No use of PVC, DEHP, DINP and BPA

Product group:	Lactose, Biopharma, Inhalation, Starch, MCC & Superdisintegrants
Brand name:	Pharmacel®, Solani Amylum, Prejel PA5 PH, Lactochem®, Respitose®, Lactopress®, Lactohale®, Pharmatose®, Primojel®, SuperTab®, Primellose®, BioHale® Sucrose,Pharmacel® sMCC
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Dear Customer,

DFE Pharma GmbH & Co. KG excipients comply with the according pharmacopoeia monographs (please see corresponding product specifications for details).

These excipients are no phthalate esters and thus the EMA guideline on the use of phthalates as excipients in human medicinal products (EMA/CHMP/SWP/362974/2012 corr 2[1]), does not apply.

We, DFE Pharma, herewith declare that:

- Our primary and secondary packaging materials do not contain Poly Vinyl Chloride (PVC)
- We do not make use of Phthalates e.g. Di(2-ethylhexyl)-phthalate (DEHP) or Di-isononyl-phthalate (DINP) in our products
- We do not make use of Bisphenol A (BPA) during the production processes and in the primary packaging

This statement substitutes all previous versions issued for the brand names mentioned above. We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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