The University *of* Western Ontario
BIOLOGICAL AGENTS REGISTRY FORM
Approved Biohazards Subcommittee: October 14, 2011
Biosafety Website: www.uwo.ca/humanresources/biosafety/

This form must be completed by each Principal Investigator holding a grant administered by the University of Western Ontario (UWO) or in charge of a laboratory/facility where the use of Level 1, 2 or 3 biological agents is described in the laboratory or animal work proposed. The form must also be completed if any work is proposed involving animals carrying zoonotic agents infectious to humans or involving plants, fungi, or insects that require Public Health Agency of Canada (PHAC) or Canadian Food Inspection Agency (CFIA) permits.

This form must be updated at least every 3 years or when there are changes to the biological agents being used.

Containment Levels will be established in accordance with Laboratory Biosafety Guidelines, 3rd edition, 2004, Public Health Agency of Canada (PHAC) or Containment Standards for Veterinary Facilities, 1st edition 1996, Canadian Food Inspection Agency (CFIA).

Electronically completed forms are to be submitted to Occupational Health and Safety, (OHS), (Support Services Building, Room 4190 or to jstanle2@uwo.ca) for distribution to the Biohazards Subcommittee. For questions regarding this form, please contact the Biosafety Officer at extension 81135 or biosafety@uwo.ca. If there are changes to the information on this form (excluding grant title and funding agencies), contact Occupational Health and Safety for a modification form. See website: www.uwo.ca/humanresources/biosafety.

Please ensure that all questions are fully and clearly answered. Failure to do so will lead to the form being returned, which will cause delays in your approval and frustration for you and your colleagues on the Committee.

If you are re-submitting this form as requested by the Biohazards Subcommittee, please make modifications to the form in bold print, highlighted in yellow. Please re-submit forms electronically.

PRINCIPAL INVESTIGATOR:	**Christopher Pin**
DEPARTMENT:	**Paediatrics**
ADDRESS:	**A5-134, Victoria Research Laboratories**
PHONE NUMBER:	**x53073**
EMERGENCY PHONE NUMBER(S):	**519-657-1263**
EMAIL:	**cpin@uwo.ca**

Location of experimental work to be carried out :

Building :	**Victoria Research Laboratories**	Room(s):	**5th floor open lab**
Building :	**Victoria Research Laboratories**	Room(s):	**A7-111**
Building :		Room(s):	

***For work being performed at Institutions affiliated with the University of Western Ontario, the Safety Officer for the Institution where experiments will take place must sign the form prior to its being sent to the University of Western Ontario Biosafety Officer (See Section 15.0, Approvals).**

FUNDING AGENCY/AGENCIES: **Internal Funding - Core Facility**
GRANT TITLE(S): **London Regional Transgenic and Gene Targeting Facility**
UNDERGRADUATE COURSE NAME(IF APPLICABLE): **N/A**

List all personnel working under Principal Investigators supervision in this location:

Name	UWO E-mail Address	Date of Biosafety Training
Linsay Drysdale	**ldrysdal@uwo.ca**	**November, 2007**
Lucimar Ferreira	**luteodoro@gmail.com**	**June, 2008**

Changes to Every Page

Please explain how the biological agents are used in your project and how they are stored and disposed of. The BARF without this description will not be reviewed.

I am the Scientific Director for the London Regional Transgenic and Gene Targeting Facility. The LRTGT regularly performs superovulation, handles DNA plasmids that are introduced into embryos and embryonic stem (ES) cells, and cultures cells in mitomycin C.

Storage: Plasmids are stored in -80oC freezers within the LRTGT. These freezers are within a locked area that allows for limited access. When these reagents are being used in tissue cultures, the experiments take place in a closed room that has limited access and is locked after hours. Cell lines are either maintained in incubators within a closed room that has limited access and is locked after hours OR are stored in -150oC freezers in restricted access areas in the London Regional Cancer Program or the London Regional Transgenic and Gene Targeting Facility. All hormones and toxins are stored in restricted areas within locked freezers. Disposal: Any media used for the culturing cells is treated thoroughly with bleach and disposed in a biological hazards waste container. Hormones/toxins are stored until used and not disposed.

Please include a ONE page research summary or teaching protocol in lay terms.
Forms with summaries more than one page will not be reviewed.

The LRTGT generates genetically modified mice as a service for London-based researchers. This includes work with both embryonic stem (ES) cells and live mice. In total, we perform five services that involve superovulation of female mice or work with tissue culture cell lines. Superovulation of female mice occurs for (1) rederivation or (2) cryopreservation of mouse lines, (3) pronuclear injection of DNA into single cell embryos, or (4) for blastocyst injections of ES cells followed by transfer to pseudopregnant females. (5) We use ES cells to alter single genes before we select correctly targeted cells and inject these into blastocyst exmrbyos.

