Corrosive Information concerning to particular hazards to man and e Classification System: The classification is according to the la data. Section 4 - I General Information: Immediately remove any clothing contar After Inhalation: In case of unconsciousness place patient sta After Skin Contact: Immediately wash with water and soap an After Eye Contact: Rinse opened eye for several minutes und	atest editions of the First Aid Meas ninated by the pro bly in side positior d rinse thoroughly	e EU-lists, and extended by company and literature sures duct. n for transportation.
After Ingestion: <u>Do not</u> induce vomiting. Drink plenty of water	and provide fresh	air. Call for a doctor immediately.
Section 5 - Fir	e Fighting Me	easures
Suitable Extinguishing Agents: CO ₂ , powder or water spray. Protective Equipment: No special measures required.	Fight larger fires v	with water spray or alcohol resistant foam.
Section 6 - Accid	ental Release	Measures
Person-Related Safety Precautions: Wear protective equipm Measures for Environmental Protection: Do not allow to enter Measures for Cleaning/Collecting: Absorb with liquid-binding Use neutralizing agent. Dispose contaminated material as wast	er sewers / surface material (sand, di	e or ground water. Dilute with plenty of water. iatomite, acid binders, universal binders, sawdust).

According to 91/155 EC DHT ELISA Kit (IB59116)

Version: 2.0 Effective: December 3, 2007 Page 5 of 9

Section 7 - Handling and Storage

Handling:

Information for Safe Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Keep container tightly closed. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Information for Fire and Explosion Protection: No special measures required.

Storage:

Requirements to be met by Storerooms and Receptacles: No special requirements. Information About Storage in One Common Storage Facility: Not required. Further Information About Storage Conditions: Keep receptacle tightly sealed.

Storage Class:

Class According to Regulation on Flammable Liquids: Void.

Section 8 - Exposure Controls and Personal Protection Gear

Additional Information About Design of Technical Facilities: No further data; see item 7. Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. Additional Information: The lists valid during the making were used as the basis. **Personal Protective Equipment:** General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with eyes and skin. Respiratory Protection: Not required. Protection of Hands: Protective and resistant gloves. Eye Protection: Tightly sealed goggles Section 9 - Physical and Chemical Properties Form: Liquid Colour: Colourless Odour: Odourless **Change in Condition** Melting Point/Melting Range: Undetermined Boiling Point/Boiling Range: Undetermined Flash Point: Not applicable Self-Igniting: Product is not self-igniting. Danger of Explosion: Product does not present an explosion hazard **Density:** Undetermined Solubility in/Miscibility With: Water: Fully miscible pH value at 20°C: <1 Section 10 - Stability and Reactivity Thermal Decomposition/Conditions to be Avoided: No decomposition if used according to specifications. Dangerous Reaction: No dangerous reactions known. Incompatibilities (Concentrated Sulfuric Acid): Avoid contact with alkaline solutions, metals, metal powders, chlorates, nitrates,

strong oxidizing or reducing materials, combustible organic materials and excess heat. **Dangerous Decomposition Products (Concentrated Sulfuric Acid):** Toxic fumes of oxides of sulfur when heated to decomposition. Will react with water or steam to produce toxic and corrosive fumes. Reacts with carbonates to generate carbon dioxide gas, and with cyanides and sulfides to from poisonous hydrogen cyanide and hydrogen sulfide, respectively.

Section 11 - Toxicological Information

Acute Toxicity

Primary Irritant Effect:

On the Skin: Caustic effect on skin and mucous membranes.

On the Eye: Strong caustic effect.

Sensitization: No sensitizing effects known.

Additional Toxicological Information: The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: Corrosive. Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

Version: 2.0 Effective: December 3, 2007 Page 6 of 9

Section 12 - Ecological Information
General Notes: Hazardous for water. Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted or unneutralized. Danger to drinking water even if small quantities leak into the ground.
Section 13 - Disposal Considerations
Product: Recommendation: Smaller quantities can be disposed of with household water.
Uncleaned Packaging: Recommended Cleansing Agents: Water, if necessary together with cleansing agents.
Section 14 - Transport Information
Special Shipping Information: Does not constitute a hazard.
Section 15 - Regulations
Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product has been classified and marked according to EC Directives. Code Letter and Hazard Designation of Product: C Corrosive Risk Phrases: R 34 – Causes burns. Safety Phrases: S 26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 36/37/39 – Wear suitable protective clothing, gloves and eye/face protection.
S 45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S 60 – This material and its container must be disposed of as hazardous waste.
Section 16 - Other Information
This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
Prepared By: QA Department (QMR)

