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This example is for illustrative purposes only; it is not directing you to a specific course of action, is not to be construed as legal advice or opinion, and is not to be taken as a position of the Ontario College of Pharmacists. While every effort will be made to ensure these examples are up to date, you must use your own professional knowledge, skills, and judgment when completing your own risk assessments and defer to the most recent guidance, references, and resources.

Non-Sterile Compounding Risk Assessment Template[1]

This tool has been published in conjunction with a companion guide – a resource intended to assist registrants' understanding of what to document, reference, and consider when determining the appropriate level of requirements for each preparation compounded at your pharmacy. Use of this form is optional. How a pharmacy chooses to document risk assessments is at the discretion of the Designated Manager or the compounding supervisor.

Complete one risk assessment for each compounded preparation.

1. **Preparation name:** 1% Hydrocortisone powder in 1% Clotrimazole cream

A. Identify the risk(s)

2. List the ingredients used in the preparation, including drugs, and active pharmaceutical ingredients (APIs). Attach safety data sheets (SDSs) if available.

Name	Manufacturer	DIN or CAS#	Physical Characteristics*	References
Hydrocortisone Acetate USP (micronized)	PQR chemicals	CAS# 123-456-7	Powder	☒ SDS ☐ Monograph
Clotrimazole Cream USP 1%	PQR chemicals	DIN# 99999999	Cream	☒ SDS ☒ Monograph

**Physical characteristics: liquid, volatile liquid, semi-solid, solid, solid powder, cream/ointment, etc.*

3. Are any of the above in the *NIOSH List of Hazardous Drugs in Healthcare, 2024?*

☒ No

☐ Yes → Check all that apply and specify which ingredients in the space provided:

☐ **Table 1 (hazardous drugs with carcinogenic properties):**
☐ **Table 2 (other hazardous drugs):**

[1] Source: Saskatchewan College of Pharmacy Professionals non-sterile compounding risk assessment template. Adapted with permission.

4. Are any of the above identified by WHMIS information as presenting a health hazard (as per section 2 of the safety data sheets [SDSs])?

☐ No
☒ Yes → Specify which ingredients and describe the health hazard(s):

Hydrocortisone acetate
- Toxic to reproduction (Category 2)
- Specific target organ toxicity, repeated exposure (Category 1 – endocrine system)
- Suspected of damaging fertility or the unborn child
- Causes damage to organs through prolonged or repeated exposure
- May cause allergic reaction
- Repeated exposure may cause skin dryness or cracking

Clotrimazole cream
- Potential for irritation of contaminated skin
- Individuals who have had a previous allergic reaction to products containing the active ingredient (clotrimazole) or other imidazoles, or any of the other components, may experience an allergic reaction

5. Does NIOSH, WHMIS information (e.g., as per SDSs), or product monographs indicate that any of the ingredients:

a) Require ventilation for preparation?

☐ No/ not applicable
☒ Yes → Please specify which ingredients and describe the risks:

Hydrocortisone acetate
Specific engineering controls state adequate mechanical ventilation (fume hood) (SDS section 8)

b) Present a reproductive risk to the compounder (if not already specified in question #4)?

☐ No / not applicable
☒ Yes → Please specify which ingredients and describe the risks:

Clotrimazole cream
SDS, section 11:
- Toxicological information indicates "May cause adverse reproductive effects"

Product monograph:
- Animal studies have not demonstrated any effects of the drug on fertility and do not indicate direct or indirect harmful effects for use in pregnancy
- No human studies of the effects on fertility have been performed, and pregnancy data in humans is limited
- Under "Use in Pregnancy" it advises that a patient should not use this in their first trimester unless directed by their physician. This is an important consideration if a compounder is/could be pregnant (e.g., accidental exposure)

c) Present any other potential risks to the compounder (i.e., any warnings or precautions)?

☒ No/ not applicable
☐ Yes → Please specify which ingredients and describe the potential risks:

6. Is there a risk of the following when compounding this preparation (check all that apply):

☒ Microbial contamination
☒ Cross contamination with other products or preparation(s)
☒ Interruption to your workflow
☐ Other risk(s); please specify (see NAPRA GD 4.1):

B. Assess the risk(s)

7. What quantity of this preparation is being compounded at a time (average?)

30 g

8. How often is this preparation compounded?

☐ Daily ☐ Weekly ☐ Monthly ☒ Other, please specify:

Once every 2 months

9. Based on the previous two questions, would you consider this to be an "occasional small quantity"?

☐ No
☒ Yes → Please outline your rationale, including consideration of *cumulative risk*:

In the past year this preparation was compounded 6 times in total
We do not routinely compound other preparations that contain hydrocortisone powder:
- Mixture report for last year indicated the other only preparation compounded that contained hydrocortisone powder was 1% hydrocortisone powder in ketoconazole 1% cream
- 1% hydrocortisone in clotrimazole preparations are usually up to 30 g
- Review of compounding activities as a whole shows that 10 preparations in total have been compounded in the last 6 months

10. What facilities and equipment are necessary to compound this preparation?

- Designated compounding area adjacent to the pharmacy's double sink
- Surfaces constructed of smooth, impervious and non-porous materials
- Surfaces of the area and the floor made of material that facilitates easy cleaning and disinfecting
- Area is kept tidy and we do not keep clutter (e.g. cardboard) or personal belongings in the area
- Compounding supplies needed: digital scale that reads to three decimal places, stainless steel spatulas, weigh boats, ointment slab, ointment jars in different sizes

11. Is additional training required to compound this preparation?

☒ No

☐ Yes → Please describe the requirements needed:

12. Based on the previous two questions, what is the complexity of this preparation?

☐ Simple ☒ Moderate ☐ Complex

Please outline your full rationale:

While the compounder must be able to demonstrate general compounding competence, compounding the preparation does not require special training, facilities, or equipment. The preparation does not require any special calculations; however, due to the absence of a USP compounding monograph, it is classified as moderate.

C. Mitigate the risk(s)

13. What personal protective equipment (PPE) is required to compound this preparation*?

PPE	Required	Type (please be specific)
Eye protection	☒ Yes ☐ No	Protective eyeglasses or chemical safety goggles
Mask / respirator	☒ Yes ☐ No	Fit-tested N95 mask
Face protection	☐ Yes ☒ No	
Gloves	☒ Yes ☐ No	Nitrile gloves
Gown / lab coat	☒ Yes ☐ No	Designated compounding lab coat
Other PPE, please specify:	☐ Yes ☒ No	

**See question 4 and consider potential routes of exposure such as skin, eye, inhalation, oral, etc.*
Note: Surgical masks do not provide respiratory protection against drug exposure and should not be used when respiratory protection against hazardous drug exposure is required (see NAPRA guidance document, section 9.2).

14. IF APPLICABLE:

a) How is the ventilation required for compounding this preparation being achieved*?

The SDS requires mechanical ventilation for hydrocortisone powder; however, due to the low frequency and volume of the preparation, as well as other risk mitigation factors that will be implemented (described below), mechanical ventilation is not required.

See question 5a.

b) How is the reproductive risk to compounding personnel being mitigated*?

Staff have received adequate training and will have access to appropriate PPE during compounding.

See question 5b.

c) How are the other risks to compounding personnel being mitigated*?

N/A

See question 5c.

15. Describe what measures you will implement to mitigate the risks below*:

Risk	Risk Mitigation Measure(s)
Microbial contamination	Maintaining a clean and sanitary compounding area, including proper cleaning of compounding equipment.
Cross contamination	Ensuring the compounding area, equipment, and supplies are cleaned, as per the pharmacy's cleaning procedures, before and after the preparation is compounded.
Interruption to your workflow	Compounding the preparation after the pharmacy closes. This will help minimize any distraction or interruption to workflow and contamination with other products.
Other risk(s):_____	

See question 6.

D. Risk Assessment – Result

16. Level of risk assigned for compounding this preparation:

☒ Level A ☐ Level B ☐ Level C

17. Outline your rationale for the level of risk assigned and describe the level of requirements that must be in place to compound this preparation.

Compound is prepared infrequently and in small quantities.

The compound will only be prepared during off hours to minimize interruption to workflow.

Risk of microbial contamination will be minimized by maintaining a clean and sanitary compounding area and ensuring proper compounding techniques.

Compounder is aware of location of the SDS binder, where to access the required PPE, and if necessary, first aid kit and supplies (e.g., eye wash).

Pharmacy has developed standardized compounding procedures that all staff are familiar with.

Verification steps (including calculations, identification of each API, lot number and expiry of each ingredient (API/excipient), and final check of finished product) will be performed by the pharmacy technician and, where possible, by a second pharmacy technician as an independent double-check.

E. Sign off

Date completed: January 9, 2026

Date last reviewed: N/A (will review annually or sooner if needed)

Name of compounding personnel completing the risk assessment: Kaity Wong

Name of non-sterile compounding supervisor: Farhan Mahmudi

Signature of compounding supervisor: *F. Mahmudi*