

Page 1 of 5

Doc. No.: CYG-LBL-00139

Safety Data Sheet:

IM Reagent

1. PRODUCT IDENTIFICATION

1.1 PRODUCT IDENTIFIERS:

Product Catalog Number:	Product Description:
IM103	Conjugate Diluent

1.2 RELEVANT IDENTIFIED USES:

Product Use: Used in Immunogenicity Kits.

1.3. DETAILS OF THE SUPPLIER OF THE SDS:

Manufacturer's Name:

Cygnus Technologies, LLC 4332 Southport Supply Rd SE Address: Southport, NC 28461 USA

1.4. EMERGENCY TELEPHONE NUMBER:

Emergency Phone: 910-454-9442 (Emergency contact)

Monday-Friday 8:30am-5:00pm

Business Phone: 910-454-9442 (Product information)

2. HAZARD IDENTIFICATION

2.1. CLASSIFICATION OF SUBSTANCE OR MIXTURE:

Classification of the substance of mixture:

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS):

H317 Skin Sensitization (Category 1)

2.2. LABEL ELEMENTS:

GHS Label Elements

Exclamation Mark Pictogram:



Signal Word: Warning

Hazard Statement(s): H317 May cause allergic skin reaction.

Prevention: P261 Avoid Breathing dust/fume/gas/mist/vapors/spray.

> P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response: P302+P352 If on skin: Wash with plenty of soap and water

> P333+P313 If skin irritation or rash occurs: Get medical advice/attention P321 Specific treatment (See supplemental first aid instruction on this label).

P363 Wash contaminated clothing before reuse.

P501 Dispose of contents/container to an approved waste disposal plant. Disposal:

2.3. OTHER HAZARDS: No other hazards known.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1. SUBSTANCE: N/A

3.2. MIXTURE:

HAZARDOUS INGREDIENTS:	CAS#	EINECS#	ICSC#	Amount	Hazard Classification	Hazard Code	
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	0.1% ($\leq 0.005\%$ active ingredient)	Skin Sens. 1	H317	
Each of the other components present is nonhazardous or less than the 1 percent concentration cut off limits (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens)					Not Classified	None	
ProClin® 300 is a registered trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow.							

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 SDS 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.



4. FIRST-AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES:

General Advice: Seek medical attention. Show SDS

EYE CONTACT: Open victim's eyes while under gentle running water. Use sufficient force to open eyelids. Have victim "roll" eyes, flush for a minimum of 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: If breathed in, move victim to fresh air. If not breathing, give artificial respiration. Seek medical attention.

INGESTION: If swallowed, call physician or poison control center for most current information. Do not induce vomiting. Rinse mouth. Take a copy of the label and SDS with the victim to the health professional.

- 4.2. MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED: See section 2 and/or 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**: Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- **5.2. SPECIFIC HAZARDS ARISING FROM THE MIXTURE**: No data available.
- **5.3. ADVICE FOR FIREFIGHTERS:**

<u>SPECIAL PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIRE-FIGHTERS:</u> Wear self contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Proper protective equipment should be used. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas Personnel should be trained for spill response operations.

6.2. ENVIRONMENTAL PRECAUTIONS: N/A

6.3. METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP: Trained personnel following pre-planned procedures should handle non-incidental 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.)

6.4 REFERENCE TO OTHER SECTIONS: For disposal see section 13.

7. HANDLING AND STORAGE

- **7.1. PRECAUTIONS FOR SAFE HANDLING**: Avoid getting the mixture ON YOU or IN YOU. Wash thoroughly after handling. Do not eat, drink, smoke, or apply cosmetics while using the mixture. Avoid breathing mists or sprays generated by the mixture. Use in a well-ventilated location. Remove contaminated clothing immediately.
- **7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**: Store product in properly labeled, closed containers. Protect from physical damage. Keep containers closed when not in use. No incompatibilities known.

8. EXPOSURE CONTROLS – PERSONAL PROTECTION

8.1. CONTROL PARAMETERS: Contains no substances with occupational exposure limit values. Please check with competent authority in each country for the most recent limits in place.

8.2. EXPOSURE CONTROLS:

8.2.1. APPROPRIATE ENGINEERING CONTROLS: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday. Use with adequate ventilation to ensure exposure levels are maintained below the established limits.

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.

8.2.2. PERSONAL PROTECTION EQUIPMENT:

RESPIRATORY PROTECTION: 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.



