

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.

Form Updated: January 2007

**Please attach a detailed synopsis of how this material will be used in your research.**

**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: Formalin (A solution of formaldehyde, formic acid and methanol)

**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 there is not an exceedance of the quantity limits.**

1. _____	<input type="checkbox"/> Purchase	<input type="checkbox"/> Use the Material
2. _____	<input type="checkbox"/> Purchase	<input type="checkbox"/> Use the Material
3. _____	<input type="checkbox"/> Purchase	<input type="checkbox"/> Use the Material
4. _____	<input type="checkbox"/> Purchase	<input type="checkbox"/> Use the Material
5. _____	<input type="checkbox"/> Purchase	<input type="checkbox"/> 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:

- Strong Acids
- Amines
- Oxidizing Materials
- Alkaline Materials
- Nitrogen Dioxide
- Performic Acid
- Other: \_\_\_\_\_

2. Please list special storage requirements (I.E.: Refrigerated, Inert Atmosphere, Desiccated, etc.):

- \_\_\_\_\_

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. Chemical Hygiene/Right-To-Know
3. Chemical Waste Management
4. Review of the OSHA Lab Standard
5. Review of the Chemical Hygiene Plan
6. Special training provided by the department/supervisor
7. Review of the departmental safety manual if applicable
8. Safety meetings and seminars
9. One-on-One hands-on training with the Principal Investigator or other knowledgeable laboratory personnel.
10. Other: \_\_\_\_\_

#### **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 – **Researchers must upgrade to chemical safety splash goggles if a splash, spray or mist hazard exists. In general, safety glasses can be worn if the fume hood sash is properly positioned to provide the splash, spray and mist protection, otherwise indirect venting chemical safety splash goggles must be worn.**
3. Lab Coat
4. Chemical Protective Gloves: Butyl Rubber

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. <input type="checkbox"/> Chemical Safety Splash Goggles	2. <input type="checkbox"/> Face Shield
3. <input type="checkbox"/> Chemical Protective Clothing (Describe): _____	
4. <input type="checkbox"/> Chemical Protective Splash Apron (Describe): _____	
5. <input type="checkbox"/> Respirator (Type): _____	
6. <input type="checkbox"/> 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: \_\_\_\_\_

### 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

4. Ingestion Emergencies –
  - a. If swallowed do NOT induce vomiting.
  - b. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
  - c. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious
  - d. Have buddy contact 911 for the Newark Campus, 9-911 for all others and locate the MSDS
  - e. Notify OHS
  
5. Inhalation Emergencies –
  - a. If fumes or combustion products are inhaled remove from contaminated area.
  - b. Lay patient down. Keep warm and rested.
  - c. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
  - d. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
  - e. Have buddy contact 911 for the Newark Campus, 9-911 for all others and locate the MSDS
  - f. Notify OHS
  
6. Injection Emergencies –
  - a. Clean the areas with soap and water
  - b. Allow the wound to bleed
  - c. Have buddy contact 911 for the Newark Campus, 9-911 for all others and locate the MSDS
  - d. 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 Contact Symptoms:** 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 material can produce chemical burns following direct contact with the skin. There is strong evidence to suggest that this material, on a single contact with skin, can cause serious, irreversible damage of organs. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. 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.
  
2. **Eye Contact Symptoms:** 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 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. Irritation of the eyes may produce a heavy secretion of tears (lachrymation). The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

3. **Ingestion 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. The material can produce chemical burns within the oral cavity and gastrointestinal tract following ingestion. There is some evidence to suggest that this material can cause, if swallowed once, very serious, irreversible damage of organs. Methanol may produce a burning or painful sensation in the mouth, throat, chest, and stomach. This may be accompanied by nausea, vomiting, headache, dizziness, shortness of breath, weakness, fatigue, leg cramps, restlessness, confusion, drunken behavior, visual disturbance, drowsiness, coma and death. These symptoms may not occur until several hours after exposure. Visual impairment produces blurring, double vision, color distortion, reduced visual field, and blindness. In higher doses, the liver, kidney, heart and muscle can all be damaged. 10mL can cause blindness, and 60-200mL will cause death in adults.
4. **Inhalation 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. The material can produce chemical burns within the oral cavity and gastrointestinal tract following ingestion. There is some evidence to suggest that this material can cause, if swallowed once, very serious, irreversible damage of organs. Methanol may produce a burning or painful sensation in the mouth, throat, chest, and stomach. This may be accompanied by nausea, vomiting, headache, dizziness, shortness of breath, weakness, fatigue, leg cramps, restlessness, confusion, drunken behavior, visual disturbance, drowsiness, coma and death. These symptoms may not occur until several hours after exposure. Visual impairment produces blurring, double vision, color distortion, reduced visual field, and blindness. In higher doses, the liver, kidney, heart and muscle can all be damaged. 10mL can cause blindness, and 60-200mL will cause death in adults.