1.0 Microorganisms

1.1 Does your work involve the use of biological agents? ☒ YES ☐ NO
(non-pathogenic and pathogenic biological agents including but not limited to bacteria and other microorganisms, viruses, prions, parasites or pathogens of plant or animal origin)? If no, please proceed to Section 2.0

Do you use microorganisms that require a permit from the CFIA? ☐ YES ☒ NO
If YES, please give the name of the species ____________________
What is the origin of the microorganism(s)? ____________________

Please describe the risk (if any) of escape and how this will be mitigated:

Please attach the CFIA permit.

Please describe any CFIA permit conditions:

1.2 Please complete the table below:

Full Scientific Name of Biological Agent(s)* (Be specific)	Is it known to be a human pathogen? YES/NO	Is it known to be an animal pathogen? YES/NO	Is it known to be a zoonotic agent? YES/NO	Maximum quantity to be cultured at one time? (in Litres)	Source/ Supplier	PHAC or CFIA Containment Level
E.coli Dh5alpha	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	**100 ml liquid**		☒ 1 ☐ 2 ☐ 2+ ☐ 3
E.coli - XL1Blue	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	**100 ml liquid**		☒ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			☐ 1 ☐ 2 ☐ 2+ ☐ 3

****Please attach a Material Safety Data Sheet or equivalent from the supplier if the bacterium used is not on this link:***
http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA_Ecoli_list.pdf

Additional Comments: **We use bacteria simply for cloning of new DNA plasmids and expansion of plasmid DNA**

2.0 Cell Culture

2.1 Does your work involve the use of cell cultures? ☒ YES ☐ NO
(If NO, please proceed to Section 3.0)

2.2 Please indicate the type of primary cells (i.e. derived from fresh tissue) that will be grown in culture:

Cell Type	Is this cell type used in your work?	Source of Primary Cell Culture Tissue	AUS Protocol Number
Human	☐ Yes ☒ No		Not applicable
Rodent	☒ Yes ☐ No	**fibroblasts (DR4 mice)**	**2008-027**
Non-human primate	☐ Yes ☒ No		
Other (specify)	☐ Yes ☒ No		

2.3 Please indicate the type of established cells that will be grown in culture in:

Cell Type	Is this cell type used in your work?	Specific cell line(s)*	Containment Level of each cell line	Supplier / Source of cell line(s)
Human	☐ Yes ☒ No			
Rodent	☒ Yes ☐ No	**Mouse ES cells R1, G4, E14Tg2A**	**All are 2**	**Andras Nagy (U of T)**
Non-human primate	☐ Yes ☒ No			
Other (specify)	☐ Yes ☒ No			

Please attach a Material Safety Data Sheet or equivalent from the supplier. (For more information, see www.atcc.org)

2.4 For above named cell types(s) indicate PHAC or CFIA containment level required ☐ 1 ☒ 2 ☐ 2+ ☐ 3

Additional Comments: **I**

3.0 Use of Human Source Materials

3.1 Does your work involve the use of human source materials? ☐ YES ☒ NO
If no, please proceed to Section 4.0

3.2 Indicate in the table below the Human Source Material to be used.

Human Source Material	**Source/Supplier /Company Name**	**Is Human Source Material Infected With An Infectious Agent? YES/UNKNOWN**	**Name of Infectious Agent (If applicable)**	**PHAC or CFIA Containment Level (Select one)**
Human Blood (whole) or other Body Fluid		☐ Yes ☐ Unknown		☐1 ☐2 ☐2+ ☐3
Human Blood (fraction) or other Body Fluid		☐ Yes ☐ Unknown		☐1 ☐2 ☐2+ ☐3
Human Organs or Tissues (unpreserved)		☐ Yes ☐ Unknown		☐1 ☐2 ☐2+ ☐3
Human Organs or Tissues (preserved)		Not Applicable		Not Applicable

Additional Comments:

4.0 Genetically Modified Organisms and Cell lines

4.1 Will genetic modifications be made to the microorganisms, biological agents, or cells described in Sections 1.0 and 2.0? ☒ YES ☐ NO If **NO**, please proceed to Section 5.0

4.2 Will genetic modification(s) involving plasmids be done? ☒ YES, complete table below ☐ NO

Bacteria Used for Cloning *	Plasmid(s) **	Source of Plasmid	Gene Transformed or Transfected	Will there be a change due to transformation of the bacteria?	Will there be a change in the pathogenicity of the bacteria after the genetic modification?	What are the consequences due to the transformation of the bacteria?
E.Coli DH5α **E.Coli XL1Blue**	**Targeting vectors#** **Transgenic constructs#**	**- genes as per requests to the LRTGT#**		**No**	**No**	**None**

**** Please attach a Material Safety Data Sheet or equivalent if available.***
***** Please attach a plasmid map.***
******No Material Safety Data Sheet is required for the following strains of E. coli:***
http://www.uwo.ca/humanresources/docandform/docs/ohs/CFIA_Ecoli_list.pdf

4.3 Will genetic modification(s) of bacteria and/or cells involving viral vectors be made?
☐ YES, complete table below ☒ NO

