OHS Registration #: _____

Expiration Date: _____

STANDARD OPERATING PROCEDURE/APPROVAL FORM
FOR CARCINOGENS AND HIGHLY TOXIC MATERIALS

Instructions: Please complete this form to request approval to use and possess highly toxic or carcinogenic material from the University Chemical Hygiene Committee as required by Chapter 12 of the University Chemical Hygiene Plan and University Policy 7-37.

Submit a separate form for each chemical. Copies of the current guidelines and Chemical Hygiene Plan are available at the DOHS web site: http://www.udel.edu/OHS/. For questions, please contact the University Chemical Hygiene Officer at 831-2103.

Section I – Information

1. Principal Investigator(s): _____
2. E-Mail Address: _____
3. Department: _____
4. Address: _____
5. Phone Number: _____ 6. Fax Number: _____
7. Lab(s) to be Used: _____
8. Chemical: Hydrazine and Hydrazine Sulfate

Section II – Use and Storage

A. Purchasing

All purchases of this material must have approval from the Principal Investigator (PI) or authorized personnel before ordering. The user is responsible to ensure that a current Material Safety Data Sheet (MSDS) is obtained unless a current one is already available within the laboratory. Quantities of this material will be limited to _____, and/or the smallest amount necessary to complete the experiment.

B. Authorized personnel

Please select the general categories of personnel who could obtain approval to use this material:

1. ☐ Principal Investigator 2. ☐ Graduate Students 3. ☐ Undergraduates
4. ☐ Technical Staff 5. ☐ Post Doctoral Employees
6. ☐ Other (Describe): _____

Please list the specific personnel and their approval level (Attach an addendum to this form for additional personnel):

NOTE: The Principal Investigator must be aware of all purchases of this material. The Principal Investigator must assure the there is not an exceedance of the quantity limits.

1. _____	☐ Purchase	☐ Use the Material
2. _____	☐ Purchase	☐ Use the Material
3. _____	☐ Purchase	☐ Use the Material
4. _____	☐ Purchase	☐ Use the Material
5. _____	☐ Purchase	☐ Use the Material

The Principal Investigator will update this section when any personnel changes occur. If changes occur, document the changes (include the record of training of additional personnel) in the laboratories files and submit an addendum to the University Chemical Hygiene Officer with all training documentation.

C. Storage

Materials will be stored according to compatibility and label recommendations in a designated area.

1. Please list compounds that this chemical is incompatible with: Avoid reaction with oxidizing agents. Avoid strong acids.

2. Please list special storage requirements (I.E.: Refrigerated, Inert Atmosphere, Desiccated, etc.): Store in original containers in approved flame-proof area. No smoking, naked lights, heat or ignition sources. DO NOT store in pits, depressions, basements or areas where vapors may be trapped. Keep containers securely sealed. Store away from incompatible materials in a cool, dry well ventilated area. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storing and handling recommendations.

3. Please list specific storage area (This Area Must be Marked and Labeled): _____

Storage areas will be inspected by laboratory personnel on a regular basis. Personnel will check for safety concerns such as improper storage, leaking/damaged container(s), damaged labels, quantities in excess of approved limits, theft/disappearance of material, etc. The inspector will also determine if an inventory reduction is possible. The Principal Investigator will designate one individual to complete this inspection.

4. Please select an inspection frequency:

☐ Weekly ☐ Biweekly

☐ Bimonthly ☐ Monthly

D. Use location:

Materials shall be used only in the following designated areas.

Check all that apply:

1. ☐ Demarcated Area in Lab (Describe): _____
2. ☒ Fume Hood 3. ☒ Glove Box
4. ☐ Other (Describe): _____

Section III – Personnel Safety and Protection

A. Training requirements:

All users must demonstrate competency and familiarity regarding the safe handling and use of this material prior to purchase. The Principal Investigator is responsible for maintaining the training records for each user of this material. Training should include the following:

1. Review of current MSDS
2. Review of the OSHA Lab Standard
3. Review of the Chemical Hygiene Plan
4. Special training provided by the department/supervisor (Right to Know)
5. Review of the departmental safety manual if applicable
6. Safety meetings and seminars
7. One-on-One hands-on training with the Principal Investigator or other knowledgeable laboratory personnel.

