



Lebensmittel - Zulassung gemäß

Verordnung (EG) Nr. 1935 / 2004

Verordnung (EU) 10 / 2011

FDA - Konform

Unbedenklichkeitserklärung gem. Verordnung (EG) Nr. 1935 / 2004 - Verordnung (EU) 10 / 2011

**Multiseal – Wellendichtring MS- Weiss
TEdiFLON – Supra HP – W**

Im Rahmen durchgeführter Untersuchungen nach Verordnung 10/2011, wurde festgestellt, dass das oben erwähnte Produkt, bzw. Material unverändert aus den Tests hervorgegangen ist und somit für den Kontakt mit Lebensmitteln eingesetzt werden kann. Die Migrationswerte liegen bei spezifischer Anwendung unter den gesetzlichen Grenzwerten. Damit erfüllt das oben genannte Produkt die Voraussetzungen und Anforderungen an Lebensmittelkontaktmaterialien aus Kunststoff gemäß Verordnung (EU) Nr. 10/2011 als Einzelmaßnahme im Sinne der Verordnung (EG) Nr. 1935/2004.

Certification of food - contact - products approval

In compliance with

Regulation (EG) No. 1935 / 2004

Regulation (EU) No. 10 / 2011

European approval for use in food contact

With respect to the analyzed parameters in compliance with EU-Regulation 10 / 2011 it was determined that the tested material or product mentioned above or mentioned within the purchase order is suitable for the use in food processing industries. As experienced from the test results the migration values of tested elements are well below the permitted threshold values or limits mentioned in the EU-regulation. Consequently the material or product fulfills all requirements and qualifications with respect to the so called food contact materials regarding EU-Regulations 10 / 2011 and 1935 / 2004.

FDA Standards - approval for use in food contact

Multiseal – Shaft Seal - MS-Standard and MS – Special - White

TEdiFLON – Supra HP – W - alternative Tedex white

TEdiFLON – Supra HP – B - alternative Tedex blue

TEdiFLON – Supra HP – R - alternative Tedex red

Additionally with respect to further analyzed parameters the material is qualified to get in contact with food according to FDA-Standards.

The Materials used in TEDIMA Multiseal – Standard and Multiseal – Special and TEdiFLON Supra HP – Sheet and Sealing Material (so called Tedex) consist of PTFE, inorganic Fillers and pigments for coloring:

Regarding the below listed TEdiFLON – Range (so called Tedex-Range) the related ingredients are listed as materials that comply with the FDA - Requirements.

The relevant material listings are given in several Codes of Federal Regulations Chapter CFR 21.ff as described below.

Material - Range	Components - Ingredients	CFR - Code FDA - Section
TEdiFLON Supra HP - R	PTFE according to	21 CFR § 177.1550
	Filler according to	21 CFR § 177.2600 article V
	Pigments according to	21 CFR § 177.2600 article VI and 21 CFR § 178.3297
	Coatings according to	21 CFR § 177.300
TEdiFLON Supra HP - B	PTFE according to	21 CFR § 177.1550
	Filler according to	21 CFR § 177.2600 article V
	Pigments according to	21 CFR § 177.2600 article VI and 21 CFR § 178.3297
	Coatings according to	21 CFR § 177.300
TEdiFLON Supra HP - W	PTFE according to	21 CFR § 177.1550
	Filler according to	21 CFR § 177.2600 article V
	Pigments according to	21 CFR § 177.2600 article VI and 21 CFR § 178.3297
	Coatings according to	21 CFR § 177.300

We therefore confirm that all materials used for TEdiFLON – Supra – HP – Sheets and Sealing Material (so called Tedex – Range) are listed as material which comply with the FDA – Requirements.

TEDIMA GmbH

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