

Compliance relating to materials intended to come into contact with foodstuffs
TRESYLENE® XXXX – PEBD

This document is valid for all densities and thicknesses

The material indicated above is in conformity with requirements of the European regulation EC N° 1935/2004 of the European Parliament on materials and articles intended for food contact within the limits set in section (2.3). It complies with the Regulation on Good Manufacturing Practise (EC) N°2023/2006. This compliance is subject to the following specification of the conditions of use by the customer:

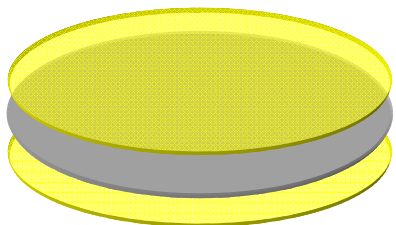
If a customer considers his application deviating from the conditions covered by this document, they are responsible for performing the appropriate testing.

Conditions of Use

Nature of the food product: : Fatty, Aqueous, Acid, Alcoholic

Contact temperature: Ambient

GENERAL PRODUCT INFORMATION



LDPE FILM

Low density expanded polyethylene foam

LDPEFILM

We obtained that information from our supplier

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This document supersedes all previous issues. Up date 04/2013 Diffusion 04/2013– PAGE 1/11



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Component	Legal reference	Status
Plastics	Regulation (EU) N° 10/2011	Monomers and additives listed; see below for further compliance aspects
Alls raw materials	EU Regulation (EC) No 1895/2005	Complies
Alls raw materials	EU Regulation (EC) No 282/2008	Recycled unused following the definition of regulation
White pigment	n.a	In accordance with RESOLUTION AP (89) I. ON THE USE OF COLOURANTS IN PLASTIC MATERIALS. COMING INTO CONTACT WITH FOOD
Alls raw materials	EU Regulation (EC) No n° 450/2009	There is no active substances or Intelligent substances, therefore the regulation does not apply

FILM IN CONTACT

• UE REGULATION

Overall Migration Limit (OML)

By reason of the nature of the material, substitution tests provided by 97/48 directive were carried out in place of analysis in olive oil at 1 hour at 100 °C + 40°C during 10 days.

Notes : recall of authorized maximal limits : 10 mg/dm² with an analytical tolerance 2 mg/dm² - 60 mg/kg with an analytical tolerance 12 mg/kg.

Tests conditions	Simulant	Mean value in mg/dm ² - rounded to the nearest 0.1
1 hour 100°C + 10 days 40°C	Acetic acid 3% (w/v)	0.4
10 days 40°C	Olive oil	2 **
3 hours 60°C + 10 days 40°C	Ethanol 95% (w/v)	.3

** For olive oil, Calculation carried out by taking into account a loss of volatile substances of 2,6 mg/dm².

In test conditions, the overall migration is within the limits set by regulations in the stimulant representing fatty, aqueous, acid foods

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Specific migration

The following monomers and additives used for the above mentioned products manufacture are submitted to specific migration limits or restrictions as defined in Regulation (EU) No 10/2011. These substances are listed below with the applicable restrictions.

Moreover, the final plastic part is subject to a global migration limit of 10 mg/dm² or 60 mg/kg

No. Component	CAS Nr. - PM	Restriction	Information
1-Octène		PM 22660-LMS=15 mg/kg	Maximum in the film 0.43 mg/6dm ²
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	PM 68320 - LMS = 6 mg/kg	Maximum in the film 0,16 mg/6dm ²
Zinc		PM 89040- SML = 25 mg/kg	Maximum in the film 0,08 mg/6dm ²

Other substances

Substances	Nr E
Silicium dioxyde	E551
Talc	E553b
Aluminium silicate	E559

• FDA

All polymers and additives for film in contact with product are in "Positive list of products accepted for the fabrication of packaging materials intended for food contact, as published by the Food and Drug Administration FDA 21 CFR Title 21 - Volume 3, revised as of April 1, 2010."

Resins are in accordance with: § 177.1520 - Olefin polymers

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Colorants are in accordance with § 178.3297 - Colorants for polymers

- **PROP 65**

We inform you that the substances listed in California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) Not intentionally used in the formulation of the film.

