

21 July 2021

Dr. Dr/Hf-hoe

UNBEDENKLICHKEITSERKLÄRUNG  
CERTIFICATE OF COMPLIANCE  
CERTIFICAT DE CONFORMITE

eingetragen  
registered no.  
registré

55048 U 21

für  
for  
pour

PJSC Sumykhimprom  
Kharkivska str., P.O.12  
40003 Sumy  
Ukraine

Produkt  
Product  
Produit

SumTITAN R-204  
SumTITAN R-206  
SumTITAN R-208  
SumTITAN R-2061  
SumTITAN R-2041  
SumTITAN R-2071

The titanium dioxide grades manufactured by the company mentioned above are used as colourants and fillers for the manufacture of plastic materials for food packaging.

They were examined by us according to the purity demands of the

BfR-Empfehlung IX. Farbstoffe zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände, neugefasst durch 218. Mitteilung, Bundesgesundheitsblatt 58 (2015) 1193, zuletzt geändert durch 222. Mitteilung, Bundesgesundheitsblatt 62 (2019) 1546, Stand vom 01.06.2019,

(BfR Recommendation IX. Colorants for Plastics and other Polymers used in Commodities, recasted by 218<sup>th</sup> Announcement, Bundesgesundheitsblatt 58 (2015) 1193, last amended by 222<sup>nd</sup> Announcement, Bundesgesundheitsblatt 62 (2019) 1546, as of 1 June 2019),

and the

BfR-Empfehlung LII. Füllstoffe, 167. Mitteilung, Bundesgesundheitsblatt 27 (1984) 289, zuletzt geändert durch 222. Mitteilung, Bundesgesundheitsblatt 62 (2019) 1546, Stand vom 01.06.2019,

(BfR Recommendation LII. Fillers, 167<sup>th</sup> Announcement, Bundesgesundheitsblatt 27 (1984) 289, last amended by 222<sup>nd</sup> Announcement, Bundesgesundheitsblatt 62 (2019) 1546, as of 1 June 2019),

as well as according to the purity demands of the

Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food adopted by the Committee of Ministers on September 13, 1989.

Furthermore, the titanium dioxide grades were examined according to the demands of the

DIN EN 71, part 3 "Safety of Toys, Migration of Certain Elements", state of August 2019.

The titanium dioxide grades comply with the demands 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 amendment by Commission Regulation (EU) 2020/1245 of 2 September 2020, Official Journal of the European Union L 288/1 of 3 September 2020,

as well as of the

BfR-Empfehlung IX. Farbstoffe zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände, neugefasst durch 218. Mitteilung, Bundesgesundheitsblatt 58 (2015) 1193, zuletzt geändert durch 222. Mitteilung, Bundesgesundheitsblatt 62 (2019) 1546, Stand vom 01.06.2019,

(BfR Recommendation IX. Colorants for Plastics and other Polymers used in Commodities, recasted by 218<sup>th</sup> Announcement, Bundesgesundheitsblatt 58 (2015) 1193, last amended by 222<sup>nd</sup> Announcement, Bundesgesundheitsblatt 62 (2019) 1546, as of 1 June 2019),

and the

BfR-Empfehlung LII. Füllstoffe, 167. Mitteilung, Bundesgesundheitsblatt 27 (1984) 289, zuletzt geändert durch 222. Mitteilung, Bundesgesundheitsblatt 62 (2019) 1546, Stand vom 01.06.2019,

(BfR Recommendation LII. Fillers, 167<sup>th</sup> Announcement, Bundesgesundheitsblatt 27 (1984) 289, last amended by 222<sup>nd</sup> Announcement, Bundesgesundheitsblatt 62 (2019) 1546, as of 1 June 2019),

as well as of the

Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food adopted by the Committee of Ministers on September 13, 1989.

Plastic materials manufactured with them 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 mentioned products are concerned.

Furthermore, the titanium dioxide grades are in compliance with the demands of the

DIN EN 71, part 3 "Safety of Toys, Migration of Certain Elements", state of August 2019, category III,

as well as of the

Code of Federal Regulations, Food and Drugs (FDA), 21 CFR Ch. I (April 1, 2020 edition), §178.3297.

Thus, the titanium dioxide grades **SumTITAN R-204**, **SumTITAN R-206**, **SumTITAN R-208**, **SumTITAN R-2061**, **SumTITAN R-2041** and **SumTITAN R-2071** according to the sample material submitted may be used safely as colourants and fillers for the manufacture of plastic materials for food packaging under precondition that the corresponding aluminium migration limits are checked on the finished products. Furthermore, the triethanolamine migration limit has to be checked on the finished products regarding the titanium dioxide grades **SumTITAN R-208** and **SumTITAN R-2041**. Regarding grade **SumTITAN R-2071** the trimethylolpropane migration limit has to be checked on the finished product.

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



Staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoff, Glas, Weichholz und  
sonstigen Metallverpackungen auf ihre  
Lebensmittelrechtliche Unbedenklichkeit

(Höfert)

Officially certified  
and authorized food  
chemist

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



**Staatlich anerkannter Sachverständiger zur Untersuchung der Gegenproben von Verpackungsmitteln aus Papier, Pappe, Kunststoffen, Glas, Weißblech und sonstigen Metallverpackungen auf ihre 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.

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Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.

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

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