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## Pharmaceutical industry best practice.



#### Suggested containment control strategy and personal protective equipment based on active pharmaceutical ingredient occupational exposure banding.

In order to properly use the information contained in the tables below, active pharmaceutical ingredients (API) must be evaluated and placed into an Occupational Exposure Band (OEB).

Occupational exposure banding, also known as hazard banding, or health hazard banding, is a process intended to quickly and accurately assign chemicals into specific categories (bands), which correspond to a range of exposure concentrations designed to protect worker health. These bands are assigned based on a chemical's toxicological potency and the adverse health effects associated with exposure to the chemical. The output of this process is an occupational exposure band. [McKernan L, Seaton M, Gilbert S [2016]. The NIOSH Decision Logic for OEBs: Applying Occupational Exposure Bands. The Synergist (March 2016)].

Each band describes a distinct range of Occupational Exposure Limits (OELs), grouped so that a single recommendation for exposure control technology and personal protective equipment (PPE) can adequately protect employees engaged in similar tasks or process.

Information and tables included in this document are not intended to cover all tasks or situations, and may not be applicable for some or all of a company's specific operations. Regional and country personal protective equipment (PPE) regulations and respiratory protective equipment (RPE) assigned protection factors (APF) vary between countries and therefore the suggested PPE ensemble may not be suitable in all cases. A detailed risk assessment should be conducted to determine applicability.

#### How to use this best practice guide

Use of this guide and suggestions herein are not a substitute for a complete and robust risk assessment and exposure assessment program. Good industrial hygiene and occupational exposure banding practices should be implemented and followed.

Suggested containment control strategy

- 1. Identify the operation/activity to be performed in the far-left column of the chart
- 2. Identify the OEB of the API handled or processed during the operation/activity in the top row of the chart
- 3. Find the intersection point of the identified OEB and activity. This is the suggested containment control strategy for the activity performed

	Occupational Exposure Band (OEB)					
Activity	OEB 1 and 2 (> 100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ΟΕΒ 4 (> 1 - 10 μg/m <sup>3</sup> )	ОЕВ 5 (< 1 µg/m³)		
Dispensing/weighing - wet powders	NA	LEV	LEV or down flow booth	Down flow booth with barriers or curtains or isolator with contained transfer ports		

Figure 1: EXAMPLE - Dispensing/weighing wet powder in OEB 4

#### Pharmaceutical industry best practice.

Suggested personal protective equipment

- 1. Identify the operation/activity to be performed in the far-left column of the chart
- 2. Identify the OEB of the API handled or processed during the operation/activity in the top row of the chart
- 3. Find the intersection point of the identified OEB and activity. This is the suggested personal protective equipment for the activity performed, without regard to engineering controls/containment

		Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 (> 1000 µg/m³)	ОЕВ 2 (> 100 - 1000 µg/m³)	OEB 3 (> 10 - 100 μg/m <sup>3</sup> )	OEB 4 (< 1 µg/m³)	OEB 5 (< 1 µg/m³)	
Weighing powders	Filtering Face Piece (FFP) or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Turbo Hood 3 Powered Air Purifying Respirator (PAPR) with full hood or class ¾ supplied air, gloves.	Class TH3 PAPR with full hood or class <sup>3</sup> / <sub>4</sub> supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category III), and booties.	Class TH3 PAPR with full hood or class <sup>3</sup> / <sub>4</sub> supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category III), and booties.	

Figure 2: EXAMPLE - Weighing powder in OEB 3

## Suggested containment control strategy for lab and areas outside manufacturing and pilot plant.

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

#### Table A

	Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 and 2 (100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m <sup>3</sup> )	ОЕВ 4 (>1 - 10 µg/m³)	ОЕВ 5 (< 1 µg/m³)	
Sample transfer	÷ ,	ntainer or zip-lock c bags	Double sealed container (e.g. bottle in bag)		
Dry powders weighing and handling (drying etc.)	Open handling <1g API permitted (Vented Balance Safety Enclosure (VBSE) recommended) >1g VBSE required	VBSE	VBSE or isolator (if quantity >10g) with appropriate contained transfer device	VBSE or isolator (if quantity >1g) with appropriate contained transfer device	
Wet Powders handling (weighing, filtration and cake handling)	Containment hood		Containment hood. For quantities >100 g, use VBSE or isolator	Containment hood. For quantities >10 g, use VBSE or isolator	
Solution/suspension handling. Open bench permitted with spill trays. Containment hood if solvents are used or aerosolisation may occur	Open bench permitted. Containment hood if solvents are used or aerosolisation may occur			tted with spill trays. if solvents are used ion may occur	
Tablets (coated uncoated) and capsules manipulation VBSE or containment hood	VBSE or cont	ainment hood	VBSE or conta	ainment hood	
Returned sample handling of broken or leaking presentations and uncoated tablets VBSE Recommended	VBSE recommended		VBSE reco	ommended	
Returned sample handling of intact: coated tablets, capsules, vials, patches, bottles open handling	Open h	andling	Open h	andling	

# Suggested PPE for lab and areas outside manufacturing and pilot plant. For operations with insufficient and/or unverified engineering controls.

