

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Union REACH regulations



1. PRODUCT IDENTIFICATION

<u>Trade Name (As Labeled):</u>	F550 CHO 3G HCP ELISA Kit
<u>Product Use:</u>	Regulations require HCPs to be reduced to the lowest levels possible. This generic ELISA kit is useful in both process development and process validation.
<u>U.N. Number:</u>	Not applicable
<u>U.N. Dangerous Goods Class:</u>	Non-regulated
<u>Manufacturer's Name:</u>	Cygnus Technologies, Inc.
<u>Address:</u>	4701 Southport Supply Rd SE Suite 7 Southport, NC 28461 USA
<u>Emergency Phone:</u>	910-454-9442 (Emergency contact)
<u>Business Phone:</u>	910-454-9442 (Product information)
<u>Date of Preparation:</u>	7/5/2011
<u>Date of Last Revision:</u>	1/28/2011
<u>Document #:</u>	600-550
<u>Revision #:</u>	D

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Product Description: This kit contains 6 components making up the F550 CHO 3G HCP ELISA kit. This product is used in laboratories to determine the presence of HCP contamination in products manufactured by expression in the CHO cell line. The kit contains a Conjugate, Coated Plate, Standards, Stop Solution, TMB Substrate and Wash Concentrate. **Health Hazards:** Possible skin and eye irritant. **Flammability Hazards:** Non-flammable solution. **Reactivity Hazards:** None known. **Environmental Hazards:** Not expected to have significant environmental effects. **Emergency Considerations:** Emergency responders must wear the proper personal protective equipment (and have appropriate fire-suppression equipment) suitable for the situation to which they are responding.

EU LABELING AND CLASSIFICATION:

EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION: This product does not meet the definition of any hazard class, as defined by the European Union Council Directives 67/548/EEC and 1999/445/EC and subsequent Directives.

EU CLASSIFICATION:

Classification: [Xi] Irritant

Risk Phrases: R36/38: Irritating to eyes and skin.

Safety Phrases: S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Annex II Hazard Symbol:



HEALTH HAZARDS OR RISKS FROM EXPOSURE:

Acute	Prolonged contact with the components in this kit may irritate the skin. Contact with eyes may cause irritation or redness. This product is to be used in a laboratory environment. Individuals using this product should be wearing the proper personal protective equipment to prevent skin and eye contact.
Chronic	None known

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3. COMPOSITION AND INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS: CONJUGATE: ANTI-CHO HCP: HORSERADISH PEROXIDASE, CAT#F551 – 12 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>97%	Hazard Classification: Not Classified Risk Phrases: None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	1-2%	Hazard Classification: Not Classified Risk Phrases: None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	<1.0%	Hazard Classification: Irritant Risk Phrases: R36/38
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Hazard Classification: Irritant Risk Phrases: R36/38
HAZARDOUS INGREDIENTS: PLATE: ANTI- CHO COATED MICROTITER PLATE, CAT#F552	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
Affinity Purified Goat Antibody to CHO HCP	Not Listed	Not Listed	Not Established	<200 µg/mL	Hazard Classification: Not Classified Risk Phrases: None
HAZARDOUS INGREDIENTS: STANDARDS: CHO HCP STANDARDS, CAT#F553, 1 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>97%	Hazard Classification: Not Classified Risk Phrases: None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	<1.0%	Hazard Classification: Not Classified Risk Phrases: None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	<1.0%	Hazard Classification: Irritant Risk Phrases: R36/38
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Hazard Classification: Irritant Risk Phrases: R36/38
HAZARDOUS INGREDIENTS: STOP SOLUTION, CAT#F006, 12 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>92%	Hazard Classification: Not Classified Risk Phrases: None
Sulfuric Acid	7764-93-9	231-639-5	0362	1-3%	Hazard Classification: Irritant Risk Phrases: R36/38
HAZARDOUS INGREDIENTS: TMB SUBSTRATE, CAT#F005 – 12mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
TMB Substrate	Aqueous Mixture	Not Listed	Not Listed	12 mL	Hazard Classification: Irritant Risk Phrases: R36/38
HAZARDOUS INGREDIENTS: WASH CONCENTRATE, CAT#F004, 50 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Risk Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>85%	Hazard Classification: Not Classified Risk Phrases: None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	6-8%	Hazard Classification: Not Classified Risk Phrases: None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	7-9%	Hazard Classification: Not Classified Risk Phrases: None
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Hazard Classification: Irritant Risk Phrases: R36/38
Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens)					Hazard Classification: Not Classified Risk Phrases: None
ProClin is a registered trademark of Rohm and Hass Company.					

