



## What USP 800 Says About Respiratory Protection

# WHAT USP 800 SAYS ABOUT RESPIRATORY PROTECTION

USP Reference (<https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>)

USP General Chapter <800> provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment.

The National Institute for Occupational Safety and Health (NIOSH) considers a drug to be hazardous if it exhibits one or more of the following characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing hazardous drugs

General Chapter <800> describes requirements including responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating and cleaning; spill control; and documentation. These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

The following info graphic from USP, on the right, provides useful information.

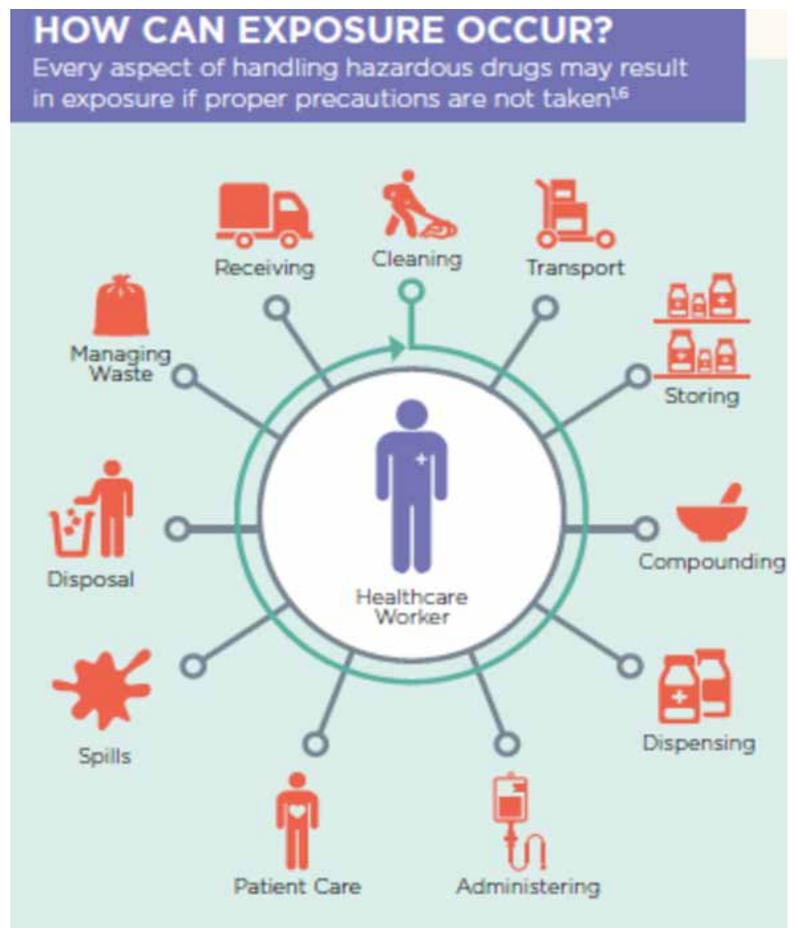


Image source: USP General Chapter <800> Info-gram

# AS PART OF USP'S SITE FAQ'S RELATED TO PPE AND THE HANDLING OF HAZARDOUS DRUGS ARE PROVIDED

<https://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>

## CONCERNING INPUT RELATED TO PPE EXCERPTS FROM THESE FAQ'S NOTE:

### *Personal Protective Equipment (PPE)*

44. Are the PPE and Engineering Controls specified in Table 5 of the current NIOSH list required?

<800> requires entities to maintain a list of HDs that include any items on the current NIOSH list that the entity handles. However, the list of PPE and engineering controls in Table 5 of the 2016 NIOSH list is a recommendation and may be used to guide the development of the entity's policy.

For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure and activities performed."

USP General Chapter <800> provides guidance relative to the use of PPE including respiratory protection. Some key points are highlighted below.

## PERSONAL PROTECTIVE EQUIPMENT

- Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues.
- Disposable PPE must not be re-used.
- Reusable PPE must be decontaminated and cleaned after use.
- The entity must develop SOPs for PPE based on the risk of exposure and activities performed.

Appropriate PPE must be worn when handling HDs including during:

- Receipt
- Storage
- Transport
- Compounding (sterile and non-sterile)
- Administration
- Deactivation/decontamination, cleaning, and disinfecting
- Spill control
- Waste disposal

## 7.5 RESPIRATORY PROTECTION

- Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required.
- A surgical N95 respirator provides the respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier to splashes, droplets, and sprays around the nose and mouth. For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles.
- **N95 respirators offer no protection against gases and vapors** and little protection against direct liquid splashes (see the Centers for Disease Control and Prevention's [CDC's] Respirator Trusted-Source Information). Fit test the respirator and train workers to use respiratory protection.
- Follow all requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134).

An appropriate full-face piece, chemical cartridge-type respirator or **powered air-purifying respirator (PAPR)** should be worn when there is a risk of respiratory exposure to HDs, including when:

- Attending to HD spills larger than what can be contained with a spill kit
- Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
- There is a known or suspected airborne exposure to powders or vapors

## 15. DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING

If warranted by the activity, respiratory protection must be used.