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

Treat symptomatically.

For acute or short-term repeated exposures to formaldehyde:

#### INGESTION:

- Patients present early with severe corrosion of the gastro-intestinal tract and systemic effects.
- Inflammation and ulceration may progress to strictures.
- Severe acidosis results from rapid conversion of formaldehyde to formic acid. Coma, hypotension, renal failure and apnea complicate ingestion.
- Decontaminate by dilution with milk or water containing ammonium acetate; vomiting should be induced. Follow with gastric lavage using a weak ammonia solution (converts formaldehyde to relatively inert pentamethylenetetramine)
- Gastric lavage is warranted only in first 15 minutes following ingestion.

**SKIN:** Formaldehyde can combine with epidermal protein to produce a hapten-protein couples capable of sensitizing T-lymphocytes. Subsequent exposures cause a type IV hypersensitivity reaction (i.e. allergic contact dermatitis).

[Ellenhorn Barceloux: Medical Toxicology].

For acute and short term repeated exposures to methanol:

- Toxicity results from accumulation of formaldehyde/formic acid.
- Clinical signs are usually limited to CNS, eyes and GI tract. Severe metabolic acidosis may produce dyspnea and profound systemic effects which may become intractable. All symptomatic patients should have arterial pH measured. Evaluate airway, breathing and circulation.
- Stabilize obtunded patients by giving naloxone, glucose and thiamine.
- Decontaminate with Ipecac or lavage for patients presenting 2 hours post-ingestion. Charcoal does not absorb well; the usefulness of cathartics is not established.
- Forced diuresis is not effective; hemodialysis is recommended where peak methanol levels exceed 50 mg/dL (this correlates with serum bicarbonate levels below 18 mEq/L)
- Ethanol, maintained at levels between 100 and 150 mg/dL, inhibits formation of toxic metabolites and may be indicated when peak methanol levels exceed 20 mg/dL. An intravenous solution of ethanol in D5W is optimal.
- Folate, as leucovorin, may increase the oxidative removal of formic acid. 4-methylpyrazole may be an effective adjunct in the treatment.
- Phenytoin may be preferable to diazepam for controlling seizure.

[Ellenhorn Barceloux: Medical Toxicology]

#### BIOLOGICAL EXPOSURE INDEX - BEI

Determinant	Index	Sampling Time	Comment
1. Methanol in urine	15 mg/l	End of shift	B, NS
2. Formic acid in urine	80 mg/gm creatinine	Before the shift at end of workweek	B, NS

B: Background levels occur in specimens collected from subjects NOT exposed.

NS: Non-specific determinant - observed following exposure to other materials.

Depending on the degree of exposure, periodic medical examination is indicated. The symptoms of lung edema often do not manifest until a few hours have passed and they are aggravated by physical effort. Rest and medical observation is therefore essential. Immediate administration of an appropriate spray, by a doctor or a person authorized by him/her should be considered.

(ICSC24419/24421)

#### 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 to 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: Remove all ignition sources. Clean up all spills immediately. Avoid breathing vapors and contact with skin and eyes. Control personal contact by using protective equipment. Contain and absorb small quantities with vermiculite or other absorbent material. Wipe up. Collect residues in a flammable waste 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: \_\_\_\_\_

#### **I. Chronic Health Effects**

Cumulative effects may result following exposure\*. 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. This material can be regarded as being able to cause cancer in humans based on experiments and other information.

Repeated or prolonged exposure to corrosives may result in the erosion of teeth, inflammatory and ulcerative changes in the mouth and necrosis (rarely) of the jaw. Bronchial irritation, with cough, and frequent attacks of bronchial pneumonia may ensue. Gastrointestinal disturbances may also occur. Chronic exposures may result in dermatitis and/or conjunctivitis. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucous production. 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. Respiratory sensitization may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping. Sensitization may give severe responses



to very low levels of exposure, i.e. hypersensitivity. Sensitized persons should not be allowed to work in situations where exposure may occur. Long-term exposure to methanol vapor, at concentrations exceeding 3000 ppm, may produce cumulative effects characterized by gastrointestinal disturbances (nausea, vomiting), headache, ringing in the ears, insomnia, trembling, unsteady gait, vertigo, conjunctivitis and clouded or double vision. Liver and/or kidney injury may also result. Some individuals show severe eye damage following prolonged exposure to 800 ppm of the vapor.

#### **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 personnel 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](mailto: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.