Virus Used for Vector Construction	Vector(s) *	Source of Vector	Gene(s) Transduced	Describe the change that results from transduction

**** Please attach a Material Safety Data Sheet or equivalent.***

4.3.1 Will virus be replication defective? ☐ YES ☐ NO

4.3.2 Will virus be infectious to humans or animals? ☐ YES ☐ NO

4.3.3 Will this be expected to increase the containment level required? ☐ YES ☐ NO

5.0 Will genetic sequences from the following be involved?

- HIV ☒ NO ☐ YES, specify
- HTLV 1 or 2 or genes from any Level 1 or Level 2 pathogens ☒ NO ☐ YES, specify
- SV 40 Large T antigen ☒ NO ☐ YES
- E1A oncogene ☒ NO ☐ YES
- Known oncogenes ☒ NO ☐ YES, specify
- Other human or animal pathogen and or their toxins ☒ NO ☐ YES, specify

5.1 Is any work being conducted with prions or prion sequences? ☒ NO ☐ YES

Additional Comments: **As part of the mandate for the London Regional Transgenic and Gene Targeting Facility, we receive plasmid DNA (digested or undigested) to either inject into one cell mouse embryos or electroporate in**

6.0 Human Gene Therapy Trials

6.1 Will human clinical trials be conducted involving a biological agent? ☐ YES ☒ NO
(including but not limited to microorganisms, viruses, prions, parasites or pathogens of plant or animal origin)
If no, please proceed to Section 7.0

6.2 If YES, please specify which biological agent will be used:
Please attach a full description of the biological agent.

6.3 Will the biological agent be able to replicate in the host? ☐ YES ☐ NO

6.4 How will the biological agent be administered?

6.5 Please give the Health Care Facility where the clinical trial will be conducted:

6.6 Has human ethics approval been obtained? ☐ YES, number: ☐ NO ☐ PENDING

7.0 Animal Experiments

7.1 Will live animals be used? ☒ YES ☐ NO If **NO**, please proceed to section 8.0

7.2 Name of animal species to be used **Mouse**

7.3 AUS protocol **# 2008-027**

7.4 List the location(s) for the animal experimentation and housing. **VRL A7-111**

7.5 Will any of the agents listed in section 4.0 be used in live animals
☐ NO ☒ YES, specify: **Some of the plasmids will be used to generate genetically modified mice**

7.6 Will the agent(s) be shed by the animal:
☐ YES ☒ NO, please justify: **The DNA will be integrated into the genome. Any DNA not integrated will be targeted by the cell for degradation**

8.0 Use of Animal species with Zoonotic Hazards

8.1 Will any animals with zoonotic hazards or their organs, tissues, lavages or other body fluids including blood be used (see list below)? ☐ YES ☒ NO - If **NO**, please proceed to section 9.0

8.2 Will live animals be used? ☐ YES ☐ NO

8.3 If **YES**, please specify the animal(s) used:

- Pound source dogs ☐ YES ☐ NO
- Pound source cats ☐ YES ☐ NO
- Cattle, sheep or goats ☐ YES, species ☐ NO
- Non-human primates ☐ YES, species ☐ NO
- Wild caught animals ☐ YES, species & colony # ☐ NO
- Birds ☐ YES, species ☐ NO
- Others (wild or domestic) ☐ YES, specify ☐ NO

8.4 If no live animals are used, please specify the source of the specimens:

9.0 Biological Toxins and Hormones

9.1 Will toxins or hormones of biological origin be used? ☒ YES ☐ NO If **NO**, please proceed to Section 10.0

9.2 If YES, please name the toxin(s) or hormones(s) **Human and equine Chorionic Gonadotrophin (HCG, ECG), Toxins: mitomycin C**
Please attach information, such as a Material Safety Data Sheet, for the toxin(s) used.

9.3 What is the LD_{50} (specify species) of the toxin or hormone **Not available for HCG or ECG; mitomycin C (30 mg/kg; rat)**

9.4 How much of the toxin or hormone is handled at one time*? **HCG (20 IU); ECG (20 IU); mitomycin C (2 mg)**

9.5 How much of the toxin or hormone is stored*? **HCG (25000 IU); ECG (25000 IU); mitomycin C (10 mg)**

9.6 Will any biological toxins or hormones be used in live animals? ☒ YES ☐ NO
If **YES**, Please provide details: **HCG and ECG (superovulate female mice) caerulein (experimental model for pancreatitis in mice)**

*For information on biosecurity requirements, please see:
http://www.uwo.ca/humanresources/docandform/docs/healthandsafety/biosafety/Biosecurity_Requirements.pdf

Additional Comments: **Not equine chorionic gonadotrophin is commonly referred to as Pregnant Mare Serum (PMS)**

