

Fresenius Kabi 01.12.2009

REACH - Information according to Article 33 - Medicinal products

Dear customer,

On October 28, 2008 European Chemical Agency the http://echa.europa.eu) released the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 (REACH). According to Article 33 of REACH suppliers of articles are obliged to communicate information on substances which are on the candidate list to customers.

Medicinal products of Fresenius Kabi that are affected by Article 33 are those in PVC containers that contain more than 0.1% (w/w) of the plasticizer Bis(2-ethyl(hexyl)phthalate) (DEHP, EC number: 204-211-0).

Based on the strategy of Fresenius Kabi to replace PVC bags with polyolefin bags (Freeflex®) there are only few products which are supplied to the European market which are still in PVC containers due to the regulatory situation. These are listed in annex 1.

Yours sincerely,

Fresenius Kabi

Dr. Åndrea Bauer Senior Vice President

Quality Management Fresenius Kabi

Dr. Clemens Haas **REACH Manager**

Business Admin. & SCM

Annex 1

Product name	Article number	Container
B 27 formule 20	B236903	PVC bag
ELO HAES 6%	3028815, B223044	PVC bag
FORMULA ACD	B223011	PVC bag
GELOPLASMA	B224102, B224103, B224114,	PVC bag
	B224116, B224118, B224161	
Glucos 50mg/ml	142604	PVC bag
HAES STERIL 10%	3006321, B223047, B223050	PVC bag
HAES STERIL 6%	B223045, B223046	PVC bag
NaCl 0,9%	2295121, B285118, B285119,	PVC bag
	B285120, B285121	
Natriumklorid 9mg/ml	144485, 542753	PVC bag
Perusliuos-K	148734	PVC bag
PFX INFUPLAS	B224117	PVC bag
PLASMION	B224101	PVC bag
Ringer Acetat	144972, 145086	PVC bag
SFX 11 (Hartmann)	2295156	PVC bag
SFX 12	2288303	PVC bag
SFX 13	2288338	PVC bag
SFX 14	2288354	PVC bag
SFX 18	2295164	PVC bag
SFX 45	2312999	PVC bag