- **Pharmacopoeia**

The polyethylene material complies with the compositional requirements of the European Pharmacopoeia, 7th Edition (7.0 – implemented 1 /01/2011),

- Paragraph 3.1.3 "polyolefines"

Regarding the European pharmacopoeia, the specific tests are in user charge.

- USA USP 34 "POLYETHYLENE CONTAINERS"

PE FOAM - NO DIRECT CONTACT

Specific restrictions on substances in plastics

This material contains no monomers which are regulated with a specific migration limit.

Dual Use Additives (Additives Having Multiple Functions)

REF N°	CAS number	CODE	Maximum amount present in the material mg / dm ² **
42500	-----	Carbonic acid and its salts	16
44160	0000077-92-9	Citric acid and its salts	24
41520	0001305-78-8	Calcium oxyde	2.4
54480	-----	Fats and oils, hydrogenated, from animal or vegetable food	2.4

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sources

**The maximum concentration is calculated based on the quantity of the substance in raw material, the dosage in the product and for the material 460 kg/m³ and 2 mm thickness.

● [DMF NUMBER FOR TRESYLENE® XXXX – PEBD](#)

DMF TYPE III – N° 18475.

● [Canadian Food Inspection Agency](#)

Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products

<http://active.inspection.gc.ca/scripts/fssa/reference/compresults.asp?lang=e&cmp=M422>

● [GENERAL INFORMATION](#)

The information below is provided by our suppliers for all raw materials used in the composition.

We inform you that this material do not contain

- substances is affected by Directive 67/548/CEE - Council Directive 67/548/EEC of 27th June 1967 with regard to the reconciliation of laws, regulations and administrative provisions connected to the classification, packaging and labelling of dangerous substances.
- CMR classified substance (Carcinogens (C) - Mutagens (M) - Toxic for reproduction (R)) category 1 and 2 held in Article R 231-51 of the Labour Code.
- Highly Preoccupying Substances (SHVC) - as defined in REACH Regulation 1907/2006 Article 7.1 – or at concentration greater than 0.1% in the articles as defined in article 7.2 and article 57.
- Substances of ECHA list updated

The absence has not been checked.

Although the above-mentioned substances are not intentionally added, it does not exclude the presence of negligible traces deriving from, among others, impurities in the components supplied by external parties and used in production – In this case, the % is below the law.

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Heavy metals

The raw materials are in accordance with the EEC regulations 94/62/EC Article 11 in respect to the Heavy metal content of the sum of lead, cadmium, mercury and chromium-VI of < 100 ppm.- modified by Directive 2004/12/EC dated 11/02/04

Derived from animal origin

Some of raw materials may contain additives containing raw materials derived from animal origin. These materials are produced according to Directive 2000/6/EC, appendix II. They are therefore regarded as safe concerning the risk of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE).

Genetically modified organisms OGM:

On the basis of our suppliers' information, the products that we deliver do not hold any genetically modified organism. Particularly, erucamide, used as slip agent comes from OGM-free areas. The presence of such constituents not being conceivable for economic reasons, they are not submitted to any particular control. Because of the complexity of the sales networks and considering the risks of cross contamination, some substances used as raw materials for the synthesis of plastic material additives (e.g. fatty acids) are likely to stem from OGMs although they do not carry any themselves. Such products are subjected to several transformation and chemical purifying processes. Thereafter they are considered safe.

The scattering of OGMs in environment is controlled by directive 18/2001/CE dated 12 March 2001 repealing directive 220/1990/CE. Moreover, some information is available on www.finances.gouv.fr/ogm/ (with some available links to European sites)

ALLERGENS SUBSTANCES

This is to certify that the following potential allergenic ingredients – food allergen – listed in annexe IIIa of EU Directive 200/13/EC incl. subsequent amendment like EU Directive 2007/68/EC are not used in the manufacturing of, and therefore are not expected to be present in the film in contact with foodstuff. Although the above-mentioned substances are not intentionally added, it does not exclude the presence of negligible traces deriving from, among others, impurities in the components supplied by external parties and used in production

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L'OREAL REQUIREMENTS

Absences of substances listed in l'OREAL document RPP900/G ANNEX III: IDENTIFICATION OF SUBSTANCES LISTED BY CAS NUMBER

● CHEMICALS SUBSTANCES

We inform you that according to the information we have from our suppliers, the raw materials in contact with food do not contain any :