10.0 Insects

10.1 Do you use insects? ☐ YES ☒ NO - If **NO**, please proceed to Section 11.0

10.2 If YES, please give the name of the species.

10.3 What is the origin of the insect?

10.4 What is the life stage of the insect?

10.5 What is your intention? ☐ Initiate and maintain colony, give location:
☐ "One-time" use, give location:

10.6 Please describe the risk (if any) of escape and how this will be mitigated:

10.7 Do you use insects that require a permit from the CFIA permit? ☐ YES ☐ NO
If **YES**, Please attach the CFIA permit & describe any CFIA permit conditions:

11.0 Plants

11.1 Do you use plants? ☐ YES ☒ NO - If **NO**, please proceed to Section 12.0

11.2 If YES, please give the name of the species.

11.3 What is the origin of the plant?

11.4 What is the form of the plant (seed, seedling, plant, tree...)?

11.5 What is your intention? ☐ Grow and maintain a crop ☐ "One-time" use

11.6 Do you do any modifications to the plant? ☐ YES ☐ NO
If yes, please describe:

11.7 Please describe the risk (if any) of loss of the material from the lab and how this will be mitigated:

11.8 Is the CFIA permit attached? ☐ YES ☐ NO
If **YES**, Please attach the CFIA permit & describe any CFIA permit conditions:

12.0 Import Requirements

12.1 Will any of the above agents be imported? ☐ YES, country of origin ☒ NO
If **NO**, please proceed to Section 13.0

12.2 Has an Import Permit been obtained from HC for human pathogens? ☐ YES ☐ NO

12.3 Has an import permit been obtained from CFIA for animal or plant pathogens? ☐ YES ☐ NO

12.4 Has the import permit been sent to OHS? ☐ YES, please provide permit # ☐ NO

13.0 Training Requirements for Personnel Named on Form

All personnel named on the above form who will be using any of the above named agents are required to attend the following training courses given by OHS:

- Biosafety
- Laboratory and Environmental/Waste Management Safety
- WHMIS (Western or equivalent)
- Employee Health and Safety Orientation

As the Principal Investigator, I have ensured that all of the personnel named on the form who will be using any of the biological agents in Sections 1.0 to 9.0 have been trained.

An X in the check box indicates you agree with the above statement... ☒
Enter Your Name Christopher Pin ***Date:*** October 12, 2012

14.0 Containment Levels

14.1 For the work described in sections 1.0 to 9.0, please indicate the highest HC or CFIA Containment Level required. ☐ 1 ☒ 2 ☐ 2+ ☐ 3

14.2 Has the facility been certified by OHS for this level of containment?
☒ YES, location and date of most recent biosafety inspection:
☐ NO, please certify
☐ NOT REQUIRED for Level 1 containment

14.3 Please indicate permit number (not applicable for first time applicants):

15.0 Procedures to be Followed

15.1 Are additional risk reduction measures necessary beyond containment level 1, 2, 2+ or 3 measures that are unique to these agents? ☐ YES ☒ NO
If **YES** please describe:

15.2 Please outline what will be done if there is an exposure to the biological agents listed such as a needlestick injury or an accidental splash:
Skin exposure: Wash the affected area thoroughly using antimicrobial soap and report incident to OHS. Splash to eyes: Immediately flush eyes with running water for 15 minutes using eyewash and forcibly hold eye(s) open to ensure effective wash behind the eyelids. Report incident to OHS. Needle stick: Wash affected area thoroughly using antimicrobial soap for 5 minutes and report incident

15.3 As the Principal Investigator, I will ensure that this project will follow the Western Biosafety Guidelines and Procedures Manual for Containment Level 1 & 2 Laboratories (and the Level 3 Facilities Manual for Level 3 projects). I will ensure that UWO faculty, staff and students working in my laboratory have an up-to-date Hazard Communication Form, found at http://www.shs.uwo.ca/workplace/workplacehealth.html

An X in the check box indicates you agree with the above statement... ☒
Enter Your Name **Christopher Pin** ***Date:*** **October 12, 2012**

15.4 Additional Comments: _____

16.0 Approvals

1) UWO Biohazards Subcommittee:
SIGNATURE: _____
Date: _____

2) Safety Officer for the University of Western Ontario
SIGNATURE: _____
Date: _____

3) Safety Officer for Institution where experiments will take place (if not UWO):
SIGNATURE: _____
Date: NOV 12, 2012

Approval Number: _____ Expiry Date (3 years from Approval): _____

Special Conditions of Approval:

Western
UNIVERSITY · CANADA

TOXIN USE RISK ASSESSMENT

Name of Toxin:	Human Chorionic Gonadotrophin (HCG)
Proposed Use Dose:	20 IU
Proposed Storage Dose:	25000 IU
LD $_{50}$ (species):	µg

Calculation:

0 µg/kg x 50 kg/person

Dose per person based on LD $_{50}$ in µg = 0

LD_{50} per person with safety factor of 10 based on LD_{50} in µg = ***0***

Comments/Recommendations:

Western
UNIVERSITY · CANADA

TOXIN USE RISK ASSESSMENT

Name of Toxin:	Equine Chorionic Gonadotrophin (ECG)
Proposed Use Dose:	20 IU
Proposed Storage Dose:	25000 IU
LD_{50} (species):	µg