B. Personal Protective Equipment:

All personnel are required to wear the following personal protective equipment whenever handling this material:

1. Proper Laboratory Attire (Pants or dresses/shorts below the knees, sleeved shirt, close-toe shoes)
2. Safety Glasses
3. Lab Coat

Personnel may be required to wear other Personal Protective Equipment when working with this material. The Principal Investigator should contact the University Chemical Hygiene Officer to discuss the selection of chemical protective clothing (aprons, suits and gloves) and respirators. Please check all that apply:

1. ☐ Chemical Safety Splash Goggles	2. ☐ Face Shield
3. ☒ Chemical Protective Gloves (Describe): Butyl Rubberm Neoprene or Nitrile	
4. ☐ Chemical Protective Clothing (Describe): _____	
5. ☐ Chemical Protective Splash Apron (Describe): _____	
6. ☐ Respirator (Type): _____	
7. ☐ Other (Describe): _____	

C. Safe Work Practices

The following safe work practices should be employed when using this material:

1. Wear all required personal protective equipment
2. Cover open wounds
3. Wash hands thoroughly when work with the material is completed

4. No mouth pipetting

5. Use of sharps, such as glass Pasteur pipettes, needles, razor blades, etc. should be avoided or minimized

6. Must not work alone in the laboratory

7. Please list any other safe work practices: Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid smoking, naked lights, heat or ignition sources. When handling, DO NOT eat, drink or smoke. Vapor may ignite on pumping or pouring due to static electricity. DO NOT use plastic buckets. Earth and secure metal containers when dispensing or pouring product. Use spark-free tools when handling. Avoid contact with incompatible materials. Keep containers securely sealed. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storing and handling recommendations. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions.

D. Personnel Decontamination

For most exposures, decontamination should occur as follows:

1. Small Skin Exposures –

    a. Wash contaminated skin in sink with tepid water for 15 minutes
    b. Have buddy locate the MSDS
    c. Wash with soap and water
    d. Contact Occupational Health and Safety at 831-8475 for further direction

2. Eye Exposure –

    a. Locate the emergency eye wash
    b. Turn eye wash on and open eyelids with fingers
    c. Rinse eyes for 15 minutes
    d. Have buddy contact 911 for the Newark Campus, 911 for all others and locate the MSDS
    e. Notify OHS

3. Large Body Area Exposure –

    a. Locate the emergency safety shower
    b. Stand under shower and turn it on
    c. Rinse whole body while removing all contaminated clothing
    d. Have buddy contact 911 for the Newark Campus, 911 for all others and locate the MSDS
    e. Rinse body for 15 minutes
    f. Notify OHS

Please list any special decontamination procedures: _____

E. Exposure Symptoms and Treatment

Please list the emergency procedures to be followed in the event of an exposure. These will be found in the MSDS for the compounds:

1. Skin/eye contact:

a. Symptoms: EYE - The material can produce chemical burns to the eye following direct contact. Vapors or mists may be extremely irritating. If applied to the eyes, this material causes severe eye damage. The material is highly corrosive. to the eyes. and is. capable of causing severe damage with loss of sight. The vapor is extremely discomforting. and is. capable of causing a mild, temporary redness of the conjunctiva (similar to wind-burn), temporary impairment of vision and/ or other transient eye damage/ ulceration. Reactions may not occur on exposure but response may be delayed with symptoms only appearing many hours later. The vapour when concentrated has pronounced eye irritation effects and this gives some warning of high vapour concentrations. If eye irritation occurs seek to reduce exposure with available control measures, or evacuate area. The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. SKIN - Skin contact with the material may produce toxic effects; systemic effects may result following absorption. The material can produce chemical burns following direct contact with the skin. The liquid is highly corrosive. to the skin. and any contact may cause rapid tissue destruction. as. severe burns. and. it is rapidly absorbed. by the skin. Bare unprotected skin should not be exposed to this material. Toxic effects may result from skin absorption. The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.

b. First Aid: Rinse with water in a emergency eye wash or safety shower while removing contaminated clothing for 15 minutes. Seek emergency medical care by dialing 911.