Version: 2.0 Effective: December 3, 2007 Page 7 of 9

	Section 1- Identification of Substance
Product Identification:	DHT ELISA Kit (IB59116) <i>TMB Substrate</i>
Supplier Information:	Immuno-Biological Laboratories, Inc. (IBL-America) 8201 Central Avenue NE, Suite P Minneapolis, MN 55432 Tel/Fax: (888) 523-1246 / (763) 780-2988 E-mail: info@ibl-america.com Internet: www.ibl-america.com
	Section 2 - Data on Components
Chemical Characterization: Prepara Description: Mixture of substances lis Hazardous Ingredients: Void.	sted below with nonhazardous additions.
	Section 3 - Hazard Identification
	ar hazards to man and environment: N/A ation is according to the latest editions of the EU-lists, and extended by company and literature
	Section 4 - First Aid Measures
After Inhalation: Remove the expose After Skin Contact: Remove contami noted. After Eye Contact: Immediately flush	move any clothing contaminated by the product. ed person to fresh air and support breathing, if necessary. Obtain medical attention. inated clothing and wash effected skin with soap and water. Seek medical attention if irritation is neves thoroughly with fresh water. Remove contact lenses, if any, and seek medical attention. nediately provided that person is conscious. Obtain medical attention.
	Section 5 - Fire Fighting Measures
	² powder or water spray. Fight larger fires with water spray or alcohol resistant foam. tained breathing apparatus and protective clothing to prevent contact with skin and eyes.
	Section 6 - Accidental Release Measures
Measures for Environmental Protect	: Wear suitable protective equipment to prevent inhalation and skin or eye contact. ction: No special measures required. Clean up small spills with a sponge or mop and water. Larger volumes can be absorbed with

According to 91/155 EC DHT ELISA Kit (IB59116)

Version: 2.0 Effective: December 3, 2007 Page 8 of 9

Section 7 - Handling and Storage

Handling:

Information for Safe Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Keep container tightly closed. Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Information for Fire and Explosion Protection: No special measures required.

Storage:

Requirements to be met by Storerooms and Receptacles: Store refrigerated (~4-8°C) in a dry, well-ventilated area away from incompatible substances (see section 10). Protect from exposure to sunlight. Information About Storage in One Common Storage Facility: Not required. Further Information About Storage Conditions: None.

Storage Class:

Class According to Regulation on Flammable Liquids: Void.

Section 8 - Exposure Controls and Personal Protection Gear

Additional Information About Design of Technical Facilities: No further data; see item 7. Ingredients with Limit Values that Require Monitoring at the Workplace: The products does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. Additional Information: The lists valid during the making were used as the basis.

Personal Protective Equipment:

General Protective and Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Avoid contact with eyes and skin.

Respiratory Protection: Not required.

Protection of Hands: Protective gloves.

Eye Protection: Goggles recommended during refilling.

Section 9 - Physical and Chemical Properties

Form: Liquid Colour: Colourless Odour: Odourless Change in Condition Melting Point/Melting Range: N/A Boiling Point/Boiling Range: 81°C Flash Point: 187°F (Closed cup) Self-Igniting: Product is not self-igniting. Danger of Explosion: Product does not present an explosion hazard Density: Undetermined Solubility in/Miscibility With: Water: Fully miscible pH value at 20°C: Undetermined

Section 10 – Stability and Reactivity

Thermal Decomposition: During heating, carbon monoxide and nitrogen oxides may be produced. **Incompatibilities:** Avoid contact with strong oxidizing agents. Protect from exposure to sunlight. **Dangerous Decomposition Products:** Toxic fumes of oxides of carbon monoxide and nitrogen oxide.

Section 11 - Toxicological Information

Acute Toxicity Primary Irritant Effect: On the Skin: Irritant to mucous membranes. On the Eye: Irritant. Sensitization: No sensitizing effects known. Additional Toxicological Information: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Version: 2.0 Effective: December 3, 2007 Page 9 of 9

Section 12 - Ecological Information			
General Notes: Slightly hazardous for water. Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted.			
Section 13 - Disposal Considerations			
Product: Recommendation: Smaller quantities can be disposed of with household water. Uncleaned Packaging: Recommended Cleansing Agents: Water, if necessary together with cleansing agents. Section 14 - Transport Information Special Shipping Information: Does not constitute a hazard.			
Section 15 - Regulations			
Labelling According to European Labelling Guidelines: Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EC Directives. Safety Phrases: S 60 – This material and its container must be disposed of as hazardous waste.			

Section 16 - Other Information

This information is prepared based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Prepared By: QA Department (QMR)