Calculation:

0 µg/kg x 50 kg/person

Dose per person based on LD_{50} in µg = 0

LD_{50} per person with safety factor of 10 based on LD_{50} in µg = ***0***

Comments/Recommendations:

Western
UNIVERSITY · CANADA

TOXIN USE RISK ASSESSMENT

Name of Toxin:	Mitomycin C
Proposed Use Dose:	2000 µg
Proposed Storage Dose:	10000 µg
LD_{50} (species):	30000 µg

Calculation:

30000 µg/kg x 50 kg/person

Dose per person based on LD_{50} in µg = 1500000

LD_{50} per person with safety factor of 10 based on LD_{50} in µg = 150000

Comments/Recommendations:

Material Safety Data Sheet

Issuing Date 08/03/10 **Revision Number** 0

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Mitomycin C

Product Code(s) J594

UN-No 2811

Synonyms AMETYCIN * AMETYCINE * 7-AMINO-9-ALPHA-METHOXYMITOSANE * MITOCIN-C * MITOMYCIN * MITOMYCIN-C * MITOMYCINUM * MMC * MUTAMYCIN * MYTOMYCIN * MITOMYCYNA C (POLISH) * NCI-C04706 * NSC 26980 * RCRA WASTE NUMBERU010 *

Distributor
AMRESCO INC.
6681 Cochran Road
SOLON, OHIO 44139

Company Phone Number 1-800-829-2805
Emergency Telephone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Emergency Overview

Suspected carcinogen
Highly toxic
Suspected mutagen
Irritant

Appearance Gray **Physical State** Powder **Odor** No information available

Potential Health Effects

Acute Toxicity

Eyes Irritating to eyes.
Skin Irritating to skin. Very toxic in contact with skin.
Inhalation Irritating to respiratory system. Very toxic by inhalation.
Ingestion Causes irritation by ingestion. Very toxic if swallowed.

Chronic Effects Suspected carcinogen. Suspected mutagen. May cause heritable genetic damage.

Aggravated Medical Conditions None known.

Environmental Hazard See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula C15H18N4O5

Chemical Name	CAS-No	Weight %
Mitomycin-C	50-07-7	95-100

4. FIRST AID MEASURES

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

Skin Contact Wash skin with soap and water.

Inhalation Move to fresh air. If breathing becomes difficult, give oxygen.

Ingestion Clean mouth with water and afterwards drink plenty of water.

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties Not flammable.

Flash Point Not determined

Suitable Extinguishing Media Dry chemical, CO2, water spray or regular foam.

Hazardous Combustion Products Carbon oxides, Nitrogen oxides (NOx)

Explosion Data
Sensitivity to Mechanical Impact Not sensitive.
Sensitivity to Static Discharge Not sensitive.

Specific Hazards Arising from the Chemical
Use water spray to cool fire-exposed containers.

Protective Equipment and Precautions for Firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA **Health Hazard** - **Flammability** - **Stability** - **Physical and Chemical Hazards** -

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Avoid contact with skin, eyes and clothing. Use personal protective equipment. Ensure adequate ventilation

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Avoid dust formation. Pick up and transfer to properly labeled containers. Ventilate area and wash spill site after material pickup is complete.

7. HANDLING AND STORAGE

Handling Handle in accordance with good industrial hygiene and safety practice.

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Mitomycin-C 50-07-7			

Engineering Measures Showers
Eyewash stations
Ventilation systems.

Personal Protective Equipment

Eye/Face Protection Tightly fitting safety goggles.

Skin and Body Protection Wear protective gloves/clothing.

Respiratory Protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Gray	**Odor**	No information available
Physical State	Powder		
Flash Point	No information available	**Autoignition Temperature**	No information available
Boiling Point/Range	No information available	**Flammability Limits in Air**	No information available
Explosion Limits	No information available		
Molecular Weight	334.3	**Solubility**	No information available
Evaporation Rate	No information available	**Vapor Density**	No information available.

10. STABILITY AND REACTIVITY

Stability Stable under recommended storage conditions.

Incompatible Products Strong oxidizing agents. Strong acids. Strong bases.

Conditions to Avoid None known based on information supplied.

Hazardous Decomposition Products Carbon oxides. Nitrogen oxides (NOx).

Hazardous Polymerization Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information Irritating to eye, skin and respiratory system. Toxic by inhalation, in contact with skin, or if swallowed.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Mitomycin-C	30 mg/kg (Rat)		

Chronic Toxicity

Chronic Toxicity Suspected carcinogen. Suspected mutagen. May cause heritable genetic damage.

Chemical Name	ACGIH	IARC	NTP	OSHA
Mitomycin-C		Group 2B		X

Target Organ Effects Bone marrow, Liver

12. ECOLOGICAL INFORMATION

Ecotoxicity
The environmental impact of this product has not been fully investigated.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of material in accordance with all federal, state, and local regulations.

