

**Dr. Ralph Derra**

Öffentlich bestellter und vereidigter Sachverständiger für  
Verpackungsmaterialien, Boden- und Luftanalysen;  
Sachverständiger in der Wasseranalytik

11 July 2024

Dr. Dr/Ni-bau

UNBEDENKLICHKEITSERKLÄRUNG  
CERTIFICATE OF COMPLIANCE  
CERTIFICAT DE CONFORMITE

eingetragen  
registered no.  
registré

62462 U 24

für  
for  
pour

Paul Hartmann AG  
Paul-Hartmann-Straße 12  
89522 Heidenheim  
Germany

Produkt  
Product  
Produit

Peha-soft® nitrile white (Lot 399814004)

The nitrile gloves distributed by the company mentioned above are used in the food industry during the preparation and handling of food.

They were examined by us according to the

Methoden zur Untersuchung von Kunststoffen, soweit sie als Bedarfsgegenstände im Sinne des Lebensmittel- und Bedarfsgegenständegesetzes verwendet werden, einschließlich der 62. Mitteilung des BfR zur Untersuchung von Hochpolymeren, Bundesgesundheitsblatt 50, 524 (2007), Stand vom April 2007,

(Methods for testing plastics as far as they are used as consumer goods as defined by the Foodstuffs and Consumer Goods Act, including the 62<sup>nd</sup> memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

for the composition as well as for the release of substances which might endanger health and to the

Series of standards EN 1186, EN 13130 and CEN/TS 14234 "Materials and Articles in Contact with Foodstuffs – Plastics", current state,

for the migration behaviour.

The nitrile gloves are in compliance with the rules of the

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, lastly modified by article 5 of the Regulation (EU) 2019/1381 of 20 June 2019, Official Journal of the European Union L 231/1 of 6 September 2019, article 3, 1. (a) and (b),

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuches (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 15. September 2021 (BGBl. I S. 4253; 2022 I S. 28), zuletzt geändert durch Artikel 11 des Gesetzes vom 6. Mai 2024 (BGBl. 2024 I Nr. 149), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code - LFGB) in the version of the notification of 15 September 2021 (BGBl. I. p. 4253; 2022 I p.28), last amended by article 11 of the act of 6 May 2024 (BGBl. 2024 I no. 149), §§ 30 and 31).

They conform to the

BfR-Empfehlung XXI. Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk, neugefasst durch 225. Mitteilung, Bundesgesundheitsblatt 65 (2022) 525-526, Stand vom 01.04.2022, zuletzt geändert durch 226. Mitteilung, Bundesgesundheitsblatt 66 (2023) 216-217, Stand vom 01.02.2023,

(BfR Recommendation XXI. Commodities based on Natural and Synthetic Rubber, recast by 225<sup>th</sup> Announcement, Bundesgesundheitsblatt 65 (2022) 525-526, as of 1 April 2022), last amended by 226<sup>th</sup> Announcement, Bundesgesundheitsblatt 66 (2023) 216-217, as of 1 February 2023),

as well as to the

BfR-Empfehlung XXI/1. Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk, neugefasst durch 225. Mitteilung, Bundesgesundheitsblatt 65 (2022) 525-526, Stand vom 01.04.2022, zuletzt geändert durch 226. Mitteilung, Bundesgesundheitsblatt 66 (2023) 216-217, Stand vom 01.02.2023,

(BfR Recommendation XXI/1. Commodities based on Natural and Synthetic Rubber, recast by 225<sup>th</sup> Announcement, Bundesgesundheitsblatt 65 (2022) 525-526, as of 1 April 2022), last amended by 226<sup>th</sup> Announcement, Bundesgesundheitsblatt 66 (2023) 216-217, as of 1 February 2023),



and keep the applicable limits of the

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Official Journal of the European Union L 12/1 of 15 January 2011, last amended by Commission Regulation (EU) 2023/1627 of 10 August 2023, Official Journal of the European Union L 201/4 of 11 August 2023,

regarding individual constituents.

Thus, the nitrile gloves **Peha-soft® nitrile white (Lot 399814004)** according to the sample material submitted may be used safely in the food industry during the preparation and handling of food. They may stand in direct contact with all types of food for a short period of time.

The maximum ratio of the food contact surface of the gloves and the amount of food shall not exceed 8.4 dm<sup>2</sup> per 5 kg food. This is equivalent to a contact of the palm and back of both hands including fingers with 5kg food.

This certificate of compliance has a validity of 2 years and consists of 4 pages.

Certification decision



staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Weißblech und  
sonstigen Metallverpackungen auf ihre  
lebensmittelrechtliche Unbedenklichkeit

(Dr. Hillmann)  
Authorized food chemist

The translation of the above stamps is given on page 4.  
La traduction des estampilles est donnée en page 4.



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Lebensmittelrechtliche Unbedenklichkeit**

Dr. Ralph Derra

Authorized expert for the analyses of packaging materials, attested by the Chamber of Industry and Commerce.

Expert autorisé pour l'analyse des matériaux d'emballage, assermenté par la Chambre d'Industrie et de Commerce.

State registered expert for the analysis of contrasting samples of packaging materials of paper, board, plastics, glass, tin plate and other metallic packaging materials as to their suitability for use with foodstuffs.

Expert public pour l'étude du contrôle des contre-échantillons d'emballages de papier, cartons, plastiques, verre, fer-blanc et d'autres emballages métalliques concernant leur conformité alimentaire.



Dr. Ralph Derra

Authorized expert for the analyses of soil and air, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse du sol et de l'air, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

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Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.

Dieses Dokument ist eine Übersetzung einer deutschen Originalversion. In Streitfällen ist das Originaldokument die rechtlich bindende Version.

A file sample of the tested material is kept at the expert's office.

This document is a translation of an original in German. In case of dispute, the original document should be taken as authoritative.