

PLASTOPIL PRODUCT DECLARATION OF COMPLIANCE FOR FOOD CONTACT PACKAGING MATERIAL

Product Designation:	TOPAZ B 440 TC AF	Plastopil Reference:	16600
Use of the article	Flexible film for packaging of foodstuffs		
Company Identification	Plastopil Hazorea Company Ltd		
Emergency Phone Number	+972-4-9598800		
Address	Industrial Area, Kibbutz Hazorea, Israel 36581		
The Manufacturer declares that the above-mentioned products are in conformity with:			
European legislation :European Commission Regulation (EU) No 10/2011, up to and including the amendment No 2016/1416 and 2017/752, 2018/79, 2018/213, 2018/831 and 2019/37. Our product complies with the legal regulations laid down in the Regulation (EC) No 1935/2004, Regulation (EC) No. 2023/2006 (Good Manufacturing Practice) and directive (EC) No. 94/62 (packaging Waste). Traceability of the product is ensured via the work order number and roll number in conjunction with the data of production.			
Date of Issue: 21.10.2020			
Polymers and additives making up this product contain the following substances listed in EU Directives on plastics in contact with food:			
Substances with Specific Migration Limits (SML's) present in the layer in contact with food			
Name	CAS Number	FCM Substance No.	SML* or SML(T)*
1-Hexene	592-41-6	356	SML=3 mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	433	SML=6 mg/kg
Diiron trioxide	1309-37-1	—	SML=48 mg/kg
Alumina	1344-28-1	—	SML=1 mg/kg
1-octene	111-66-0	264	SML=15 mg/kg
Aluminium	—	—	SML=1mg/kg expressed as Al
Maleic Anhydride	108-31-6	234	SML(T)=30 mg/kg, expressed as Maleic Acid
Caprolactam	105-60-2	212	SML(T)=15 mg/kg
Vinyl acetate	108-05-4	231	SML=12 mg/kg
Terephthalic acid	100-21-0	785	SML(T)=7.5 mg/kg expressed as terephthalic acid
Ethylene glycol	107-21-1	227	SML(T)=30mg/kg expressed as ethylene glycol
Diethylene glycol	111-46-6	263	SML(T)=30 mg/kg expressed as ethyleneglycol
Terephthalic acid dichloride	100-20-9	191	SML(T)= 7,5mg/kg, ND
Acetaldehyde	75-07-0	128	SML(T)= 6mg/kg, ND
Antimony trioxide	1309-64-4	398	SML(T)= 0,04mg/kg, ND
Catalyst	65104-06-5	1	Not in union list.
Catalyst	5593-70-4	1	Not in union list.

2-Ethyl-1-hexanol	104-76-7	209	SML=30 mg/kg
Isophthalic acid	121-91-5	291	SML(T)=5 mg/kg
HDI	822-06-0	372	SML=ND. 1 mg/kg in final product (expressed as NCO). ²
Adhesion promoter	919-30-2	377	SML=0.05 mg/kg.
Dual Use Substances			
Name	CAS Number	FCM Substance No.	SML* or SML(T)*
Calcium carbonate/E170/	471-34-1	—	No SML
Magnesium oxide/E530/	1309-48-4	397	SML=60 mg/kg
Polyethyleneglycol/E1521/	25322-68-3	638	SML=60 mg/kg
Silica/E551/	7631-86-9	504	SML=60 mg/kg
Boric acid/E284/	10043-35-3	584	SML(T)=6 mg/kg
3,5-Di-tert-butyl-4-hydroxytoluene/BHT/E321/	128-37-0	315	SML=3mg/kg
Polyethyleneglycol sorbitan monooleate/E494/	9005-65-6	569	SML=60 mg/kg
Ethanol/E1510/	64-17-5	113	SML=60 mg/kg
Cellulose, 2-hydroxypropyl ether/E463/	—	—	—

*SML- specific migration limit in food or in food simulant

*SML(T)- specific migration limit in food or in food simulant FOR A GROUP OF SUBSTANCES

*FCM SUBSTANCE No.-UNIQUE IDENTIFICATION NUMBER OF THE SUBSTANCE

1-Built into polymer chain

2-Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.

SML: Calculation of “worst case“ migration (100%) for above mentioned substances shows that none can exceed their respective SML. Calculation is based on maximum amount of substances found in raw materials according to our suppliers’ Declarations of Compliance.

Reference:

Regulation (EU) No 10/2011, Annex V, 2.2.2: "To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration."

Restrictions on the use of food packaging materials under heating are based on two considerations:

- 1) The possible **migration** of substances from the packaging to the food
- 2) The **physical integrity of the package** over time when filled and heated. This concerns both the intrinsic heat resistance of polymers present in the multilayer structure as well as heat resistance of seals (possibly between differing polymers).

Migration tests⁽¹⁾ conducted on TOPAZ B 440 TC AF show that the product meets the overall migration requirements of Regulation (EU) 10/2011 PIM and amendments for use with aqueous, acidic, dry and fatty foodstuffs for

- (a) high temperature applications

Integrity of the package under all possible configurations of content, heating temperature and time cannot be determined in advance. The customer should consult with Plastopil technical personnel regarding specific applications. Finally, the customer must determine by appropriate field tests whether the durability of the material is suitable for the proposed application.

Ratio of food contact surface area to volume used to establish the compliance of the material or article	6 dm ² /kg
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It should be noted that the representative samples have been tested for the above mentioned conditions only.
It is the responsibility of the legal entity responsible for placing on the market of the article to ensure that the usage of the articles is safe. Lawful and technically suitable and can be determined through mutual consultation and agreement.

This assessment refers exclusively to the product as manufactured at date of issue according to extant regulations. In the case of a change of the raw materials composition of the product, the legal regulations or new toxicological finding it loses its validity.
This Declaration is valid for a period of 3 years when product and regulations remain unchanged. It should be renewed in all cases when the previous conformity is no longer ensured and in case of changes it in the regulations.
In addition, it is the responsibility of our customers (of the downstream user (s) to determine that their use of our product (s) is safe, and according to the information given in this document, lawful and technically suitable so that no change in flavor, taste or organoleptic properties occur. Because use conditions and applicable laws may differ from one location to another, the customer is responsible for determining whether products and information in this document are appropriate for the customers use. The purchaser remains responsible for determining whether the use complies with all regulations.

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