Page 3 of 5

Doc. No.: CYG-LBL-00139

Safety Data
Sheet:

IM Reagent

EYE PROTECTION: Tightly fitting safety 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.

SKIN PROTECTION: Compatible protective gloves recommended. Use proper glove removal technique and ensure outside of glove is not touched. 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. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. described in U.S. OSHA 29 CFR 1910.136.

8.2.3. ENVIRONMENTAL EXPOSURE CONTROLS: N/A

9. PHYSICAL and CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

No data available **ODOR:** APPEARANCE/COLOR: No data available **ODOR THRESHOLD:** No data available **PH**: No data available MELTING POINT/FREEZING POINT: No data available INITIAL BOILING POINT/RANGE: No data available **FLASH POINT:** No data available **EVAPORATION RATE** (n-BuAc=1): No data available No data available UPPER/LOWER FLAMMABILITY/ No data available FLAMMABILITY (SOLID/GAS): **EXPLOSIVE LIMITS:**

VAPOR PRESSURE: No data available **VAPOR DENSITY:** No data available **RELATIVE DENSITY:** No data available WATER SOLUBILITY: No data available PARTITION COEFFICIENT:n-octanol/water: No data available **AUTO-IGNITION TEMPERATURE:** No data available **DECOMPOSITION TEMPERATURE:** No data available **VISCOSITY:** No data available **EXPLOSIVE PROPERTIES:** No data available **OXIDIZING PROPERTIES:** No data available

9.2. OTHER SAFETY INFORMATION: No data available

10. STABILITY AND REACTIVITY

10.1. REACTIVITY: No data available.

10.2. CHEMICAL STABILTY: Stable under recommended storage conditions.

10.3. POSSIBLE OF HAZARDOUS REACTIONS:No data available.10.4. CONDITIONS TO AVOID:No data available.10.5. INCOMPATIBLE MATERIALS:No data available.10.6. HAZARDOUS DECOMPOSITION PRODUCTS:No data available.

11. TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON LIKELY ROUTES OF EXPOSURE: See Section 4

SYMPTOMS RELATED TO THE PHYSICAL, CHEMICAL AND TOXICOLOGICAL CHARACTERISTICS: See Section 4.

DELAYED AND IMMEDIATE EFFECTS AND ALSO CHRONIC EFFECTS FROM SHORT AND LONG TERM EXPOSURE:

Irritancy of product: None known.

<u>Sensitization to the product</u>: 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.

<u>Mutagenicity</u> – 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.

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

NUMERICAL MEASURES OF TOXICITY: None known

CARCINOGENICITY

NTP Regulated - No

IARC Regulated - No

OSHA Regulated - No

ACGIH Regulated - No

610-REAGENTS1

CYG-LBL-00139 Rev: 01 Eff: 04 Dec 2020



Page **4** of **5**

Doc. No.: CYG-LBL-00139

Safety Data
Sheet:

IM Reagent

12. ECOLOGICAL INFORMATION

12.1. TOXICITY: No data available.

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. 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

<u>13.1. PREPARING WASTES FOR DISPOSAL:</u> 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

14.1. US DOT, IATA, IMO, ADR:

DOT Classification Non-regulated material.

DOT Labeling Requirements None.

IATA Labeling Requirements None.

<u>U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS</u>: 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.

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

<u>INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION</u>: 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

15.1. 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: No; Chronic health: No; Fire: No; Reactivity: No

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

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

<u>CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65)</u>: 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:

<u>CANADIAN DSL/NDSL INVENTORY STAUS</u>: All of the components of this product are on the DSL Inventory or exempt.

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

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Not regulated

EUROPEAN ECONOMIC COMMUNITY INFORMATION:

<u>EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION</u>: 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.)

<u>Classification</u> – R43 May cause sensitization by skin contact <u>Risk Phrases</u> –R43 May cause sensitization by skin contact Safety Phrases – S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Salety Fillases – \$20. In case of contact with eyes, thise infinitediately with plenty of water and seek medical advic

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

<u>Japanese Existing National Inventory of Chemical Substances (ENCS)</u> – Listed or exempt

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

Swiss Giftliste List of Toxic Substances - Listed or exempt

U.S. TSCA - Listed or exempt

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3 H317 Skin Sensitization (Category 1)

Prepared By: Yvonne Fenrich

Date: 03DEC2020

All chemicals may pose unknown hazards and should be used with cautions. This Safety Data Sheet (SDS) 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 SDS. 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 SDS is based on technical data judged to be reliable, *Cygnus Technologies*, *LLC* 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 SDS Sheet