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DECLARATION OF COMPLIANCE FOR FOOD CONTACT MATERIALS

DOC ISSUED BY

Bagla Group, B-2/6 Safdarjung Enclave, Delhi - 110029, India

FILM TYPE

POF Shrink Film

EC COMPLIANCE

Bagla Group has the guarantee from its producers that all raw materials and additives used in the production of POF Shrink Film comply with:

- Regulation (EC) 10/2011, and its subsequent alterations up to and including EC 2020/1245.
- Regulation EC 1935/2004 including articles 3, 11 sub 5, 15 and 17;
- The relevant prescriptions on Good Manufacturing Practice for Food Contact Materials of (EC2023/2006;)
- EC1994/62 and its subsequent alterations up to and including 2018/852 on packaging and packaging waste and that the combined amount of lead, cadmium, mercury and hexavalent chrome does not exceed 100ppm and no substances dangerous to the environment are used in this product.
- EuPIA Guidelines on Printing Inks applied to the non-food contact surface of food packaging materials and articles.

OVERALL MIGRATION

Tests in an accredited and independent external laboratory, according to ISO 17025 standard, have been carried out as defined in Regulation (EC) 10/2011. The simulators used and test conditions are mentioned in the following table:

	TEST CONDITIONS	
Food Simulants	Time (Days)	Temperature (°C)
A - Aqueous Foods (10% ethanol)	10	40
B – Acidic Foods (3% acetic acid)	10	40
D2 – Fatty Foods (vegetable oil)	10	40



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The film has been tested on simulators A; B and D2 at OM2 test conditions of the Regulation (EC) 10/2011, which means that the film has been validated to be in contact with any food type, during an extended storage period at room temperature or less, including heating up to 70° C during 2 hours maximum, or heating up to 100°C during 15 minutes maximum.

The results obtained in the OVERALL MIGRATION, are below the limits defined in Regulation (EC) 10/2011, currently defined as 10 mg/dm2 of the surface area. According to the test values obtained, carried out in accredited external laboratories by ISO 17025 standard, the film can be in contact with all food types.

SPECIFIC MIGRATION

1. Monomers /additives subject to restriction as listed in EC 10/2011, Annex I.

Worst case calculations have been used to determine the specific migration of each of the substances, based upon a surface to volume ratio of 6dm2 per kilo of food. The results obtained for these substances are well below the limits defined in Regulation EC 10/2011.

FCM Nr	Ref Nr	Substance	SML (mg/kg)
264	22660	1-Octene	<15
433	68320	octadecyl-3-(3,5-di-tert-butyl-4-hydroxyfenyl)propionaat	<6
231	10120	vinylacetaat	<12
69	74400	tris(nonyl- en/of dinonylfenyl)fosfiet	<30
356	18820	1-hexeen	<3
661	95360	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazi ne 2,4,6(1H,3H,5H)-trion	<5
282	18430	Monomer hexafluoropropylene	NA
710	46884	monoethyl-3,5-di-tert-butyl-4-hydroxybenzylfosfonaat, calciumzout	<5
128	10060	aceetaldehyd	<6
184	15940/18867 /4862	1,4-dihydroxybenzeen	<0.6
477	46720	2,6-di-tert-butyl-4-ethylfenol	<4.8



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2. Monomers / additives not subject to restriction as listed in EC 10/2011, Annex I.

FCM Nr	Ref Nr	Substance
125	16950	ethylene
106	89040	stearic acid

3. Metals as listed in EC 10/2011, Annex II.

Specific migration tests have been carried out to determine the specific migration of metals. The results obtained for the migration of these substances stay well below the limits as defined in Annex II of EC 10/2011.

Substance	SML (mg/kg)
aluminium	<10
zinc	<5
barium	<1
cobalt	<0.05
copper	<5
iron	<48
lithium	<0.6
manganese	<0.6
nickel	<0.02
mercury	ND (<0.01)
lead	ND (<0.01)
cadmium	ND (<0.002)
arsenic	ND (<0.01)
cadmium	ND (<0.01)
arsenic	<0.04

4. Specific migration Primary Aromatic Amines PAA as listed in EC 10/2011, Annex II.

Results obtained for PAA are well below the limits defined.



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3. Specific migration Pthtalates according to EC10/2011, Annex I.

When contamination occurs from sources other than food contact materials this has to be taken into account when testing for compliance of the food contact materials, in particular for phthalates (FCM substance 157, 159, 283, 728, 729) referred to in Annex I.

Residuals of DiBP (CAS 84-69-5), DBP (CAS 84-74-2) and DEHP (CAS 117-81-7) were not detectable with a detection limit of 0.0007 mg/kg.

DUAL USE ADDITIVES

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts, it is the salt that matters, not the authorized acid, phenol or alcohol.

FCM Nr	Ref Nr	Substance
86240	E551	Silicium dioxid
14680 and 44160	E330	Citric Acid
-	E170	Calcium carbonate
-	E1730	Aluminium
76960	E1521	Polyethylene Glycol
10090 and 30000	E260	Acetic Acid

MOSH / POH AND MOAH

Currently there is no SML established for MOSH / POH in European legislation nor in the draft "mineral oil ordinance" of the 22nd German Consumer Goods Ordinance. The draft "mineral oil ordinance" of the 22nd German Consumer Goods Ordinance refers to a MOAH SML < 0,5 mg/kg.

The sample was subjected to solvent extraction and analysed with HPLC GC-FID methods to determine the presence of MOSH and MOAH fractions. The potential migration was established using worst case calculation. This analysis indicates a potential migration of MOAH < 0,5 mg/kg.

The film complies with current recommendations on MOSH and MOAH.

NIAS

No other substances were found that may cause concern for the use of this film in direct contact with food.



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Disclaimer

It should be noted that the product has been tested in these specific time & temperature conditions. It is the responsibility of the downstream user to determine that the usage of the product is safe, lawful and technically suitable for the specific application and that no change in flavor, taste or organoleptic properties occurs in case the product will be used in a different manner than tested.

The information in this document is valid until it will be replaced by an improved version. Possible amendments in the law and possible modifications to the product may lead to changes in the status of this document. We therefore recommend to verify at regular intervals the legal status of this document.

India, February 2023

Dinesh Kumar Quality Director