



**Declaration of Compliance for Articles intended to come into Contact with Foodstuffs according to
Art. 16 of EU Regulation 1935/2004 and Annex IV of EU Regulation 10/2011**

We hereby confirm that our products:

- Stretch PVC film CE/C2
- Shrink PVC Film
- Stretch PVC film SMS
- Rigid PVC Film
- Stretch PVC film SAO

Comply with legal requirements laid down in the framework regulation (EC) 1935/2004 and Plastics Regulation 10/2011/EC as amended:

Regulations (EU) 184/2011, 1282/2011, 125/2012, 1183/2012, 202/2014, 2015/174

GMP - Good Manufacturing Practice

This article is manufactured acc. to GMP as set out in Regulation (EC) 2023/2006.

Traceability

Traceability as defined in art. 17 of Regulation 1935/2004 are ensured by the lot number on the tube and box label - part 4: traceability applied in the plastic chain.

According to the information provided by our raw material suppliers:

The raw materials used comply with Regulation (EU) No 10/2011, Chapter II -section 1 for what is concerning monomers or other starting substances and additives.

Material	PVC	CAS No	9002-86-2	Content	65-75%
-----------------	-----	---------------	-----------	----------------	--------

Monomers/additives subject to restriction can be contain or included in the composition of the current products.

Material meets requirements of Regulations (EC) 1935/2004 and 10/2011 with Annex 1 as a positive list for monomers and additives. The ingredients used in formulation are not likely to alter the organoleptic properties of foodstuffs.

Dual use additives can be added in the articles according to the information provided by our raw materials

suppliers with no intention to be released into food and no impart odour or taste, nor should the SML be exceeded. Below substances do not exhibit technological function in the food and present below limits subject to a restriction as defined in Regulation 10/2011.

GMS	E471	Calcium stearate	E470a
Silicon dioxide	E551	2,6- di-tert-butyl-p-cresol (BHT)	E321

Above mentioned article do not contain postconsumer recycled plastics; statement of compliance with Regulation 282/2008 is not required.

Specification of the intended use or restrictions

The above article under normal and foreseeable conditions of use is suitable for contact with acid, aqueous, fatty foodstuffs, for any long term storage at room temperature or below. Films are used at room temperature and less



This document edit by the Food Contact Materials Section, The Standards Institution of Israel



All calculations have been carried out under the condition that 1 kg of food is in contact with 6 sq.dm of packaging

Severe conditions -refrigerated and deep-frozen storage (minus 40/maximum plus 40°C) room temperature or below.

Maximum contact temperature 40°C.

Overall migration

When used as specified, the overall migration (OM) as well as specific migration does not exceed the legal limits. Migration tests carried out following the Regulation 10/2011 confirm an OM results below to 10 mg/sq. dm or 60 mg/kg of food simulatant in simulants A, B, D2 for 10 days at 40°C.

	Simulant A	Simulant B	Simulant D2
All PVC film types	<10	<10	<10 (Factors X - X/4)

Specific Migration Limit (SML)

SM has been evaluated in compliance with Regulation 10/2011 by calculation or, if necessarily, in experimental way. All calculations have been carried out under the condition that 1 kg of food is in contact with 6 sq.dm of packaging product in simulants A, B, D2 for 10 days at 60°C. We report the analysis or calculated results as mg/kg.

		CAS No	Ratio	SML, mg/kg	Specific migration, mg/kg
Phthalates					
Terephthalic acid, bis (2-ethylhexyl) ester		6422-86-2	0-12	60	<60
Di-2-(ethylhexyl) adipate		103-23-1	0-6	18	<18
1,2-cyclohexyldicarboxylic acid, diisononyl ester		166412-78-8	0-15	60	<60
Phthalates					Results, mg/kg
Dibutyl	DBP	84-74-2		0.3	ND
Benzyl Butyl	BBP	85-68-7		30	ND
Diethyl Hexyl	DEHP	117-81-7		1.5	ND
Di-(isodecyl)	DINP	28553-12-0		-	-
Di-(isodecyl)	DIDP	26761-40-0		-	-
Total DINP, DIDP				9	ND
Diallyl phthalate	DAP	132-17-9		0.01	ND
					Specific migration, ppb/dm²
Vinylchloride monomer		75-01-4		0.01	ND
Dual use additives					
Sorbitane monostearate		1338-41-6		no	<0.1
Octadecylceramide		10094-45-8		5	<5
2,6- di-tert-butyl-p-cresol (BHT)		128-37-0		3	<3

Calculation of "worst case" migration (100%) for the above substances shows that none can exceed respective SML. Calculation is based on maximum amount of substances found in raw materials according to our supplier's Declaration of Compliance.

Also, calculation of "worst case" migration (100%) shows that OML of 10mg/dm² or 60 mg/kg food cannot be exceeded.

It is valid for above simulants. The final item producer is responsible for the evaluation of overall/specific migration at the real time/temperature conditions or used under conditions deviating from test conditions.



This document edit by the Food Contact Materials Section, The Standards Institution of Israel



Conclusion

We also declare that should we or any occasion change the composition of our products in a way that would interfere with the declaration, we will inform your company

This declaration is valid for a period of 12 months. It should be renewed in the case of a change of the raw materials, composition of the product, the legal regulations or new toxicological realizations.

This document is electronically generated and valid without signature

Additional information

Phthalates:

The phthalates are not intentionally added to product formulation. Further, none of the constituent raw materials is specified by its supplier to contain phthalates as an impurity. Maximum residuals are not more

Polycyclic Aromatic Hydrocarbons (PAHs) Directive 2005/69/EC

We do not intentionally use the following polycyclic aromatic hydrocarbons (PAHs) in the manufacture of or formulation of this product. However, this product has not been tested for this chemical substance

Bisphenol A (Regulation 321/2011)

We do not intentionally use the following Bisphenol A in the manufacture of or formulation of this product. However, this product has not been tested for this chemical substance

Primary Aromatic Amines (PAA) Regulation 10/2011

We do not intentionally use the following PAA in the manufacture or formulation of this product. However, this product has not been tested for this chemical substance.

Polybrominated phenyls , Naphthalenes , Ethers (PentaBDE, OctaBDE, DecaBDE, PBB) (Directive 2003/11/EC)

and polychlorinated biphenyls (PCB) are not used as intentional additive or ingredient. However, this product has not been tested for this chemical substance

Triclosan - 2,4,4-trichloro-2-hydroxydiphenyl ether (Directive 2010/169/EC)

Biocide is not used as intentional additive or ingredient. However, this product has not been tested for this chemical substance.

Heavy metals: RoHS, WEEE, Packaging Waste, CONEG

This product meets the relevant requirements of the following Directives or Regulations:

10/2011/EU as amended

2002/95/EC (RoHS) as amended

2002/96/EC (WEEE) as amended

Regulation (EC) 1907/2006, annex XVII, as amended

Regulation (EC) 1907/2006, annex XVII, as amended

2000/53/EC on end-of life vehicles (ELV)

Packaging recoverable for material recycling (EN 13430, ISO 17422; ISO 15270; Directive 282/2008/EC)

This grade is recyclable. Mechanical recycling is the primary option, depending of the requirements of the application and the intended article specification.

Composting - CEN Standard EN 13432. Product is neither biodegradable nor compostable.

Date: 17.07.2016



This document edit by the Food Contact Materials Section, The Standards Institution of Israel