Non-sterile compounding risk assessment example

Compound Hydrocortisone 1% / Ketoconazole 2% 1:1 cream

Consider active pharmaceutical ingredients (APIs) and attach Safety Data Sheets (SDSs) if available

Hydrocortisone 1% cream	**DIN**	999 999	**SDS**	Yes ☐	No ☒	**Manufacturer**		
Ketoconazole 2% cream	**DIN**	999 998	**SDS**	Yes ☐	No ☒	**Manufacturer**		
Hydrocortisone powder	**DIN**		**SDS**	Yes ☒	No ☐	**Manufacturer**	ABC Chemicals	
Ketoconazole powder	**DIN**		**SDS**	Yes ☒	No ☐	**Manufacturer**	ABC Chemicals	

NIOSH Classification?

Yes ☐ No ☒

Table 1 ☐ Table 2 ☐ Table 3 ☐

Is this toxic to reproduction?

Yes ☒ No ☐

WHIMIS Health Hazard?

Yes ☒ No ☐

Description (as per Section 2 of SDS)

Hydrocortisone – Toxic to reproduction, possible endocrine system organ toxicity with repeated exposure.

Ketoconazole – Oral and reproductive toxicity. Possible liver toxicity with repeated exposure.

Product monograph contraindications, warnings, or precautions?

Hydrocortisone 1% cream – Contraindicated in hypersensitive individuals.

Ketoconazole 1% cream – Contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation. Precaution in pregnancy due to teratogenic effect if absorbed.

Complexity of this compound (as per USP 795):

(Simple) Moderate Complex

Is this compound only prepared occasionally?

Yes ☒ No ☐

Describe how often this compound is prepared (for example, daily, weekly, monthly).

Weekly

Are there only small quantities of ingredients being prepared?

Yes ☒ No ☐

On average, what quantity of this preparation is being prepared at a time?

50 grams

Do the concentration of ingredients in the product present a health risk to the compounder?

Yes ☐ No ☒

Physical characteristics of the ingredients

Liquid Volatile Liquid Semi-Solid Solid Powder (Cream/Ointment)

Does preparation require special education or competencies for your compounding personnel?

Yes ☐ No☒

If yes, then describe this in the master formulation record and consider whether level B or C requirements apply:

Are there verification steps during compounding?

Yes ☒ No ☐

Do you have appropriate facilities and equipment to prepare this compound?

Yes ☒ No ☐

Is ventilation required for preparation (as per section 8 of SDS or product monograph)?

SDS Yes ☒ No ☐

Product Monograph Yes ☐ No☒

Is your workflow uninterrupted?

Yes ☒ No ☐

If no, describe your processes to address the situation in order to meet standards:

Is there a risk of microbial contamination?

Yes ☒ No ☐

There is a higher risk of contamination for creams as per the guidance document.

Is there risk of cross contamination with other products?

Yes ☐ No ☒

Exposure risk to compounding personnel (as per section 2 of the SDS or product monograph)

From SDS

Skin	Yes ☒	No ☐
Eye	Yes ☒	No ☐
Inhalation	Yes ☒	No ☐
Oral	Yes ☐	No ☒
Other	_____	

From product monograph

Skin Yes ☒ No ☐

Eye Yes ☒ No ☐

Inhalation Yes ☐ No ☒

Oral Yes ☐ No ☒

Other _____

Personal Protective Equipment (PPE) deemed necessary (as per the SDS, product monograph and assessment of risk)

Gloves

Regular ☒ Chemotherapy ☐ Double gloves ☐

Compounding jacket / gown

Designated compounding jacket ☒ Disposable hazardous gown ☐

Mask Yes ☐ No ☒ Type _____

Eye protection Yes ☒ No ☐

Other PPE necessary (head, hair, or shoe covers) None

Is an eye wash station required?

Yes ☒ No ☐

Is a safety shower required?

Yes ☐ No ☒

Risk level assigned

(Level A) Level B Level C

Rationale and other risk mitigation measures

Simple compound, non-NIOSH. Health hazards minimized by cream formulation. Small volume, low frequency and low ingredient concentration. Ventilation not necessary. No SDS specifically available for the creams. SDS available only for powders which were reviewed. Product monographs reviewed for warnings, contraindications and precautions.

Compounding Supervisor / Date: Bob Bloom 05/24/17