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: Paraformaldehyde

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.
Section II – Material Storage

1. ______
2. ______
3. ______
4. ______
5. ______

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 storage with oxidizers. Avoid contamination of water, foodstuffs, feed or seed.
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. 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:

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<thead>
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<tbody>
<tr>
<td>1.</td>
<td>☐ Chemical Safety Splash Goggles</td>
</tr>
<tr>
<td>3.</td>
<td>☒ Chemical Protective Gloves (Describe): Butyl, Nitrile</td>
</tr>
<tr>
<td>4.</td>
<td>☐ Chemical Protective Clothing (Describe): _____</td>
</tr>
<tr>
<td>5.</td>
<td>☐ Chemical Protective Splash Apron (Describe): _____</td>
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<tr>
<td>6.</td>
<td>☐ Respirator (Type): _____</td>
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<tr>
<td>7.</td>
<td>☐ Other (Describe): _____</td>
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</table>

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

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:** This material can cause eye irritation and damage in some persons. 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. This material can cause inflammation of the skin on contact in some persons. Regular skin contact may cause brown discoloration with tanning effect, hardening of skin, with cracking and possible dermatitis following. Bare unprotected skin should not be exposed to this material. Sensitization may result in allergic dermatitis responses including rash, itching, hives or swelling of extremities. Sensitization reactions may appear suddenly after repeated symptom free exposures. The material may accentuate any pre-existing dermatitis condition.
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: Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. Considered an unlikely route of entry in commercial/industrial environments. Ingestion may result in nausea, abdominal irritation, pain and vomiting.
   b. First Aid: • IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY BY CALLING 911. For advice, contact a Poisons Information Center or a doctor.

3. Inhalation
   a. Symptoms: Harmful by inhalation. The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of the material, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation hazard is increased at higher temperatures.
   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:

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].

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 contact with skin and eyes. Control personal contact by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable labelled container for waste disposal.

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

Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population. There is sufficient evidence to suggest that this material directly causes cancer in humans.

Principal routes of exposure are usually by inhalation of generated dust and skin contact, eye contact with the material and inhalation of vapour. The dust from the material is highly irritating even destructive to tissues of the mucous membranes and upper respiratory tract. Paraformaldehyde solid and solutions, when heated evolve formaldehyde gas. When administered by inhalation, formaldehyde induced squamous cell carcinomas of the nasal cavity in rats of both sexes. Although excess occurrence of a number of cancers has been reported, the evidence for a possible involvement of formaldehyde is strongest for nasal and nasopharyngeal cancer. The occurrence of these cancers showed an exposure-response gradient in more than one study, but the numbers of exposed cases were often small and some studies did not show excesses. In humans formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx and nasal passages.
**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 be 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.

<table>
<thead>
<tr>
<th>Date and Initial</th>
<th>1. Complete a Standard Operating Procedure/Approval Form For Carcinogens and Highly Toxic Materials and submit this form to OHS for review</th>
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<tbody>
<tr>
<td></td>
<td>2. Review and make OHS’s changes and recommendations</td>
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<td>3. Meet with a member of the University Chemical Hygiene Committee to review the approval form and the use of the material.</td>
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<td>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.</td>
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<td>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.</td>
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<td>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.</td>
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<td>7. Conduct a trial run with OHS present.</td>
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<td>8. Have OHS present the first time a process using this material occurs.</td>
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