Contaminated Packaging Dispose of in accordance with all federal, state and local regulations.

Chemical Name
Mitomycin-C - 50-07-7

Chemical Name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - U Series Wastes
Mitomycin-C - 50-07-7					U010

14. TRANSPORT INFORMATION

DOT Regulated
- **Proper Shipping Name** TOXIC SOLID, ORGANIC, N.O.S. (CONTAINING MITOMYCIN C)
- **Hazard Class** 6.1
- **UN-No** 2811
- **Packing Group** II

IATA Regulated
- **UN-No** 2811
- **Proper Shipping Name** TOXIC SOLID, ORGANIC, N.O.S. (CONTAINING MITOMYCIN C)
- **Hazard Class** 6.1
- **Packing Group** II

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	Does not Comply
IECSC	Does not Comply
KECL	Does not Comply
PICCS	Does not Comply

AICS Complies

U.S. Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)
This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

CERCLA

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Mitomycin-C	10 lb	10 lb

U.S. State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Mitomycin-C	50-07-7	Carcinogen

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Mitomycin-C	X	X	X		X

International Regulations

Mexico - Grade No information available.

Canada

WHMIS Hazard Class
Not determined

16. OTHER INFORMATION

Issuing Date 08/03/10

Revision Date

Revision Note No information available.

Disclaimer
The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide 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.

End of MSDS

Conforms to 93/112/EC and ISO 11014-1

SAFETY DATA SHEET

CALBIOCHEM®

Order Number

Customer Number

1. Identification of the substance/preparation and of the company/undertaking

Product name : Gonadotropin, Pregnant Mare Serum

Chemical formula : N/A

Synonym : PMSG

Catalog # : 367222

Supplier : Manufactured by EMD Biosciences, Inc.
10394 Pacific Center Court
San Diego, CA 92121
(858)450-5558/(800)854-3417
FAX: (858)453-3552

Emergency telephone number : **Call Chemtrec®**
(800)424-9300 (within U.S.A.)
(703)527-3887 (outside U.S.A.)

2. Composition / information on ingredients

Substance/Preparation : Substance

Chemical name*	CAS No.	EC Number	Symbol	R-Phrases
1) Gonadotropin, Pregnant Mare Serum	9002-70-4	Not available.	Xn	R40

3. Hazards identification

Physical/chemical hazards : Not applicable.

Human health hazards : WARNING!
POSSIBLE BIRTH DEFECT HAZARD.
MAY CAUSE BIRTH DEFECTS BASED ON ANIMAL DATA.
MAY CAUSE ALLERGIC RESPIRATORY AND SKIN REACTION.
MAY CAUSE DAMAGE TO THE FOLLOWING ORGANS: REPRODUCTIVE SYSTEM, GASTROINTESTINAL TRACT.
POSSIBLE CANCER HAZARD
CONTAINS MATERIAL WHICH MAY CAUSE CANCER BASED ON ANIMAL DATA.
CONTAINS MATERIAL WHICH MAY CAUSE HERITABLE GENETIC EFFECTS BASED ON ANIMAL DATA.

4. First-aid measures

First-Aid measures

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin Contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Eye Contact : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Effects and symptoms

Inhalation : Hazardous in case of inhalation (lung sensitizer).

Skin Contact : Hazardous in case of skin contact (sensitizer).

Aggravating conditions : Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

5. Fire-fighting measures

Flammability of the Product : May be combustible at high temperature.

Extinguishing Media

Suitable : SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Hazardous thermal (de)composition products : These products are nitrogen oxides (NO, NO2...).

Special fire-fighting procedures : Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Protection of fire-fighters : Be sure to use an approved/certified respirator or equivalent.

6. Accidental release measures

Personal precautions : Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Small Spill and Leak : Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill and Leak : Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary systen

7. Handling and storage

Handling : Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not breathe dust. Avoid contact with skin. Wear suitable protective clothing. If you feel unwell, seek medical attention and show the label when possible.

Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 4°C (39.2°F).

Packaging materials

Recommended use : Use original container.

8. Exposure controls/personal protection

Engineering measures : Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Hygiene measures : Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of day.

Ingredient Name	Occupational Exposure Limits
1) Gonadotropin, Pregnant Mare Serum	Not available.

Personal protective equipment

Respiratory system : Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.

Skin and body : Lab coat.

Hands : Gloves.

Eyes : Safety glasses.

Protective Clothing (Pictograms) :

9. Physical and chemical properties

Physical state : Solid. (Solid powder.)

Color : White.

Molecular Weight : Not available.

Solubility : Easily soluble in cold water.

Flash point : Not available.

Explosive properties : Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

10. Stability and reactivity

Stability : The product is stable.

Conditions to avoid : Not available.

Hazardous Decomposition Products : These products are nitrogen oxides (NO, NO2...).

11. Toxicological information

RTECS # : **TU4517000**

Local effects

Skin irritation : Not available.

