Decision algorithm for diclofenac

1. Is the product found in Table 1 of the NIOSH list – Antineoplastic (cytotoxic) Drugs?
   - No
   - Yes

2. Does the NIOSH or WHMIS information indicate that this material requires ventilation for preparation? Or is it a reproductive risk to the compounder?
   - No
   - Yes

3. Occasional small quantity? Must not be considered in isolation; if there is uncertainty as to the level of risk, then defer to the higher standard.
   - No
   - Yes

4. Do these ingredients require greater precautions to protect patient or personnel?
   - No
   - Yes

Level A
Designated and separate compounding area

Level B
Separate room (ventilated or with containment device)

Level C
Separate room under negative pressure with containment device

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1. NIOSH list - No
   - Health Hazard under the Hazardous Products Act - Yes
   - According to one company’s safety data sheet (SDS) for diclofenac powder, this chemical poses the following health hazards:
     - Acute Toxicity - Oral (Category 3)
     - Acute Toxicity - Dermal (Category 4)
     - Skin Irritation (Category 2)
     - Eye Irritation (Category 2A)
     - Toxic to Reproduction (Category 2)
     - Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, gastrointestinal tract, liver)
     - Acute Aquatic Toxicity (Category 3)
   - Yes.

2. Yes. According to one company’s SDS for diclofenac powder, compounding with this chemical requires “Adequate mechanical ventilation, fume hood, eye wash station, and safety shower” and is a reproductive risk.

3. Occasional small quantities of materials must not be considered in isolation. If several different high-risk or low-risk preparations are being compounded, the cumulative risk must be considered, even if they are compounded on different days. This must be documented in the risk assessment. Licensees must avail an environment and equipment that ensures the safety of pharmacy personnel when evaluating level of risk. If there is uncertainty as to the level of risk, then the licensee shall defer to the higher standard.

4. Yes. According to one company’s SDS for diclofenac powder, compounding with this chemical requires the following personal protective equipment (PPE):
   - Eyes - Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
   - Skin - Wear appropriate gloves to prevent skin exposure.
   - Clothing - Wear appropriate protective clothing to minimize contact with skin. Respirators - Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.