

Closed System Transfer Device Reconstitution and Administration Components

Vial Adaptor With Toxi-Guard® technology

TECHNICAL DATASHEET

The Chemfort[™] Vial Adaptor family is PVC-free and offers 4 sizes that firmly connect onto any standard vials, that have a cap dimension of 13 & 20 mm (ref. MG245248), 28 mm (ref. MG245266) or 32 mm (ref. MG245269). Equipped with the Toxi-Guard[®] technology, an immediate pressure equilibration is ensured, reducing the extra step of pre-priming. The Toxi-Guard[®] system contains a 100% activated carbon drug binding matrix (charcoal) and a 0.2 micron hydrophobic and oleophobic membrane. The membrane prevents airborne contaminants and particles from entering the drug or fluid path. The active carbon prevents the escape of cytotoxic and other hazardous drug vapors, aerosols and droplets into the environment during drug reconstitution.

Once connected to the Chemfort[™] Syringe Adaptor/Syringe Adaptor Lock, a safe drug transfer is made possible from the vial to another container (e.g. a semi-rigid bottle, an infusion bag, an elastomeric pump or a medication cassette reservoir for an ambulatory infusion pump).

The intuitive design makes it easy to use: with minimal effort both Chemfort[™] components can be connected and a "click" sound will indicate a safe connection. A pinch on the SA/SAL wings will disconnect the two components. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. Also, in case of multiple-use vials, a protective cap can be used for safe storage of the vial.

The Chemfort[™] portfolio has no known incompatibilities with hazardous drug solvents.

Indications for Use:

Chemfort[™] is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol, or liquid form during preparation, reconstitution, compounding and administration, minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs.

Chemfort[™] prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.



Chemfort[™] Keeps you safe. Simply click

Vial Adaptor

TECHNICAL DATASHEET

		Vial Adaptor 20 mm with 13 mm Convertor	Vial Adaptor 28 mm	Vial Adaptor 32 mm		
Order Information	Article number / Reference	MG245248	MG245266	MG245269		
	User box quantity	50 pcs	20 pcs	25 pcs		
	Transport box quantity	200 pcs	80 pcs	100 pcs		
Product Characteristics	Product technical data					
	Cap dimension of fitting vial	13 & 20 mm	28 mm	32 mm		
	External fitting	Tight circular grip around the neck of the vial	Tight circular grip around the neck of the vial	Tight circular grip around the neck of the vial		
	Spike type	2-way spike with separate air and fluid path	2-way spike with separate air and fluid path	2-way spike with separate air and fluid path		
	Protective cap	Yes (white)	Yes (white)	Yes (blue)		
	Fluid path volume	0.15 ml	0.15 ml	0.15 ml		
	Membrane pore size	0.2 micron	0.2 micron	0.2 micron		
Tolerates desinfection with alcohol 70% and chlorhexidine in alcohol (5 mg/70% alcohol)	Septum piercings	Up to ten times	Up to ten times	Up to ten times		
	Shelf life	3 years	3 years	3 years		
	Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide		
Material	Component	Material	Material	Material		
Specifications	Spike	Polypropylene	Polypropylene	Polypropylene		
	Injection point cover	Polyethylene	Polyethylene	Polyethylene		
	Elastomeric sealing	Polyisoprene	Polyisoprene	Polyisoprene		
Free of PVC, DEHP and Latex. Non-Pyrogenic. Free from lead, cadmium, arsenic and chrome. Meets standards and regulations with regards to the environment	13 mm convertor	PET				
	Protective cap	Polypropylene	Polypropylene	Polypropylene		
	0.2 micron membrane	Acrylic co-polymer	Acrylic co-polymer	Acrylic co-polymer		
	Charcoal filter	Charcoal Zorflex®	Charcoal Zorflex®	Charcoal Zorflex®		
	Filter base	Polypropylene	Polypropylene	Polypropylene		
	Filter cover	PET	PET	PET		
Regulation	CE 0483					
-	EDA E40/lc) Classed up des 0	ND product code	FDA 510(k) Cleared under ONB product code			

Symbols taken from ISO 15223-1:2016









Keep away from sunlight



STERILE EO

Donawa Lifescience Consulting Srl REP Piazza Albania 10, 00153 Rome, Italy

Non-

pyrogenic



CE0483

Disposal of components should be according to local regulations and procedures for handling of hazardous drugs





SIMPLIVI∧[™] Simplivia Healthcare Ltd. North Industrial Zone

P.O. Box 888 Kiryat Shmona, Israel 1101801





in

