

Information on SVHC on Substances of Very High Concern (SVHC Candidates) in articles acc. to REACH

References to the individual articles contained within a product group are part of separate article statements which can be found on the Fresenius Medical Care website: https://www.freseniusmedicalcare.com/en/svhc/

Product group Immunosorba Accessories Kit Art-ADAsorb

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
F00009150	ART Inlet Line Immunosorba	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009151	ART Plasma Line Immunosorba	"Adsorber lines"	
F00009146	ART ADAsorb Infusate Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
5030321	HEPARIN NEEDLE LUER-LOCK 30 ML	"Heparin Needle"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	·

Product group Immunosorba Accessories Kit Art-ADAsorb w/o NaCl

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
F00009150	ART Inlet Line Immunosorba	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009151	ART Plasma Line Immunosorba	"Adsorber lines"	
F00009146	ART ADAsorb Infusate Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
5030321	HEPARIN NEEDLE LUER-LOCK 30 ML	"Heparin Needle"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ



Product group Globaffin Accessories Kit Art- ADAsorb

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
F00009147	ART Inlet line	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009149	ART Plasma line	"Adsorber lines"	
F00009146	ART ADAsorb Infusate Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
5030321	HEPARIN Needle LUER-LOCK 30 ML	"Heparin Needle"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	

Product group Globaffin Accessories Kit Art- ADAsorb w/o NaCl

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
F00009147	ART Inlet line	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009149	ART Plasma line	"Adsorber lines"	
F00009146	ART ADAsorb Infusate Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
5030321	HEPARIN NEEDLE LUER-LOCK 30 ML	"Heparin Needle"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ

Product group Monet-Kit

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
5004821	Monet	"Plasma filter"	
F00009147	ART Inlet line	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009152	ART Filtration Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	



Product group Monet-Kit w/o NaCl

Article number	Article name	Reference name for SVHC information	Comments
5008031	plasmaFlux P2 dry	"Plasma filter"	
5004821	Monet	"Plasma filter"	
F00009147	ART Inlet line	"Adsorber lines"	
F00009148	ART Outlet line	"Adsorber lines"	
F00009152	ART Filtration Line	"Adsorber lines"	
9796281	WASTE BAG 10L	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ

Product group Monet - BioRet Kit

Article number	Article name	Reference name for SVHC information	Comments
5004821	Monet	"Plasma filter"	
F00008600	BioRet Tubing Set	"Other: BioRet Tubing Set (ARIES Biomedical)"	

Product group DALI 500-Kit

Article number	Article name	Reference name for SVHC information	Comments
9795301	DALI 500-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	

Product group DALI 500-Kit w/o NaCl

Article number	Article name	Reference name for SVHC information	Comments
9795301	DALI 500-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	



Product group DALI 750-Kit

Article number	Article name	Reference name for SVHC information	Comments
9795311	DALI 750-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	

Product group DALI 750-Kit w/o NaCl

Article number	Article name	Reference name for SVHC information	Comments
9795311	DALI 750-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	

Product group DALI 1000-Kit

Article number	Article name	Reference to SVHC information	Comments
9795301	DALI 500-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
9795231	Adsorber-connector	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	



Product group DALI 1000-Kit w/o NaCl

Article number	Article name	Reference to SVHC information	Comments
9795301	DALI 500-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
9795231	Adsorber-connector	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	

Product group DALI 1250-Kit

Article number	Article name	Reference to SVHC information	Comments
9795301	DALI 500-ADSORBER	"Adsorber DALI"	
9795311	DALI 750-ADSORBER	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
9795231	Adsorber-connector	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00004549	NaCl 0,9% Frekaflex 1000mL	"FrekaFlex (NaCl solution"	
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	-

Product group DALI 1250-Kit w/o NaCl

Article number	Article name	Reference to SVHC information	Comments
9795301	DALI 500-ADSORBER(CE)	"Adsorber DALI"	
9795311	DALI 750-ADSORBER(CE)	"Adsorber DALI"	
9796281	WASTE BAG 10L	"Adsorber lines"	
9795201	DALI Inlet Bloodline	"Adsorber lines"	
9795211	DALI Return Bloodline	"Adsorber lines"	
9795231	Adsorber-connector	"Adsorber lines"	
F00010073	ACD-A Solution 1000 ml (Safe Lock)	"Other: ACDA-solution (Fresenius KABI)"	Article numbers might differ
F00009154	DALI Adsorber Pressure Line	"Adsorber lines"	

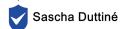


NB: REACH Article 3/3 defines "articles" as "objects which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

This statement represents our current state of knowledge and can be updated at any time. This statement does neither represent a guarantee of any product properties nor releases any party from its responsibilities, especially defined by local legislation. Fresenius Medical Care accepts no responsibility for injury or loss which may arise from reliance on information contained in this document.

Bad Homburg, 12.07.2022

—DocuSigned by Sascha Duttiné



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