2. Ingestion:

a. Symptoms: Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual. The material can produce chemical burns within the oral cavity and gastrointestinal tract following ingestion. Considered toxic by all exposure routes. The material is highly corrosive. and. toxic. even. fatal. if swallowed. Ingestion may result in nausea, pain, vomiting. Vomit entering the lungs by aspiration may cause potentially lethal chemical pneumonitis. At sufficiently high doses the material may be nephrotoxic (i.e. poisonous to the kidney). At sufficiently high doses the material may be hepatotoxic (i.e. poisonous to the liver). Hydrazine (and some of its derivatives), is a strong convulsant in laboratory animals and can cause central nervous system (CNS) depression or stimulation. Symptoms of CNS depression may include nonspecific discomfort, giddiness, headache, dizziness, nausea, anaesthetic effects, slowed reaction time, slurred speech and may progress to unconsciousness. Serious poisonings may result in respiratory depression and may be fatal. CNS stimulation may produce dyspnea, coughing, bronchospasm, and laryngospasm. Muscular involvement may produce symptoms ranging from fasciculation to spasticity or seizures. Headache, dizziness and confusion may also result as can hyperpyrexia or a sensation of warmth. Other symptoms may include nausea, vomiting, diarrhoea and difficulty in urination. Cardiovascular involvement may produce alterations in blood pressure or arrhythmia. Pulmonary oedema and cardiovascular collapse also seem to be a feature of acute hydrazine poisonings. Animals that survive for more than a day frequently develop liver necrosis and renal failure. As judged by a few severe poisonings, man reacts like monkey in the sense that liver injury is more severe than kidney failure. Severe hypoglycaemia may develop even earlier than liver necrosis although this is rarely mentioned in the literature. Ingestion of alkaline corrosives may produce burns around the mouth, ulcerations and swellings of the mucous membranes, profuse saliva production, with an inability to speak or swallow. Both the esophagus and stomach may experience burning pain; vomiting and diarrhea may follow. Epiglottal swelling may result in respiratory distress and asphyxia; shock can occur. Narrowing

of the esophagus, stomach or stomach valve may occur immediately or after a long delay (weeks to years). Severe exposure can perforate the esophagus or stomach leading to infections of the chest or abdominal cavity, with low chest pain, abdominal stiffness and fever. All of the above can cause death.

b. First Aid: • If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Contact 911 immediately.

3. Inhalation

a. Symptoms: Harmful by inhalation. Toxic by inhalation. If inhaled, this material can irritate the throat and lungs of some persons. The vapor is highly discomforting. to the upper respiratory tract. and may be. toxic. if inhaled. Inhalation hazard is increased at higher temperatures. If exposure to highly concentrated vapor atmosphere is prolonged this may lead to narcosis, unconsciousness, even coma and unless resuscitated - death. Symptoms of inhalation of hydrazine (and some of its derivatives), may include nausea and headache. Central nervous system (CNS) excitability may lead to convulsions and, in severe cases, respiratory arrest and death. Several instances of systemic poisoning, by hydrazine, have been reported in humans. These mainly involve the CNS, respiratory system and stomach. CNS stimulation may produce twitching of the extremities, clonic movements, hyperreflexia, convulsions and pyrexia; these may progress to lethargy, ataxia, confusion, coma and hypotension. Oliguria, haematuria, hyperglycaemia and/ or hypoglycaemia and elevated LFTs are common. Leucocytosis, parasthaesia and peripheral neuropathies may be delayed for several days. Respiratory (and dermal) exposure may produce deficits in concentration, comprehension, memory, task performance and mood status. Irritation of the mucous membranes may produce rhinitis, salivation, coughing, choking and dyspnoea. The material may produce respiratory tract irritation, and result in damage to the lung including reduced lung function.

b. First Aid: Move to fresh air. Seek emergency medical care by dialing 911. Provide CPR if necessary.

4. Injection

a. Symptoms: May be fatal

b. First Aid: Seek emergency medical care by dialing 911.

The ChemWatch MSDS, which is available at http://www.udel.edu/OHS/ oftentimes, has treatment information for Emergency Room Personnel and Doctors to follow. Please list any information that can be provided to assist with the treatment:

NOTES TO PHYSICIAN

For acute or short-term repeated exposures to highly alkaline materials:

- Respiratory stress is uncommon but present occasionally because of soft tissue edema.
- Unless endotracheal intubation can be accomplished under direct vision, cricothyroidotomy or tracheotomy may be necessary.
- Oxygen is given as indicated.
- The presence of shock suggests perforation and mandates an intravenous line and fluid administration.
- Damage due to alkaline corrosives occurs by liquefaction necrosis whereby the saponification of fats and solubilization of proteins allow deep penetration into the tissue.

