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9 June 2021

Dr. Dr/Ha-hoe

**UNBEDENKLICHKEITSERKLÄRUNG
CERTIFICATE OF COMPLIANCE
CERTIFICAT DE CONFORMITE**eingetragen
registered no.
registré

54780 U 21

für
for
pourUPM Raflatac OY
Tesomankatu 31
33101 Tampere
FinlandProdukt
Product
Produit

RP31 Purus

The product manufactured by the company mentioned above is an adhesive grade, which is used for the reverse coating of labels intended for labelling blood bags.

Samples coated with the product 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 62nd memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

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

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

in consideration of the demands of the

DIN EN ISO 3826-1 „Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel“, Stand von 2020, Abschnitt 8.5 Anforderungen an das Etikett (e),

(DIN EN ISO 3826-1 „Plastics Collapsible Containers for Human Blood and Blood Components - Part 1: Conventional containers“, as of 2020, Paragraph 8.5 label requirements (e)),

for the migration behaviour in this particular application.

According to the analyses performed, the labels coated with the adhesive grade can meet the demands 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, modified by app. no. 5.17 of the regulation (EC) No 596/2009 of 18 June 2009, Official Journal of the European Union L 188 of 18 July 2009, article 3, 1. (a) and (b),

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 3. Juni 2013 (BGBl. I S. 1426), zuletzt geändert durch Artikel 97 der Verordnung vom 19. Juni 2020 (BGBl. I S. 1328), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code - LFGB) in the version of the notification of 3 June 2013 (BGBl. p. 1426), last amendment by article 97 of the decree of 19 June 2020 (BGBl. I p. 1328), §§ 30 and 31),

as far as the adhesive is concerned.

Applicable limit values laid down in 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 amendment by Commission Regulation (EU) 2020/1245 of 2 September 2020, Official Journal of the European Union L 288/1 of 3 September 2020,

are met by the samples coated with the adhesive grade.

Therefore the demand of the

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(DIN EN ISO 3826-1 „Plastics Collapsible Containers for Human Blood and Blood Components - Part 1: Conventional containers“, state of 2020, Paragraph 8.5 label requirements (e)),

that there should be no negative impact on the blood, is considered as met.

Thus the adhesive **RP31 Purus** according to the sample material submitted may be safely used for the reverse coating of labels intended for labelling blood bags.

This certificate of compliance represents the latest technical standard and is based on the certificate of compliance no. 49956 U 19 of 16 July 2019.

It has a validity of 2 years and consists of 4 pages.

Certification decision



Staatlich anerkannter Sachverständiger
zur Untersuchung der Gegenproben von
Verpackungsmitteln aus Papier, Papp,
Kunststoffen, Glas, Weißblech und
sonstigen Metallverpackungen auf ihre
Lebensmittelrechtliche Unbedenklichkeit


(Dr. Hasselberg)
Officially certified
and authorized food
chemist



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lebensmittelrechtliche Unbedenklichkeit**

Dr. Ralph Derra

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

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

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.

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.