For operations with insufficient and/or unverified engineering controls.

This chart offers suggestions only and should not be used without verifying that the Personal Protective Equipment (PPE) is appropriate for your unique situation.

#### Table B

	Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 and 2 (100 µg/m³)	OEB 3, 4 and 5 (< 100 μg/m³)			
Powder manipulation	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves and appropriately fitted filtering facepiece respirator			
Solutions and suspensions (no aerosols)	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves, lab coat, safety glasses and spill trays			
Potentially contaminated batch record handling	NA	Minimum required lab PPE, gloves, lab coat and safety glasses			
Returned sample handling of broken or leaking presentations and uncoated tablets	Minimum required lab PPE, gloves	Minimum required lab PPE, gloves, lab coat and safety glasses			

## Suggested Personal Protection Equipment for production/pilot plant (without regards to engineering controls/containment strategy).

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

#### Table C

		Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 (1000 µg/m³)	ОЕВ 2 (> 100 - 1000 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 µg/m³)	
Weighing	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	
QA sampling	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	
Granulation/ compounding and other powder manipulation processes area. (assuming EC not at prescribed levels)	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	

GMP = Good Manufacturing Process

APF = Assigned Protection Factor

r PAPR = Powered Air Purifying Respirator

HEPA= High Efficiency Particulate Air

	Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 (1000 µg/m³)	ОЕВ 2 (> 100 - 1000 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 µg/m³)
Compression/ encapsulation	Gloves, long sleeved GMP clothing and safety equipment for the area. Unless hand scooping is used then FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, GMP and safety equipment for the area.	Class TH3 PAPR with full hood or class 3/4 supplied air, gloves.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.
	Coating Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Working in the area before or after the pan has been changed - FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Working in the area before or after the pan has been changed - FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves
Coating		Charging the coating pan - FFP or half mask respirator, gloves, GMP clothing and safety equipment for the area.	Charging the coater - Class TH3 PAPR with full hood or supplied air, gloves.	Charging the coater - Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	(taped cuffs), disposable or launderable coveralls (category 111), and booties.
Solutions/ suspensions (no aerosolisation or powders.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.

		Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 (1000 µg/m³)	ОЕВ 2 (> 100 - 1000 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 µg/m³)	
Packaging (uncoated tablets, hot side work)	Gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area. During cleaning and hopper filler operator - Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	
Packaging coated tablets, capsules, liquids or cold side work)	Gloves, long sleeved GMP clothing and safety equipment for the area.	Gloves, long sleeved GMP clothing and safety equipment for the area.				
	BIBO (Bag In Bag Out) HEPA's should be used.	BIBO HEPA's should be used.	BIBO HEPA's should be used for HEPA cartridge change out.	BIBO HEPA's should be used for HEPA cartridge change out.	BIBO HEPA's should be used for HEPA cartridge change out.	
Dust collector change out (HEPA or waste)	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	

BIBO= Bag In Bag Out

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		Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 (1000 µg/m³)	ОЕВ 2 (> 100 - 1000 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 µg/m³)	
Personal decontamination required			Decontamination procedure required	Decontamination procedure required	Decontamination procedure required	
	Decontamination	Decontamination	PPE decontamination is required upon leaving the area.	PPE decontamination is required upon leaving the area.	PPE decontamination is required upon leaving the area.	
	procedure required	Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials, etc	Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials, etc	Ensure contamination doesn't occur or isn't spread outside the area (personnel and equipment, materials, etc		
Emergency containment breaches	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	FFP or half mask respirator, gloves, long sleeved GMP clothing and safety equipment for the area.	BIBO HEPA's should be used for HEPA cartridge change out.	Class TH3 PAPR with full hood or supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	Class TH3 PAPR with full hood or class 3/4 supplied air, double gloves (taped cuffs), disposable or launderable coveralls (category 111), and booties.	

#### Suggested containment control strategy for production or pilot plant.

This chart offers suggestions only and should not be used without verifying that the technology works for your unique situation.