Alkalis continue to cause damage after exposure.

INGESTION:
• Milk and water are the preferred diluents
No more than 2 glasses of water should be given to an adult.
• Neutralizing agents should never be given since exothermic heat reaction may compound injury.
* Catharsis and emesis are absolutely contra-indicated.
* Activated charcoal does not absorb alkali.
* Gastric lavage should not be used.
Supportive care involves the following:
• Withhold oral feedings initially.
• If endoscopy confirms transmucosal injury start steroids only within the first 48 hours.
• Carefully evaluate the amount of tissue necrosis before assessing the need for surgical intervention.
• Patients should be instructed to seek medical attention whenever they develop difficulty in swallowing (dysphagia).
SKIN AND EYE:
• Injury should be irrigated for 20-30 minutes.
• Eye injuries require saline. [Ellenhorn & Barceloux: Medical Toxicology]
In poisonings involving hydrazine:
Correction of early hypoglycaemia, with large parenteral doses of pyridoxine appears to suppress convulsions and other neurological effects.
In man, hydrazine-induced hyperexcitability and coma may respond to massive doses of pyridoxine but there is no evidence that liver necrosis or damage can be prevented or corrected by this antidote.
GOSSELIN, SMITH & HODGE: Clinical Toxicology of Commercial Products, 5 th Ed.

F. Spills

The laboratory should be prepared to clean up minor spills (25 ml/25 g or less) of highly toxic/carcinogenic materials should they occur in a properly operating fume hood. Chemical spill clean up guidance can be found at http://www.udel.edu/OHS/chemspillkit/chemspillkit.html. Laboratory personnel cleaning up a spill will wear all personal protective equipment listed above and manage all cleanup debris according the waste disposal section. Notify OHS of any spills, even if the lab staff handled the clean-up.

Please list the following:

1. Location of Spill Cleanup Materials for a small spill: _____

2. Any special measures/cleanup material required to cleanup a spill: Environmental hazard - contain spillage. Clear area of personnel. Avoid breathing vapours and contact with skin and eyes. Wear fully protective PVC clothing and breathing apparatus. Clean up all spills immediately. Remove all ignition sources. Contain and absorb spill with sand, earth, inert material or vermiculite. If product enters drains, waterways or watercourses, flush at least ten (10) times the volume of water to the drain. Place spilled material in clean, dry, sealable, labelled container. .

If a spill is large or occurs outside of a fume hood, the laboratory occupants should immediately vacate the laboratory, close all doors and contact Occupational Health & Safety at 831-8475 during working hours or 911 after hours. If the laboratory personnel determine that the spill is not contained to the lab or could cause harm to people outside the laboratory, they should pull the building fire alarm and go to the Emergency Gathering Point to await the University Police and Emergency Responders. The responsible/knowledgeable person should provide the University Police and the Emergency Responders with the following:

1. Common Name of the Material Involved

2. A copy of a MSDS, if possible

3. Any pertinent information related to the emergency, such as location in the lab, other hazards in the lab, etc.

G. Emergency Phone Numbers:

Below are a list of emergency numbers to contact in the event of an emergency:

1. Police, Fire or Medical Emergency, call – 911 on the Newark Campus, 9-911 for all others

2. Occupational Health & Safety – X8475

Please provide a list of other emergency phone numbers, such as after hour contacts for laboratory personnel or any other important phone number, to be used in the event of an emergency: _____

H. Other Special precautions

Please list any other special precautions or procedures not listed in the above sections. Please be as specific as possible:

CHRONIC HEALTH EFFECTS
There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.
Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.
There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.
This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects. This has been demonstrated via both short- and long-term experimentation.
Considered toxic by all exposure routes.
Principal routes of exposure are usually by.
inhalation of vapor.
skin contact / absorption of the material.
Some evidence exists that this material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects. This has been demonstrated via both short- and long-term experimentation.
Hydrazine derivatives tend to be local irritants and cause convulsions, liver damage, and destruction of red blood cells. They also damage the kidneys, and cause stimulation of the central nervous system with tremors and convulsions, progressing to depression, respiratory collapse and death.
When administered orally, hydrazine induced pulmonary adenomas and adenocarcinomas in mice.
Inhalation induced lung carcinomas and lymphosarcomas of the spleen in female mice. A study of 423 men, involved in the manufacture of hydrazine revealed three stomach, one prostate and a neurogenic cancer.