### 15.2 DECONTAMINATION

To provide protection to the worker performing this task, respiratory protection may be required.

## 16. SPILL CONTROL

- All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators (see Personal Protective Equipment).
- If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available.
- Written procedures should address use of appropriate full-face piece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

# RESPIRATORY SOLUTIONS FROM ILC DOVER TO CONSIDER

To view the NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016 visit link below:

<https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSH PUB2016161>

Formulation	Activity	Respiratory Protection	Respiratory Solutions from ILC Dover to consider*
All types of hazardous drugs	Receiving, unpacking, and placing in storage	Yes, when spills and leaks occur	Sentinel XL with OV/AG/HE filter
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	Yes, if not done in a control device	Sentinel XL with HEPA filter
Oral liquid drug or feeding tube	Compounding	Yes, if not done in a control device	Sentinel XL with OV/AG/HE filter
Topical drug	Compounding	Yes, if not done in a control device	Sentinel XL with OV/AG/HE filter
	Administration	Yes, if inhalation potential	Sentinel XL with OV/AG/HE filter
Subcutaneous/Intramuscular injections from a vial	Preparation (withdrawing from vial)	Yes, if not done in a control device	Sentinel XL with OV/AG/HE filter
Solutions for irrigation	Compounding	Yes, if not done in a control device	Sentinel XL with OV/AG/HE filter
	Administration (bladder, HIPEC, limb perfusion, etc.)	Yes	Sentinel XL with OV/AG/HE filter
Powder/Solution for inhalation/Aerosol treatment	Compounding	Yes, if not done in a control device	Sentinel XL with HEPA filter for powder and OV/AG/HE for solution
	Aerosol Administration	Yes	Sentinel XL with HEPA filter for powder and OV/AG/HE for solution
	Administration	Yes, if inhalation potential	Sentinel XL with HEPA filter for powder and OV/AG/HE for solution
Drugs and metabolites in body fluids	Disposal and Cleaning	Yes, if inhalation potential	Sentinel XL with OV/AG/HE filter
Drug-contaminated waste	Disposal and Cleaning	Yes, if inhalation potential	Sentinel XL with OV/AG/HE filter
Spills	Cleaning	Yes	Sentinel XL with OV/AG/HE filter

\*head cover vs. hood selection varies depending on concentration and toxicity of the HD. Select a hood if uncertain.

# ILC DOVER HEALTHCARE RESPIRATORY SOLUTIONS FOR INFECTIOUS DISEASE AND HAZARDOUS DRUG PROTECTION

All head covers and hoods are compatible with either filter. Select your required level of protection based on the respiratory/splash risk level.



S-4001 Head Cover  
APF 25



S-3101 XL Clear Hood  
APF 1,000



S-2028 BioShield™ Full Hood  
APF 1,000



S-4002 P100/HEPA Cartridge  
Select for particulate only filtration



S-4012 OV/AG/HE Cartridges  
Select for organic gases, vapors,  
and particulates



Sentinel XL Blower supports all healthcare protective solutions – infectious disease, CBRN Decon operations, and hazardous drug protection



S-2001 CBRN Hood  
 Laboratory Respiratory Protection  
 Level (LRPL) of 10,000 - specified in  
 NIOSH CBRN PAPR standard



S-2016 CBRN Cartridges  
 Select for broad CBRN protection  
 For use only with S-2001 hood

## USP <800> HAZARDOUS DRUG (HD) KITS

The following kits have been specifically designed to address HD needs. The S-3000-25 through S-3000-28 are full respirator systems while the S-3000-29 through S-3000-31 are conversion kits designed for Sentinel XL owners to adapt their system to HD drug applications.

Sentinel XL USP 800 Kits		Air Delivery System			Hoods and Head Covers			Power Supply			Suspension	Carriers	Filters
Description	Part number	Blower	Flow Meter	HP Breathing Tube (33 inch)	Head Cover (white)	BioShield Full Hood with taped seams	Sentinel Clear Hood	Battery Rechargeable NiMH	Smart Battery Charger	Alkaline Battery Pack	Quick-Loc™ Waist Belt	HP Duffie Bag	OV/AG Filter Cartridges
		S-2002	S-2010	S-4005	S-4001	S-2028	S-3101	S-2003	S-2009	S-4013	S-4011	S-2020	S-4012
HP Sentinel Full Hood System with alkaline pack (USP 800)	S-3000-25	■	■	■		■				■	■	■	■
HP Sentinel Full Hood System with NiMH battery (USP 800)	S-3000-26	■	■	■		■		■	■		■	■	■
HP Sentinel Clear Hood System with alkaline pack (USP 800)	S-3000-27	■	■	■			■			■	■	■	■
HP Sentinel Clear Hood System with NiMH battery (USP 800)	S-3000-28	■	■	■			■	■	■		■	■	■
Sentinel Head Cover HD Conversion Kit (USP 800)	S-3000-29			■	■								■
Sentinel Clear Hood HD Conversion Kit (USP 800)	S-3000-30			■			■						■
Bioshield™ Full Hood HD Conversion Kit (USP 800)	S-3000-31			■		■							■



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