Note: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

See Section 2 for full text of Ingredient Risk Phrases and Safety Phrases

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4. FIRST-AID MEASURES

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to health professional with contaminated individual.

EYE CONTACT: If chemical contacts the eyes, open victim's eyes while under gentle running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. Remove contact lenses, if worn. Seek medical attention if irritation persists.

SKIN CONTACT: Wash contacted area with soap and water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if irritation develops and persists.

INHALATION: Not a normal route of entry, however if chemical is inhaled, or breathing is difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If chemical is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, have convulsions, or who cannot swallow. Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and MSDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Non-flammable

AUTOIGNITION TEMPERATURE: Not applicable

FLAMMABLE LIMITS (in air by volume, %): Lower N/A Upper N/A

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

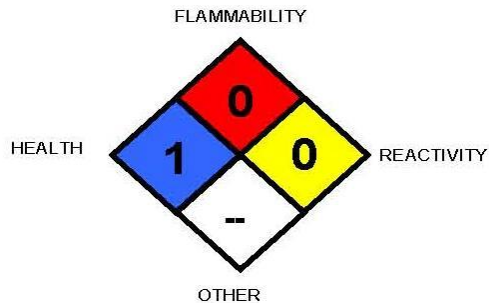
UNUSUAL FIRE AND EXPLOSION HAZARDS: The product is a water-based mixture with no known fire or explosion hazards.

EXPLOSION SENSITIVITY TO MECHANICAL IMPACT: Not sensitive

EXPLOSION SENSITIVITY TO STATIC DISCHARGE: Not sensitive

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING



Hazard Scale: 0 = Minimal 1 = Slight
2 = Moderate
3 = Serious 4 = Severe

6. ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE: Proper protective equipment should be used. Personnel should be trained for spill response operations.

Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Absorb spilled material using polypads or other suitable absorbent material. Place all spill residue in an appropriate container and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations.)

7. HANDLING AND STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing mists or sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

STORAGE AND HANDLING PRACTICES: Store product in properly labeled, closed containers at temperatures between 2-8°C. Protect from physical damage. Keep containers closed when not in use.

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8. EXPOSURE CONTROLS – PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the established limits.

Currently, International exposure limits are not established for all the components of this product. Please check with competent authority in each country for the most recent limits in place.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection,) and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: If exposure limits are exceeded, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134,) equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION: Splash goggles or safety glasses with side shields recommended. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

HAND PROTECTION: Compatible protective gloves recommended. Wash hands after removing gloves. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

BODY PROTECTION: Use body protection appropriate for task. Coveralls, rubber aprons, or chemical protective clothing made from natural rubber are generally acceptable, depending upon the task. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

9. PHYSICAL and CHEMICAL PROPERTIES

VAPOR DENSITY: N/A

SPECIFIC GRAVITY @ 20°C: No Data (water=1)

VAPOR PRESSURE: No Data @20°C

APPEARANCE, ODOR and COLOR: This product contains both clear and colored liquids with a varying mild odor.

EVAPORATION RATE (n-BuAc=1): N/A

SOLUBILITY IN WATER: Soluble

pH: Not Established

10. STABILITY AND REACTIVITY

STABILITY: Stable under ordinary conditions of use and storage.