Section VI – Waste Disposal

The authorized person using this material is responsible for the safe collection, preparation and proper disposal of waste unless otherwise stated below. Waste shall be disposed of as soon as possible and in accordance with all laboratory and University procedures. All personal must obtain chemical waste disposal training via DOHS.

Specific instructions:

Collect solid waste material in a 7mil polyethylene bag and label with an orange chemical waste label. Collect liquid waste in a "Justrite" container provided by DOHS. Label with a hazardous waste label. Use proper laboratory ventilation such as a fume hood to manage both liquid and solid wastes. Contact DOHS for removal. Do not put in the normal trash or pour any solutions down the drain.

Section V – Signature and Verification

Your signature below indicates that you have completed this form accurately to the best of your knowledge, you acknowledge all requirements and restrictions of this form and that you accept responsibility for the safe use of the material.

1. Prepared By: _____ Date: _____

   Signature: _____

2. Principal Investigator: _____ Date: _____

   Signature: _____

Section VI – Approval Process

A. University Chemical Hygiene Officer Approval

The Principal Investigator should have this form completed as accurately as possible. Please e-mail or fax this form to the University Chemical Hygiene Officer at eich@udel.edu or 831-1528. The Chemical Hygiene Officer will review and verify the form and make any necessary changes or updates.

1. University CHO: _____ Date: _____

Signature: _____

B. Conditional Approval to Purchase and Use

This form will then be e-mailed or faxed to a member of the University Chemical Hygiene Committee (CHC), usually from the same department as the requesting PI. The Committee Member will meet with the Principal Investigator or designee and discuss the form and the use of the material. If the Committee Member finds the procedure acceptable, they can offer a conditional approval for purchase and use of this material.

2. CHC Member: _____ Date: _____

Signature: _____

C. Full Approval

A signed copy of the form will be sent, via campus mail, to the University Chemical Hygiene Officer, who will bring it up at the next Chemical Hygiene Committee Meeting for full approval. All approvals will be good for two years. The complete, signed approval form will kept on file with Occupational Health & Safety and a copy will be sent to the Principal Investigator to keep on file.

3. Acceptance: _____ Date: _____

CHC Chair: _____

Signature: _____

D. Approval Expiration

The approval for use and purchase of this material will expire should any of the approved information change, with the exception of Section II, B and C, Authorized Personnel and Storage Location, or two years after CHC approval. If, at the end of two years, the procedure is substantially the same, the Principal Investigator can complete a renewal form and send it to the University CHO, who can approve the renewal for an additional two years.

CHECKLIST FOR POSSESSION AND USE OF CARCINOGENS AND HIGHLY TOXIC MATERIALS

The checklist is provided to assist a researcher with the approval process for possession and use of carcinogens and highly toxic materials. This form may be kept on file in the laboratory with the SOP to serve as documentation. The complete procedure can be found in the University Chemical Hygiene Plan in Chapter 12.

Date and Initial	
_____	1. Complete a Standard Operating Procedure/Approval Form For Carcinogens and Highly Toxic Materials and submit this form to OHS for review
_____	2. Review and make OHS's changes and recommendations
_____	3. Meet with a member of the University Chemical Hygiene Committee to review the approval form and the use of the material.
_____	4. Submit (via campus mail) the completed and signed form back to the University Chemical Hygiene Officer for conditional approval to purchase and use the material. The University Chemical Hygiene Committee will review this form at the next scheduled meeting for full approval.
_____	5. Complete a Job Hazard Analysis (JHA) for each experiment in which this compound is used. These JHAs must be kept on file in the laboratory and updated every 5 years or when a process changes.
_____	6. Provide and document training for every worker who will use the material. Training shall include hands-on instruction as well as review of the JHA, SOP and the University Chemical Hygiene Plan; specifically Chapter 12.
_____	7. Conduct a trial run with OHS present.
_____	8. Have OHS present the first time a process using this material occurs.