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08.09.2022

Declaration of compliance for materials and articles intended to come into contact with food

Pentaprint® PVC PR-M180/09-04/8400-482_8-ZZZ
Pentaprint® PVC PR-M180/09-04/8400-482D8-ZZZ
Pentaprint® PVC PR-M180/09-07/9400-482D8-ZZZ
Pentaprint® PVC PR-M180/23-04/8400-120_1-ZZZ
Pentaprint® PVC PR-M180/23-07/9400-120_1-ZZZ
Pentaprint® PVC PR-M180/23-51/9500-100_0-ZZZ
Pentaprint® PVC PR-M180/23-71/9400-100_0-ZZZ

The films are suitable for food contact in compliance with the following European Regulations:

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, as amended.

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, last amended by Regulation (EU) 2020/1245.

According Regulation (EC) No 1935/2004 specific substances not regulated in Regulation (EU) No 10/2011 like pigments comply with national regulations or applicable Recommendations of the Council of Europe.

The films do not contain any Post Consumer Recycling material.

The products are produced using Good Manufacturing Practice in accordance with Regulation (EC) No 2023/2006.

Overall migration

The overall migration limit of 10 mg/dm² area resp. 60 mg/kg of food for plastic materials and articles intended to be brought into contact with food intended for infants and young children is met under testing condition OM2, 10 d at 40°C in the food simulants A, B, D2

Specific migration

For substances with subject to specific migration limits (SML) - as listed in the annex - the compliance is ensured either by worst case calculation, when the content is known, by determination of the residual



content according Annex V 2.2.2. of Regulation 10/2011 or by migration measurements in contact with the appropriate food simulant for the substance under standardized testing condition according Annex V 2.1.4.: 10 d at 60°C.

Substances of annex II

The films comply with the specific migration limits of the substances of table 1 of annex II of Regulation (EU) No 10/2011.

Intended food contact conditions

Compliant for all type of foods for any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Ratio of food contact surface

For the above mentioned films article 17 (2) c) applies. Sheets and films that are not yet in contact with food, the compliance is established by a surface to volume ratio of 6 dm² per kg of food.

Dual Use Additives

Dual Use Additives according EU Regulation No 10/2011 are additives which are authorised for the manufacture of plastic materials and articles and at the same time authorised as food additive or flavouring substances. The film may contain dual use additives as listed in the annex.

Non-intentionally added substances – NIAS and degradation products

Annex IV paragraph 6 of Regulation (EU) No 10/2011 refers to degradation products for which restrictions and/or specifications are set out in Annexes I and II to this Regulation. The identified substances are listed in the annex of this declaration. Non-intentionally added substances have been risk assessed and no substances, for which genotoxicity has not been ruled out, have been identified exceeding the migration limit of 0,00015 mg/kg food.

European packaging directive

Additionally the products are in compliance with the European packaging directive 94/62/EC, amended by the directives 2004/12/EC, 2005/20/EC and 2013/2/EU.

General

The adherence to the requirements of the European Regulation (EC) No 1935/2004, particularly the suitability of the articles for the intended use, the effect to impairment of organoleptic characteristics such as smell and taste of the food as well as the compliance to all possible restrictions, must be guaranteed by the person, who brings the articles into the circulation.

It is the responsibility of the user to test the suitability of our products for the intended food application. We accept no liability for losses arising from the inadequate suitability of our products for the food.


This letter is intended for your company only and replaces previous declarations of compliance. After a break in delivery lasting more than 12 months, this letter ceases to be valid for new deliveries of the relevant product.

You will be informed of any changes in the composition of our above mentioned products which are relevant to food contact legislation.



This declaration is valid as long as no new or amended legislation comes into force and will then be updated accordingly.

Yours sincerely,
Klöckner Pentaplast Europe GmbH & Co. KG

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**Annex****Substances with specific migration limits (SML)**

Substance	Ref. No	SML (mg/kg food)
vinyl chloride	26050	QMA 1 mg/kg
acetic acid, vinyl ester	10120	12,00
alkyl(C8-C22)sulphonic acids	34230	6,00
mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	67680	1,20
di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	50320	0,006
monomethyltin tris(ethylhexyl mercaptoacetate)	67515	0,18 (T) (9)
dimethyltin bis(ethylhexyl mercaptoacetate)	49595	0,18 (T) (9)
2-ethyl-1-hexanol	17050	30,00
acrylic acid, n-butyl ester	10780	6,00 (T) 22
methacrylic acid, methyl ester	21130	6,00 (T) 23
butadiene	13630	QMA 1 mg/kg
soybean oil, epoxidised	88640	30,00 (reduced)
ethyleneglycol	16990/53650	30 (T) (2)
2,6-di-tert-butyl-p-cresol	46640	3,00
tert-butyl-4-hydroxyanisole	40720	30,00
adipic acid, bis(2-ethylhexyl) ester	31920	18,00
triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	94400	9,00
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	6,00
2,4-dimethyl-6-(1-methylpentadecyl)phenol	49485	1,00
crotonic acid	14800	0,05
divinylbenzene	16690	ND = 0,01
aluminium	-	1,00

(T): group SML

Non-intentionally added substances – NIAS and degradation products

The following substances are identified as NIAS or degradation products:

Substance	FCM substance No.	CAS No	Ref. No	SML (mg/kg food)
2-ethyl-1-hexanol	209	0000104-76-7	17050	30



Dual Use Additives:

Dual Use Additive	Ref. No	E-No.
glycerolester	-	E471
oxidized polyethylene wax	80077	E914
talc	92080	E553b
silica	86240	E551
aluminium silicate	62720	E559
citric acid	14680/44160	E330
methylhydroxypropylcellulose	66700	E464
butylated hydroxytoluene	46640	E321
calcium carbonate	42500	E170
sodium carbonate	42500	E500
sodium phosphate	-	E339
sodium adipate	-	E356
titanium dioxide 1)	93440	E171

1) if film is opacified with titanium dioxide

The information about the substances is based on our current state of knowledge and on information from our raw material suppliers.