#### Table D

	Occupational Exposure Band (OEB)			
Activity	ОЕВ 1 and 2 (> 100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m³)	ОЕВ 4 (> 1 - 10 µg/m³)	OEB 5 (< 1 μg/m³)
Dispensing/weighing - wet powders	NA	LEV	LEV or down flow booth	Down flow booth with barriers or curtains or isolator with contained transfer ports
Dispensing/weighing - dry powders	LEV	LEV or down flow booth or ventilated enclosure	Down flow booth with barriers or curtains or isolator with contained transfer ports	lsolator with contained transfer ports
Dispensing dry powders into liquids. Appropriate contained transfer technology, (e.g. SBV, PTS, DCS, etc), direct connection between processing units or isolator. Solids/liquids disperser/homogeniser - recommended	Solids/liquids disperser/homogeniser - recommended		Appropriate contained transfer technology, (e.g. SBV, PTS, DCS, etc), direct connection between processing units or isolator Solids/liquids disperser/homogeniser - recommended	
Powder Sampling (when dedicated sampling port is not available)	LEV	LEV or down flow booth	Down flow booth	PAT, isolator or through appropriate contained transfer device
TD centrifuge discharge isolator/glove bag or change technology	NA		lsolator/glove bag or change technology	
BD centrifuge discharge	NA	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports

	Occupational Exposure Band (OEB)			
Activity	ОЕВ 1 and 2 (> 100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m <sup>3</sup> )	ОЕВ 4 (> 1 - 10 µg/m³)	OEB 5 (< 1 μg/m³)
Hor. centrifuge discharge	NA	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports
Inv. basket centrifuge discharge	NA	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner	Appropriate contained transfer device or isolator with contained transfer ports
Other liquid filtration systems when solids are waste	NA	Thoroughly wash out the unit before opening for disposal	Safely dispose after proper wetting. Use disposable bags/cartridges if possible. Dispose in contained manner, e.g. while using "Bag in Bag" or "Cartridge in Bag" technology	
Filter dryer discharge	LEV or suitable enclosue	Suitable enclosue (e.g. inflatable seal)	Suitable continuous liner or other appropriate contained transfer technology	
Fluidised bed dryer or spray dryer charging	LEV	LEV and direct connection or remote charging	Appropriate contained transfer using vacuum, gravity or both. (SBV or similar if disconnections are required)	
Fluidised bed dryer or spray dryer discharging	LEV	LEV and direct connection	Contained transfer technology (vacuum system for side discharge or bottom gravity discharge with SBV)	
Fluidised bed dryer or spray dryer cleaning WIP or glove bag/box isolator	HEPA vacuum a	nd wet methods	WIP or glove b	ag/box isolator
Tray dryer change. NA if material is wet enough if not see discharge below	LEV reco	mmended		is wet enough charge below
Tray dryer discharge down flow booth with barriers or Down flow booth with barriers or curtains, isolator or change technology (one pot etc.)	LEV or down flow booth		curtains, isolator or	h with barriers or change technology ot etc.)
Lyophilising/freeze drying discharge down flow booth with barriers or curtains or isolator	LEV			h with barriers or or isolator
Lyophilising/freeze drying cleaning WIP, vial wash down or glove bag/box isolator	HEPA vacuum a	nd wet methods	WIP, vial wash down or glove bag/box isolator	

	Occupational Exposure Band (OEB)				
Activity	ОЕВ 1 and 2 (> 100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m <sup>3</sup> )	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 μg/m³)	
Vacuum dryers charge/ discharge direct connection with appropriate contained transfer device	Direct connection		Direct connection with appropriate contained transfer device		
Vacuum dryers cleaning WIP or CIP through appropriate contained transfer device	Direct connection			o contained transfer or built in	
Tumble blending (V, bin cone), charging/discharging	LEV	LEV and direct connection	Appropriate contained transfer device		
Tumble blending (V, bin cone), cleaning WIP or CIP through appropriate contained transfer device or built in	HEPA vacuum and wet methods		WIP or CIP through contained transfer device or built in		
High sheer mixing/ granulating charge/discharge	LEV	LEV and direct connection	Appropriate contained transfer device		
High sheer mixing/ granulating heel removal	LEV	LEV and direct connection	Isolator/glove bag for product heel removal or one pot processor		
High sheer mixing/granulating cleaning WIP or CIP through appropriate contained transfer device or built in	HEPA vacuum a	nd wet methods	WIP or CIP through contained transfer device or built in		
Tablet coating charge appropriate contained transfer device	LEV (may be built in)		Appropriate contai	ned transfer device	
Tablet coating cleaning WIP (may be built in)	HEPA vacuum and wet methods		WIP (may	be built in)	
Roller compactor charge/discharge	LEV or down flow booth	LEV and direct connection or down flow booth		ned transfer device, oof seals	

