

Declaration of Compliance for Articles intended to come into Contact with Foodstuffs according to Art. 16 of EU Regulation 1935/2004, Annex IV of EU Regulation 10/2011, Commission Regulation (EU) 2016/1416 of EU Regulation 10/2011

Our Product : *PVC Stretch Films

EU Regulatory Status of the Article PVC Films

EC Regulation 1935/2004

PVC films complies with the safety aspects set out in Article 3 of the Framework Regulation (EC) 1935/2004.

GMP

PVC films 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.

Traceability

Manufacturer/importer has systems in place fulfilling the relevant aspects on traceability as required in article 17.1 of Regulation (EC) No. 1935/2004.

Recycling

The product does not contain recycled materials that falls under regulation (EC) 282/2008.

Used monomers and additives.

Product has been manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation 10/2011/EC.

Other substances used in the formulation of PVC films

Other substances used in the manufacturing of PVC films are listed in:

All other substances are separated from the food by a functional barrier complying with article 19 of EU regulation 10/2011/EC (up to and including the amendment 2015/174/EC)

Pigments and colorants

Colorants and/or pigments used in the formulation of PVC films, that are not regulated by 10/2011/EC (up to and including the amendment 2015/174/EC), are in compliance with:

Resolution AP (89) 1 of the Council of Europe "On the use of colorants in plastic materials coming into contact with food", II, 2 (purity).

Overall Migration

When used as specified, the overall migration (OM) as well as specific migration do not exceed the legal limits.

Migration tests carried out following the Regulation 10/2011 confirm an OM results below to 10 mg/dm² or 60 mg/kg of food simulant 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)

Additives

Additives used in the formulation of PVC films are listed in EU regulation 10/2011/EC (up to and including the amendment 2015/174/EC).

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 foods is in contact with 6 dm² of packaging product in simulants A, B, D2 for 10 days at 40°C. We report the analysis or calculated results as mg/kg.

Specific migration of residual monomers

Material	CAS No	SML, mg/kg
Phthalates		0.1
Terephthalic acid, bis (2-ethylhexyl) ester	6422-86-2	60
Bis (2-ethylhexyl) ester, adipic acid	103-23-1	18
1,2-cyclohexyldicarboxylic acid, diisononyl ester	166412-78-8	60
Phthalates		
Dibutyl	DBP	84-74-2
Benzyl Butyl	BBP	85-68-7
Diethyl Hexyl	DEHP	117-81-7
Total DINP, DIDP		9
Diallyl phthalate	DAP	132-17-9
		0.01
		Specific migration, ppb
Vinylchloride monomer		75-01-4
Dual use additives		mg/kg
Sorbitane monostearate		1338-41-6
Octadecylceramide		10094-45-8
2,6-di-tert-butyl-p-cresol (BHT)		128-37-0
		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 the substances found in raw materials according to our supplier's Declaration of Compliance.

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

Substances listed in Annex II (1), metals

PVC films does not contain intentionally added metals. Metals cannot be released above the detection limit.

PAA's (Primary Aromatic Amines) covered by Annex II (2) to the Plastics Regulation

PVC films does not contain intentionally added PAA's. PAA's cannot be released above the detection limit.

Dual use additives

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.

Calcium stearate E470a

Final use of PVC Films

PVC films are allowed to be in contact with acid, aqueous, fatty foodstuffs, for any long term storage at room temperature or below. Films are used at room temperature and less severe conditions-refrigerated and deep-frozen storage (minus 40/maximum plus 40°C) room temperature or below. Maximum contact temperature 40°C.

Substances harmful to the environment (EN 13428, 13429, 13431, 13432)

Phthalates (Directive 2005/84/EC) – We hereby declare, that the above mentioned product is free of **Phthalates**, in particular also free of Dibutyl phthalate (DBP), Diethyl phthalate (DEP), Dimethyl phthalate (DMP), Diisononyl phthalate, Diethylhexyl phthalate (DEHP), Di-isodecyl phthalate (DIDP), Di-n-octyl phthalate (DNOP) and Benzylbutyl phthalate. Further, none of the constituent raw materials is specified by its supplier to contain phthalates as an impurity.

