

Confirmation regarding absence of substances	Letter No.	Dress No.
	Date:	26.05.2023

#CHANGE CONTROL REPORT

Page / Edition	Replaces Page/ Edition	Reason for Change
1/1 26.05.2023	-	new

Department	Date	Signature
RP-MA-PMP-DE	26.05.2023	

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
hartmann.info

P.O. Box 1420
89504 Heidenheim
Germany



Helps. Cares. Protects.

PAUL HARTMANN AG, P.O. Box 1420, 89504 Heidenheim, Germany

For the exclusive use in tender applications
(supplied either by the HARTMANN GROUP
directly or through its customer)

Your ref.	Contact
-	
Your letter of	Phone
-	+49 7321 36 3175
Our Ref.	Fax
-	-
Date	E-Mail
26.05.2023	

Confirmation regarding the absence of substances

Dear Madam or Sir,

Herewith we confirm that all products and packaging belonging to the Foliodress® assortment, including the raw materials as well as the finished goods, are not intentionally made with the below listed substances. Furthermore, to the best of our knowledge, the substances are not used in the production processes.

- Biocides / Antimicrobial agents, (Definition of biocidal product according to Article 3 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council),
- PVC
- Formaldehyde (CAS no. 50-00-0, shall not exceed 75 ppm (75 mg/kg) in the product)
- Alkylphenol ethoxylates (APE, at higher levels in total 10mg/kg)
- Dyes and colorants above 50mg / kg of material (Dyes and colorants according to Regulation (EC) No. 1223/2009)
- CMR-/PBT-/vPvB-substances, Phthalates
- Added Natural Rubber latex

Additionally, we confirm that to the best of our knowledge the adhesive on all Foliodress® range of products including standard sets, drapes, and accessories, do not contain the monomers of acrylates, isocyanates, and epoxy. Further, we confirm that the self-adhesives which are used for the fixation on the patient, to the best of our knowledge do not contain colophony

This statement is only valid as long as there have been no changes in materials, intended use and/or applied standards. This statement replaces all previous statements on this topic.

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
hartmann.info

P.O. Box 1420
89504 Heidenheim
Germany



Helps. Cares. Protects.

Kind regards



ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Stefan Müller

Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim

Commercial Register of the District Court of Ulm file no. HRB
661090