	Occupational Exposure Band (OEB)			
Activity	ОЕВ 1 and 2 (> 100 µg/m³)	ОЕВ 3 (> 10 - 100 µg/m <sup>3</sup> )	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 μg/m³)
Roller compactor cleaning WIP/CIP or isolator	HEPA vacuum a	nd wet methods	WIP or CIF	or isolator
Milling cleaning WIP/CIP or isolator	HEPA vacuum a	nd wet methods	WIP or CIF	or isolator
Milling charge, discharge and operation	LEV or down flow booth			ned transfer device, oof seals
Sieving/screening charge/discharge	LEV or down flow booth	LEV and direct connection or down flow booth	Appropriate contained transfer device, leak proof seals	
Sieving/screening cleaning WIP/CIP or isolator	HEPA vacuum and wet methods		WIP or CIP or isolator	
Packaging hopper filling and operation (uncoated tablets or powder filling). Appropriate contained transfer device for the hopper (if possible), and contained ventilated filler	LEV at hopper and filler		Appropriate contained transfer device for the hopper (if possible), and contained ventilated filler	
Packaging hopper/filler cleaning (uncoated tablets or powder filling) WIP, mist in place or isolator	HEPA	vacuum	WIP, mist in pl	ace or isolator
Compression and encapsulation charging	LEV	LEV and drum lift and direct connection	Appropriate contained transfer device	
Compression and encapsulation in process checks automated or contained (VBSE, etc.)	NA		Automated or cont	tained (VBSE, etc.).
Compression/encapsulation product recovery	LEV	LEV and direct connection	Cyclone with co	cuum system or ontained transfer WIP or CIP

	Occupational Exposure Band (OEB)				
Activity	OEB 1 and 2 (> 100 μg/m³)	ОЕВ 3 (> 10 - 100 µg/m <sup>3</sup> )	ОЕВ 4 (>1 - 10 µg/m³)	OEB 5 (< 1 μg/m³)	
Compression/encapsulation cleaning WIP or CIP or isolator	HEPA vacuum		WIP or CIP or isolator		
Extruding and spheronising charging/discharging appropriate contained transfer device	LEV		Appropriate contained transfer device		
Extruding and spheronising cleaning WIP or CIP or isolator	HEPA vacuum and wet methods		WIP or CIP or isolator		
Vacuum cleaner bag change out BIBO filter change and appropriate contained transfer device	LEV		BIBO Filter change and appropriate contained transfer device		
Container typer suitable container - required	Suitable container - recommended		Suitable container - required		
Transdermal film coating additional specific local ventilation or containment recommended to control volatile APIs or solvents	Additional specific local ventilation or containment recommended to control volatile APIs or solvents		Additional specific local ventilation or containment recommended to control volatile APIs or solvents		
Personnel decontamination methods required - misting shower for decontamination of personnel PPE, etc., policy and training unless in controlled containment: recommended	NA		required - misting shower for decontamination of personnel PPE, etc., policy and training unless in controlled containment: recommended		
Equipment/material transfer contaminated items must be cleaned or contained prior to transfer. Cleaning with compressed air is not allowed	Contaminated items must be cleaned or contained prior to transfer. Cleaning with compressed air is not allowed		Contaminated items must be cleaned or contained prior to transfer. Cleaning with compressed air is not allowed		
Batch record handling electronic batch records or glove box or recording done in a uncontaminated area unless, in controlled containment - NA	NA		Electronic batch records or glove box or recording done in a uncontaminated area unless, in controlled containment - NA		

#### Pharmaceutical industry best practice.

APF	Assigned Protection Factor	LEV	Local Exhaust Ventilation	
ΑΡΙ	Active Pharmaceutical Ingredient	NA	Not Applicable	
BIBO	Bag In Bag Out	OEB	Occupational Exposure Band	
BD	Bottom Discharge	OEL	Occupational Exposure Limit	
BSC	Bio-safety Cabinet	PAT	Process Analytical Technology	
CIP	Clean In Place	PPE	Personal Protective Equipment	
DCS	Distributed Control System	PTS	Powder Transfer System	
FA	Fresh Air	SBV	Split Butterfly Valve	
FBD	Fluidised Bed Dryer	TD	Top Discharge	
GMP	Good Manufacturing Process	V	V-shaped style tumble blender	
HEPA	High Efficiency Particulate Air IPI - Isolated Process Intermediate Isolator - Glove Box or Flexible Glove Bag		Ventilated Balance Safety Enclosure	
			Wash In Place	

#### Disclaimer

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