



Non-sterile Compounding Risk Assessment

Compound:

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

Name:

DIN:

SDS:

Manufacturer:

Yes No

Yes No

Yes No

Yes No

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)

Product monograph contraindications, warnings, or precautions?



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 (example: daily, weekly, monthly)

Are there only small quantities of ingredients being prepared?

Yes No

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

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

Yes No

Physical characters 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 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

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)



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 measured

Compounding Supervisor

Date