DECOMPOSITION PRODUCTS: When stored as labeled, no known hazardous decomposition products are formed during the shelf life of this product.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: No information available

HAZARDOUS DEPOLYMERIZATION: Will not occur

CONDITIONS TO AVOID: Temperatures above or below the recommended range of 2-8°C

11. TOXICOLOGICAL INFORMATION

TOXICITY DATA: No data available

SUSPECTED CANCER AGENT: The components of this product are not listed by agencies tracking the carcinogenic potential of chemical compounds as follows:

Carcinogenity

NTP Regulated – No

IARC Regulated – No

OSHA Regulated – No

IRRITANCY OF PRODUCT: None known

SENSITIZATION TO THE PRODUCT: This product is not known to cause human skin or respiratory sensitization.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system.

Mutagenicity – The components of this product are not reported to produce mutagenic effects in humans.

Embryotoxicity – The components of this product are not reported to produce embryotoxic effects in humans.

Teratogenicity – The components of this product are not reported to produce teratogenic effects in humans.

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Reproductive Toxicity – The components of this kit are not reported to produce reproductive effects in humans.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION

ENVIRONMENTAL FATE: No data available

ENVIRONMENTAL TOXICITY: No data available

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Members States and Japan.

14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

DOT Classification Non-regulated material

DOT Labeling Requirements None

IATA Labeling Requirements None

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

SARA REPORTING REQUIREMENTS None

MARINE POLLUTANT This product contains no component listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.

TSCA All components in this product mixture are listed on the USA Toxic Substances Control Act (TSCA) inventory of chemicals or are exempt from listing.

SARA 311/312: Acute health: Yes; Chronic health: No; Fire: No; Reactivity: No

U.S. CERCLA REPORTABLE QUANTITY (RQ): None

U.S. TSCA INVENTORY STATUS – All of the components of this product are listed in the TSCA Inventory or exempt.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): This product does not contain any component above the 0.1% level which is listed as a California Proposition 65 chemical. Note the chemical identity of some or all components present is confidential business information (trade secret) and is being withheld as permitted by 29CFR1910.1200 (i).

CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: All of the components of this product are on the DSL Inventory or exempt.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the CEPA First Priorities Substance Lists.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Not regulated

EUROPEAN ECONOMIC COMMUNITY INFORMATION:

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EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION: This product does not meet the definition of any hazard class, as defined by the European Union Council Directives 67/548/EEC and 1999/445/EC and subsequent Directives. For information on classification under CLP Regulation (EC) 1271/2008, please refer to section 16 (Other Information.)

Classification – [Xi] Irritant

Risk Phrases –R36/38: Irritating to eyes and skin.

Safety Phrases – S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Annex II Hazard Symbol –



AUSTRALIAN INFORMATION FOR PRODUCT:

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) STATUS: All components of this product are listed on the AICS or exempt.

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS: Not applicable

JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS: The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

INTERNATIONAL CHEMICAL INVENTORIES:

Listing of the components on individual country Chemical Inventories is as follows:

Asia-Pac – Listed or exempt

Australian Inventory of Chemical Substances (AICS) – Listed or exempt

Korean Existing Chemicals List (ECL) – Listed or exempt

Japanese Existing National Inventory of Chemical Substances (ENCS) – Listed or exempt

Philippines Inventory of Chemicals and Chemicals Substances (PICCS) – Listed or exempt

Swiss Giftlist List of Toxic Substances - Listed or exempt

U.S. TSCA - Listed or exempt

16. OTHER INFORMATION

Prepared By: Brian Neal

Date: January 28, 2011

All chemicals may pose unknown hazards and should be used with cautions. This Material Safety Data Sheet (MSDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this MSDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this MSDS is based on technical data judged to be reliable, *Cygnus Technologies, Inc.* assumes no responsibility for the completeness or accuracy of the information contained herein. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers and protection of the environment.

End of MSDS Sheet