Sensitization : Hazardous in case of skin contact (sensitizer), of inhalation (lung sensitizer).

Acute toxicity : LD50: Not available.
LC50: Not available.

Chronic toxicity : Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Other Toxic Effects on Humans : Not available.
Hazardous in case of skin contact (sensitizer), of inhalation (lung sensitizer).

May cause congenital malformations in the foetus.

Not available.

Specific effects

Carcinogenic effects : Not available.

Mutagenic effects : Not available.

Reproduction toxicity : Classified Reproductive system/toxin/female, Reproductive system/toxin/male [SUSPECTED].

Teratogenic effects : Classified POSSIBLE for human.

12. Ecological information

Ecotoxicity : Not available.

Toxicity of the Products of Biodegradation : The product itself and its products of degradation are not toxic.

13. Disposal considerations

Methods of disposal; Waste of residues; Contaminated packaging : Waste must be disposed of in accordance with federal, state and local environmental control regulations.

14. Transport information

International transport regulations

Land - Road/Railway

ADR/RID Class : Not controlled under ADR (Europe).

Sea

IMDG Class : Not controlled under IMDG.

Air

IATA-DGR Class : Not controlled under IATA.

Special Provisions for Transport Not applicable.

15. Regulatory information

EU Regulations

Hazard symbol(s) :

Classification : Harmful

Risk Phrases : R68- Possible risks of irreversible effects.

Safety Phrases : S22- Do not breathe dust.
S36- Wear suitable protective clothing.

Contains : - Gonadotropin, Pregnant Mare Serum

U.S. Federal Regulations : TSCA: No products were found.
SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: No products were found.
SARA 311/312 MSDS distribution - chemical inventory - hazard identification: No products were found.
SARA 313 toxic chemical notification and release reporting: No products were found.
Clean Water Act (CWA) 307: No products were found.
Clean Water Act (CWA) 311: No products were found.
Clean air act (CAA) 112 accidental release prevention: No products were found.
Clean air act (CAA) 112 regulated flammable substances: No products were found.
Clean air act (CAA) 112 regulated toxic substances: No products were found.

HCS Classification : CLASS: Target organ effects.

State Regulations :

WHMIS (Canada) : CLASS D-2A: Material causing other toxic effects (VERY TOXIC).
No products were found.

16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	2
Fire Hazard		1
Reactivity		0
Personal Protection		E

National Fire Protection Association (U.S.A.)

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes 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 cannot guarantee that these are the only hazards that exist.

Material Safety Data Sheet

Revision: 6/07/2004

Hazard information is provided for compliance with both the UK Chemicals (Hazard Information and Packaging) (CHIP) Regulations and the US Hazard Communication Standard (HCS)

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY

PRODUCT NAME: Chorionic Gonadotropin (HCG) 5,000 I.U./ vial

PRODUCT CODE: 13662

EEC NUMBER: 232-660-2

SUPPLIER:
USB Corporation, 26111 Miles Road, Cleveland, Ohio 44128 Phone: (216) 765-5000

Emergency Contact:
Chemtrec (800) 424-9300
Outside USA & Canada 703 527 3887

COMPOSITION/ HAZARDOUS COMPONENTS

HAZARD	CAS NO.	%WT	TLV	CHIP R & S Phrases
Chorionic Gonadotropin (HCG) 5,000 I.U. / vial	9002-61-3	2.7%	---	R:36/37/38 Irritating to eyes, respiratory system and skin. S:24/25 Avoid contact with skin and eyes. S:36/37 Wear suitable protective clothing and gloves.

HAZARDS IDENTIFICATION

CHIP
Irritant
HCS
Irritant

FIRST-AID MEASURES

EYES: Flush with water for 15 minutes. Seek medical advice if irritation persists.
SKIN: Flush with water, then wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse. Seek medical attention if irritation persists.
INHALATION: Remove the victim from exposure and move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Keep victim quiet and warm. Seek immediate medical attention.
INGESTION: Drink water and seek immediate medical attention. Avoid alcoholic beverages. Never give anything by mouth to an unconscious person.

FIRE-FIGHTING INFORMATION

Use media suitable to extinguish the supporting or surrounding fire. Wear NIOSH (or equivalent) approved self contained breathing apparatus. For small fires only: use carbon dioxide, dry powder or foam. Emits toxic fumes under fire conditions. May be combustible at high temperature.
Flash Point = No data available.

ACCIDENTAL RELEASE MEASURES

Wear appropriate personal protective equipment and clothing including lab coat, safety goggles, gloves and NIOSH-approved respirator. Collect in a manner that does not create dust and place in a suitable waste container. Avoid contact of material with skin or eyes. Use adequate ventilation.

HANDLING AND STORAGE

Caution: Handle all products prepared from human sources as if they were capable of transmitting infectious agents. Avoid accidental inoculation, intravenous injection or contact with open wounds. Wash thoroughly after handling. Observe universal precautions when working with this product. Products from human sources have been tested and found negative for Hepatitis B and HIV viruses. Wear appropriate personal protective equipment and clothing including lab coat, safety goggles, gloves and NIOSH-approved respirator. Avoid contact of material with skin or eyes. Use adequate ventilation. Store ambient away from incompatible materials.