Chemical name	CAS N°
1,2-DICHLOROBENZENE	95-50-1
1,3 –Butadiene, 2-methyl- (Isoprene)	
2,2-Bis(phenyl-4-glycidoxy)propane - / Bisphenol A diglycidyl ether;	01675-54-3
2-EHA (2-ETHYLHEXYLACRYLATE)	
4-methylbenzophenone / 4MeBP	134-84-9
Acetic acid ethenyl ester (Vinyl acetate) ACIDE ETHYL-2 HEXANOIQUE	
acrylamide	79-06-01
AHTN (6-Acetyl-1,1,2,4,4,7-hexamethyltetralin)	
Alkyl phenol ethoxylates (APEOs) and derivatives thereof	

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AlkylPhenol Ethoxylate APE	
Azodicarbonamide	
BENZIDINE	92-87-5
Benzophenone (C6H5)2CO, generally abbreviated Ph2CO	119-61-9
Benzopyren	50-32-8
Benzyl butyl phtalates BBP	85-68-7
BHT	128-37-0
Bis(2-ethylhexyl) phtalates (DEHP)	117-81-7
Bis(2-methoxyethyl) phtalate	117-82-8
Bisphenol F-DIGLYCIDYL ETHER - BFDGE	054208-63-8
bisphénol S, 4,4'-sulfonyldiphénol	80-09-1
Bisphenol-A	80-05-7
Boric acid, borates and perborates	
CFC / HCFC / HBFC / HFC	
Cyclohexasiloxane, dodecamethyl- (D6)	
DI-(n-OCTYL) phtalate DOP	
Dibutylphtalate (DBP)	84-74-2
DI-ORTHO phtalate	

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Dioxins

Ethers de glycol - (EGME – EGMEA – EGEE – EGEEA – TEGDME – EGDME)

EVA

Hydrazine

Hydroxybenzophenone

Lactose

LATEX

Mélamine

NAPHTALENE

91-20-3

N-éthyl ortho-toluene sulfonamide

1077-66-1

N-éthyl para-toluene sulfonamide

80-39-7 (NETSA)

Nitrites - Nitrozamines

Nitromusks and polycyclic musks, including for example:

- Musk xylene: 5-tert-butyl-2,4,6-trinitro-m-xylene
- Musk ambrette: 4-tert-butyl-3-methoxy-2,6-dinitrotoluene
- Moskene: 1,1,3,3,5-pentamethyl-4,6-dinitroindan
- Musk tibetine: 1-tert-butyl-3,4,5-trimethyl-2,6-dinitrobenzene
- Musk ketone: 4'-tert-butyl-2',6'-dimethyl-3',5'-dinitroacetaphenone
- HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta(g)-2-benzopyran)

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Nonylphenoethoxilate(NPE)	
Nonylphenols (NP)	
NOVOLAC GLYCIDYL ETHER - NOGE	
NTA(nitrilo-tri-acetate)	
Oxirane, (chlromethyl) – (Epichlorohydrin)	
Phenol, 4,4- (1-methylethylidene) bis- (Bisphenol A)	
Phtalates and derivates	
Polychlorinated Biphenyls (PCBs)	
POLYCYCLIC AROMATIC HYDROCARBONS - PAH - Hydrocarbures polycycliques aromatisés	7782-50-5
Polyvinyl chloride, commonly abbreviated PVC	
semicarbazide (SEM)	57-56-7
Sulfonates de perfluorooctane	Directive 2006/122/CE
Tribromophénol TBP - Tribromoanisole TBA	
Trichloroanisoles (TCA)	
Triclosan 5-chloro-2-(2,4-dichlorophenoxy)phenol	3380-34-5

We do not deliberately introduce these substances during our manufacturing process.
Of course, this guaranty does not rule out the presence of infinitesimal traces following an unknown process.
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Please note that, in any case our Company does not carry out any specific analyses in order to detect the presence of above mentioned substances. Due to the evolution of regulations and laws the status of the above mentioned product could eventually change. If you have any doubt relating to this declaration, please contact us for an update.

Update

02/2013- substances / (UE) n° 321/2011 - (UE) n° 1282/2011 - (UE) n° 1183/2012

03/2013 - (EC) No n° 450/2009

04/2013 - SUBSTANCES

I AUBRIOT - QD

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