



## Conformity with Regulations

Gasket & Lining Material

CRP-13-335

# F 217

PLASTIC FORMULATION

uncolored and white

### FOOD CONTACT <sup>(1)</sup>

#### US:

Is in compliance with F.D.A.: 21 CFR

- 177.1520 Olefin Polymers (c)3.2a
- 177.1350 Ethylene-vinyl acetate copolymers (a)(1)
- 175.105 Adhesives
- 175.300 Resinous and polymeric coatings
- 178.3297 Colorants for polymers

#### EU:

Is in compliance with Regulation (EC) No. 1935/2004 of the European parliament and of the Council on materials and articles intended to come into contact with food.

Has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Is in compliance with Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, effectively replacing Commission Directive 2002/72/EC and amendments.

All composing ingredients are listed in Annex I of Commission Regulation (EU) No. 10/2011, or otherwise authorized in accordance with the requirements laid down in this regulation.

Does not contain monomers which are regulated with a specific migration limit.

Contains one or more intentionally incorporated additives which are regulated with a specific migration limit:

Tris(methylene diphosphoryl) phosphate EC Ref. No. 74400	SML=30mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate EC Ref. No. 68320	SML=6mg/kg
Zinc Oxide EC Ref. No. 96240	SML=25mg/kg

...\*

<sup>(1)</sup> For general information, please refer to the website: [www.triseal.com](http://www.triseal.com)

This document is a technical specification and is not intended to be used as a contract. It is subject to change without notice. The user of this document is advised to check the latest version of this document on the website: [www.triseal.com](http://www.triseal.com)

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Contains one or more intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex IV of Commission Regulation (EU) No. 10/2011:

...\*

Overall (OML) migration testing was performed on a representative sample under the following conditions:

- Sample specification: F 217-5
- Sample thickness: 1,5mm
- Food simulants: A, B, D2 (representing contact with all food types)
- Test conditions: 10 days at 40°C

The overall migration limit (OML) of 10mg/dm<sup>2</sup> was not exceeded.

The results of this test do not exclude the possibility that this material will still comply under other test conditions.

No specific (SML) migration testing was performed on this material.

Please note that it is the responsibility of every actor within the supply chain to ensure compliance to the existing Regulations for every step under his responsibility. It remains the responsibility of the food packager to ensure the suitability of our product for a specific use with a specific type of food through testing

*Faint text, likely a reference to a certificate or test report.*

*We verify that after migration test by Tekni-Plex Europe NV, the product remains in compliance with above mentioned information.*

Best Client  
Product Steward  
Tekni-Plex Europe NV

Also belongs to the Group of Companies

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*Faint text, likely a disclaimer or legal notice.*

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## Declaration of Conformity / Safe-Gard® Type B SG-205

Article No.: Safe-Gard® Type B SG-205

We hereby confirm that the product " Safe-Gard® Type B SG-205 (Cardboard 900my / Adhesive / Paper uncoated 60g / Adhesive / PET film 12my / Wax 6g/m<sup>2</sup> / Paper uncoated 60g / PE film 14my / Aluminium 25my / Surlyn film 23g)" fulfils the requirements of the EU common and national regulations in the appropriate current version for direct or indirect contact with food. In particular this is valid for the following regulations:

- 1.) EU-Regulation 1935/2004 regarding materials that are intended to be in contact with food
- 2.) EU-Regulation 10/2011 and all amendments, including EU Regulation 98/8/EG of 8 Februar 2011, EU Regulation 1282/2011 of 28. November 2011, EU Regulation 1183/2012 of 30. November 2012
- 3.) BfR-Recommendations XXVIII, BfR XXV, XXXVI, XVII
- 4.) Foodstuffs Act (LFGB) § 30 and § 31
- 5.) FDA-Paragraphs CFR 21 § 175.105, § 175.300, § 176.180, § 176.260, § 176.320, § 177.1630
- 6.) EU-Packaging guidelines 94/62/EC, especially, article 11 (heavy metal content) and addendum 2004/12/EC
- 7.) CH-Regulation on materials SR 817.0, SR 817.02 und SR 817.023.21 of 01, April 2010
- 8.) EU-Regulation 2023/2006 on good manufacturing practice for materials with food contact
- 9.) The Commodities Regulation: Revised version of 23.12.97 (last amended on 23.09.09)
- 10.) CEPE/EuPIA
- 11.) Use of aluminum according to DIN EN 602, EN 573 and ASTM B479

According to the statement of our suppliers, the above named product contains the following substances, which have the specific migration limits (SML), and do not exceed the threshold value. This information is to be treated as confidential and may not be passed on to third parties:

Description	PM Ref.No	CAS-No.	Critical value
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	2082-79-3	SML = 6 mg/kg
3,5-Di-tert-butyl-4-hydroxytoluene (BHT, E321)	46640	128-37-0	SML = 3 mg/kg
Refinde waxes	95859	-	-
Wax	95858	-	SML = 0,05 mg/kg
2,4-bis(octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	40000	991-84-4	SML = 30 mg/kg
Ethylene glycol	16990/53650	107-21-1	SML = 30 mg/kg
Terephthalic acid	24910	100-21-0	SML = 7,5 mg/kg
Antimony trioxide	35760	1309-64-4	SML = 0,04 mg/kg
Phosphoric acid (E338)	23170/72640	7664-38-2	-
Diphenylmethane-4,4'-diisocyanate	16630	101-68-8	QMT = 1 mg/kg NCO
Vinylacetate	10120	108-05-4	SML = 12 mg/kg
Diethylene glycol	15760	111-46-6	SML = 30 mg/kg
Acetaldehyde	10060	75-07-0	SML = 6 mg/kg
2-Methyl-4-isothiazolin-3-on	66755	2682-20-4	SML = 0,5 mg/kg
2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	38560	7128-64-5	SML = 0,6 mg/kg
Zinkoxid	96240	1314-13-2	SML = 25 mg/kg



Methacrylsäure	20020	79-41-4	SML = 6 mg/kg
Calcium Carbonat (E170)	42500	471-34-1	SML = 50 mg/kg
Siliziumdioxid (E551)	86240	7631-86-9	SML = 60 mg/kg
Oleylpalmitamid	69840	16260-09-6	SML = 5 mg/kg

**Declaration concerning Dual Use:**

The following dual-use chemicals are being used: **E170, E321, E338, E551 and E650.**

**Specification for the intended use or restrictions:**

Type / types of foods to come into contact with the material:

fatty  
dry  
aqueous  
alcoholic

Duration and temperature of treatment and storage in contact with the food:

**Storage at room temperature up to 6 months**

Type / types of food that the material should not come into contact:

acid

Ratio of food contact surface area to volume, with which the compliance of the material or article was determined:

6 dm<sup>2</sup> / kg

**Shelf Life**

One year after production at 4,5°C - 43,3°C (40°F - 110°F) and maximum 75% r. H..

**Barrier values**

WVTR	< 0.01 g/m <sup>2</sup> 24h	38°C, 90% r.h. DIN 53122
O2TR	< 0.01 cm <sup>3</sup> /m <sup>2</sup> 24h atm	23°C, 0% r.h. DIN 53380





**Declaration on active and intelligent contact materials:**

The product contains no components of an active or intelligent packaging, as defined in Regulation 1935/2004/EC, respectively in VO 450/2009/EG.

**Statement Reg. 1935/2004/EC (framework regulation), traceability and marking:**

We confirm compliance with the GMP regulation in accordance with VO 1935/2004/EC. The demands required by these regulations for film and packaging manufactures in particular traceability and marking of products is fulfilled by us.

**Declaration concerning regulation (EU) No. 2023/2006 (GMP):**

The demands required by these regulations for film and packaging manufactures, in particular the existence of a quality assurance system, a quality control system and sufficient documentation of the production are met by us. Our quality system includes the necessary processes which guaranteed the microbiological purity and pest control. The Selig Switzerland Ltd is certified ISO9001, HACCP and BRC / IOP.

**Declaration concerning regulation (EC) No 1907/2006 (REACH):**

The product contains no chemicals of "Candidate List of Substances of Very High Concern for authorization" (SVHC) of ECHA (EC 1907 2006 (REACH)), version of 16. December 2013.

**Recycled plastics declaration (EU Directive 282/2008/EC):**

With regard to the EU Directive 282/2008/EC the product contains no recycled plastics.

**Declaration of genetically modified organisms (GMOs):**

The product do not contain any genetically modified organisms (GMOs) there is no gene technology during production. GMO contamination during production is not possible.

**Declaration concerning allergens (EU Directive 2000/13/EC and following (2003/89/EC)):**

The product contains no allergens according to Annex IIA of the EU Directive 2003/89/EC.

**Declaration of synthetic nano materials:**

The product is not produced with the help of nano technology and do not contain nanoscale particles.

**Declaration on phenols:**

Phenols are not intentionally added to the product.

**Declaration Epoxy derivatives**

Selig Switzerland Ltd confirms that the product is in compliance with the requirements of Articles 2, 3 and 4 of Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

**Declaration on Bisphenol A(BPA):**

Bisphenol A (BPA) are not intentionally added to this product and are not contained therein.



**Global migration:**

The test conditions for global migration were selected according to the requirements of Regulation (EU) No 10/2011. The sample was placed for 10 d at 40 ° C in contact with isooctane.

The migration was carried out according to EN 1186 in an external laboratory.

Under the test conditions following global migration value was determined under the limit of  $10 \pm 3$  mg/dm<sup>2</sup>: isooctane = 0.8 mg/dm<sup>2</sup>.

The suitability of our product needs to be evaluated in each case by processing and storage tests by the customer. The validity of the statements made hereby implies that our product is processed appropriately. Since we have no influence on the use of our product at the customer, we cannot assume any expressed or implied warranty or other liability in connection with the use of the information contained in this document.

Date: 24.01.2014 / Signature: Karin Meyer

R&D Supervisor for Food regulation and compliance

**Selig Group**

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This declaration of conformity contains the food regulatory information according to European and Swiss law, as per our present state of knowledge.