For Further Information, contact your local USB Authorized distributor, Amersham Biosciences

Asia Pacific +852 2811 8693	**Canada** 1 800 463 5800	**Former Soviet Union** +7 (095) 232 0250	**Japan** 81 3 5331 9337	**Norway** 63 89 23 10	**Spain** 935 944 950	**USA** **USB Corporation** (216) 765-5000 If purchased from Amersham Biosciences use 1 800 526 3593
Australia +61 2 9894 5188	**Central and East Europe** +43 1 982 3826	**France** 0169 18 28 00	**Latin America** +55 11 3667 5700	**Portugal** 01 417 70 35	**Sweden** 018 164000	
Austria 01 576 0616 10	**Denmark** +45 4516 2400	**Germany** 07 61 49 03 0	**Middle East and Africa** +30 (1) 96 00 687	**South East Asia** 60 3 724 2080	**Switzerland** 01 802 81 50	
Belgium 0800 73888	**Finland** 358 (9) 512 3940	**Italy** 02 27322 1	**Netherlands** 0165 580 410	**South East Europe** +43 (1) 982 3826	**UK** 0800 515313	

MSDS information may be continued on back of page.

PERSONAL PROTECTION

Caution: Handle all products prepared from human sources as if they were capable of transmitting infectious agents. Avoid accidental inoculation, intravenous injection or contact with open wounds. Wash thoroughly after handling. Observe universal precautions when working with this product. Products from human sources have been tested and found negative for Hepatitis B and HIV viruses. Wear appropriate personal protective equipment and clothing including lab coat, safety goggles, gloves and NIOSH-approved respirator. A qualified industrial hygienist should evaluate the need for respiratory protection. Use respiratory protection approved by NIOSH (or equivalent) and appropriate to the hazard. Avoid contact of material with skin or eyes. Mechanical ventilation or local exhaust as needed to control exposure to dust, vapors or mists. Access to a safety shower and eye-wash.

PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White, lyophilized powder
Vapor Pressure: No data available
Solubility (Water): Soluble
Percent Volatile: No data available
Chemical formula: No data available
Boiling Point: No data available
Vapor Density: No data available
Specific Gravity: No data available
Evaporation Rate: No data available
Melting Point: No data available

STABILITY AND REACTIVITY

Product is stable under normal conditions. Incompatible with strong oxidizing agents. Hazardous decomposition products may include toxic fumes and gases. Hazardous polymerization will not occur.

TOXICOLOGICAL INFORMATION

EFFECTS OF OVEREXPOSURE:
EYES: No toxicity data found, but contact may cause irritation and slight corneal injury.
SKIN: No toxicity data found, but contact may cause irritation and/or allergic reaction.
INHALATION: No toxicity data found, but excessive dust may cause irritation if inhaled.
INGESTION: May cause irritation of the digestive tract.
ADDITIONAL INFORMATION:
Mutation and reproductive effects data under RTECS MD6953000.
Caution: Handle all products prepared from human sources as if they were capable of transmitting infectious agents. Avoid accidental inoculation, intravenous injection or contact with open wounds. Wash thoroughly after handling. Observe universal precautions when working with this product. Products from human sources have been tested and found negative for Hepatitis B and HIV viruses. Signs and symptoms of overexposure include: headaches, irritability, restlessness, depression, tiredness, edema, precocious puberty and gynecomastia. Hypersensitivity reactions both localized and systemic in nature, including erythema, urticaria, rash, angioedema, dyspnea and shortness of breath, have been reported. Adverse reproductive effects have been reported in humans.
Reproductive: Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)(1978). Post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)(1970).
Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)(1960). Testes, epididymis, sperm duct (1959).
Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) (1947). Fetal death (1917).
Maternal Effects - ovaries, fallopian tubes, uterus, cervix, vagina (1960). Menstrual cycle changes or disorders (1974).
Effects on Newborn - growth statistics (e.g.%, reduced weight gain) (1949).
Definitions: RTECS = Registry of Toxic Effects of Chemical Substances.

ECOLOGICAL INFORMATION

No information available.

DISPOSAL CONSIDERATIONS

Dispose of material in accordance with applicable local, state, and federal regulations.

TRANSPORTATION INFORMATION

US DOT / IATA: No information available.

REGULATORY INFORMATION

RCRA - No applicable information.
SARA 302 - This material does not have an RQ or a TPQ.
SARA 313 - This material is not reportable under Section 313.
EPA TSCA Section 8(b) - This chemical substance is **NOT** specifically listed on the EPA TSCA Inventory. It is supplied for research and development use only, by or directly under the supervision of technically qualified individuals. **NOT** for manufacturing or commercial purposes.
Exposure Limits - Not established.
California Proposition 65 - No applicable information.