Polychlorinated and Polybrominated phenyls, Naphthalenes, Ethers and Terphenyls

We hereby declare, that the above mentioned product is free of **polybrominated biphenyls (PBB)**, polybrominated diphenyl ether (PBDE) and polychlorinated biphenyls (PCB). Further, none of the constituent raw materials is specified by its supplier to contain PBB, PBDE or PCB as an impurity.

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

2,4,4-trichloro-2-hydroxydiphenyl ether (CAS number 3380-34-5) is not used in the manufacture of or the formulation of this product. However, we do not test this product for these chemical substances.

Chlorinated Paraffins

Chlorinated paraffins, including short-chain chlorinated paraffins, are not used in the manufacture of or the formulation of this product. However, this product has not been tested for these chemical substances.

Fluorocarbons

Fluoroteleimers, Zonly fluoroadditives (DuPont trade name), perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorochemicals (PFC) or other fluorocarbon substances are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Vinyl Chloride and Polyvinyl Chloride (PVC)

Vinyl chloride monomer (CAS number 75-01-4) is none at PVC resins that are used in the formulation of this product.

Formaldehyde

We hereby declare, that the product is free of Formaldehyde.

Biocide Dimethyl Fumarate (DMF)-(EU 2009/251/EC)

Dimethyl fumarate is not used in the manufacture of or formulation of this product. However, we do not test this product for this chemical substance.

Heavy metals content in waste Directive 94/62/EC and USA CONEG

Regarding the regulations where in the sum of the concentration levels of Cd, hexavalent Cr, Pb, Hg, incidentally present shall not exceed 100 ppm, the above mentioned products do not comply.

Heavy metals (ELV Directive 2000/53/EC as amended)

The quantity (statistically evaluated) of Cd, Pb, Cr (VI), Hg present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2005/673/EC of September 20th (amending Annex II of Directive 2000/53/EC) which establishes: 0.1% Lead; 0.1% Chromium; 0.1% Mercury; 0.01% Cadmium

Acrylamide

Acrylamide (CAS number 79-06-1) is not used in the manufacture of or the formulation of this product. However, we do not test this product for acrylamide.

Polycyclic Aromatic Hydrocarbons (PAHs)

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

Bisphenol A

Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

Epoxy Regulation (EC) N.1895/2005

BADGE, NOGE AND BFDGE are not used in the formulation of this product according to requirements. However, this product has not been tested for this chemical substance.

Tallow

Tallow derived additives are not intentionally used in the manufacture of or formulation of this product.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow"

We do not use components derived from animal sources in the manufacture of or formulation of this product.

Dioxin

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

Organo-tin Compounds

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product. However, this product has not been tested for these substances.

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

This product has potential to be recycled by recovery technology.
Packaging does not biodegradable.

Composting – CEN Standart prEN 13432

This product is not suitable for composting.

Energy Recovery – CEN Standard prEN 13431

The calorific gain from polyethylene/polypropylene in an energy recovery process is 24 MJ/kg.

Nanomaterials (2015/174/EC)

Nanomaterial is not used in the manufacture of or the formulation of this product.

SVHC Substances (ECHA/PR/15/09)

According to the Article 33(1) of the REACH Regulation products doesn't exceed 0.1% by weight of any Substances of Very High Concern (SVHC). And Pro-pack's product doesn't contain of any chemicals which list in SVCH list.

FCM Substances (EU 10/2011: 2018/79, 2018/213, 2018/831)

The substances which mentioned in EU 10/2011: 2018/79, 2018/213, 2018/831 regulation is not used in the manufacture of the formulation of this product.

This declaration is based on information of our supplier and therefore Impack Verpakkingen B.V. is not liable in any way for any misunderstandings or incomplete information.

IMPACK VERPAKKINGEN B.V.



Kevin Gecer

Impack Verpakkingen B.V.
David Ricardostraat 14
NL-7559SH HENGELO
T: +31-(0)74-267 23 37
Info@im-pack.com

DATE: 18/03/2024