

STRUCTURE

PS 21 exists of

- release coating (= in the cap)
- polystyrene foam (available with SFYP print in black or red)
- pressure sensitive (PS) adhesive (= contact layer)

Property of Tekni-Plex

(1) Declaration based on certificates received from our suppliers.

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FOOD CONTACT ⁽¹⁾

US:

The composing ingredients are in compliance with FDA - 21 CFR:

- 177.1640 Polystyrene and rubber-modified polystyrene
- 177.1210 Closures with sealing gaskets for food containers
- 175.300 Resinous and polymeric coatings
- 175.125 Pressure-sensitive adhesives

PS 21 liners are manufactured under current Drug Master File # DMF 001378.

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.

Most ingredients are in compliance with Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet).

Adhesives and coatings are not plastics and are therefore not in scope of Commission Regulation (EU) No. 10/2011.

However, most components present in the adhesive composition are listed in the positive list of Commission Regulation (EU) No. 10/2011.

Based on information from our suppliers, the following substances which are regulated with a specific migration limit or other restriction/specification are present:

2,4-bis(octylthiomethyl)-6-methylphenol (756)		
EC Ref. No. 40020	CAS No. 110553-27-0	SML(T) = 5 mg/kg
2,6-di-tert-butyl-4-ethylphenol (477)		
EC Ref. No. 46720	CAS No. 4130-42-1	SML = 4,8 mg/kg
2,6-di-tert-butyl-p-cresol (315)		
EC Ref. No. 46640	CAS No. 128-37-0	SML = 3 mg/kg
acetic acid, vinyl ester (231)		
EC Ref. No. 10120	CAS No. 108-05-4	SML = 12 mg/kg
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (433)		
EC Ref. No. 68320	CAS No. 2082-79-3	SML = 6 mg/kg

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zinc

SML = 5 mg/kg

Contains the following 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:

2,6-di-tert-butyl-p-cresol (315)

EC Ref. No. 46640

CAS No. 28-37-0

E321

The above material is designed for contact with dry solid products only and is not to be used at temperatures above 20°C for extended periods of time.

No specific (SML) or overall (OML) 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. Since Tekni-Plex Europe nv is not always informed of the conditions under which its products are used or processed, it cannot make any other guarantees of compliance other than towards the composition. 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.

ALLERGENS ⁽¹⁾

Based on our suppliers' certifications on the materials used for the above compound, we can safely state that allergens as defined in Regulation (EU) No. 1169/2011 and amendments are not intentionally used. Allergens are neither produced nor stored at Tekni-Plex Europe nv.

PRINTING INKS ⁽¹⁾

The use of printing inks finding their application in food packaging materials is limited to exterior surface printing or lamination printing between film layers. In the latter case a layer with functional barrier is required. Based on supplier certifications the ingredients of the printing inks are listed on the Swiss Ordinance, Annex 6 (SR 817.023.21). Printing inks are no plastic materials and hence the Commission Regulation (EU) 10/2011 is not applicable. They are not yet covered by EU legislation.

HEAVY METALS ⁽¹⁾

Complies with CONEG Regulations on heavy metal content (the cumulative content of Pb, Cd, Hg and Cr(VI) does not exceed 100 ppm).

Complies with Commission Directive (EU) No. 94/62/EC and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet).

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REACH ⁽¹⁾

Does not contain any substances as part of the formulation which are classified carcinogenic, mutagenic, toxic to reproduction or dangerous for the environment exceeding the threshold of 0,1% w/w, according to Regulation (EC) No. 1272/2008 as amended and/or Regulation (EC) No. 1907/2006 as amended (i.e. up to the date of issuance of this Regulatory Data Sheet).

Does not contain SVHC substances in concentrations exceeding the legal threshold of 0,1% w/w, as published on the ECHA candidate list, current edition at the date of publication of this datasheet.

Since the presence of these substances are not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

Tekni-Plex Europe nv will actively inform its customer base in case ingredients that are part of the formulation become listed.

BSE/TSE ⁽¹⁾

Some of our raw materials are produced using substances of animal origin (additives based on fatty acids e.g. stearates). The manufacturing process of those substances includes a multistep chemical treatment involving high temperatures, high pressures and long residence time. Therefore, we can safely state that the material does not bear the risk of being contaminated with BSE/TSE infected materials according to the Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev. 3).

ROHS ⁽¹⁾

The chemical composition complies with Directive 2011/65/EU and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet) repealing Directive 2002/95/EC of the European Parliament and of the council on the restriction of use of certain Hazardous Substances in electrical and electronic equipment (RoHS).

CALIFORNIA PROPOSITION 65 ⁽¹⁾

None of the ingredients are expected to cause any contravention of the regulation of Safe Drinking Water and Toxic Enforcement Act of 1986, or the California Proposition 65 (current version).

Since the presence of these substances is not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

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CONFLICT MINERALS ⁽¹⁾

The above compound is a 100% synthetic product. Minerals do not form an integral part of the formulation, nor are minerals used in supporting or adjuvant production processes.

Based on the above, we can safely assume that minerals, especially conflict minerals, are not present in the above compound. Therefore we can state that the 2010 Frank-Dodd Wall Street Reform and Consumer Protection Act (more specifically Title XV section 1502) and the Regulation (EU) 2017/821 of the Parliament and of the Council and future amendments are not directly applicable to this compound, nor to the products produced, using this compound. Incidental presence of metal contaminants is not tested.

PRESENCE OF SUBSTANCES ⁽¹⁾

Based on our suppliers' certifications on the materials used for the above layer we state that the following substances are present in the finished product in concentrations not exceeding the legal limits:

- 1-hydroxy-4-((4-Methylphenyl)amino)anthraquinone (CAS No. 81-48-1)

ABSENCE OF SUBSTANCES AND CHEMICALS ⁽¹⁾

Based on our suppliers' certifications on the materials used for the above compound, we can safely state that the following substances are either not intentionally used, no longer present in the finished product or not present above applicable legal thresholds:

- Bisphenol A
- Dimethylfumerate (DMF)
- GMO
- Latex
- Melamine
- MOSH/MOAH
- Nanomaterials
- Nitrosamines
- Nitrocellulose
- Nickel
- Pesticides
- PFAS
- Phthalates
- PVC
- Residual solvents
- Trimethylolpropane triacrylate (TMPTA, CAS No. 15625-89-5)

Since the presence of these substances is not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

Tekni-Plex Europe nv

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