



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

Compliance relating to materials intended to come into contact with foodstuffs
TRESYLENE® XXXX S **OENOSEAL® XXXX S**

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).

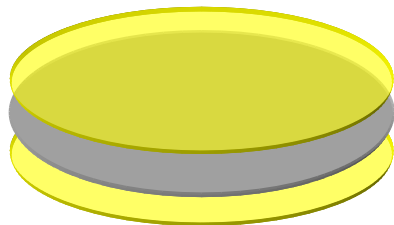
It complies with the Regulation on Good Manufacturing Practise (EC) N°2023/2006.

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.

Types of packaging – Application – Caps metal – Wine – alcoholic till 95° - fatty, acqueous, acid, and fatty food

Contact temperature: Ambient

GENERAL PRODUCT INFORMATION



PEbd - PVDC- PEbd

Low density expanded polyethylene foam

PEbd - PVDC- PEbd



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

Component	Legal reference	Status
Material in object	REGULATION (EC) No 1005/2009	The material is not affected by this regulation
Plastics	Regulation (EU) N° 10/2011 and updates 1282/2011 et 1183/2012	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
Alls raw materials	EU Regulation (EC) No n° 450/2009	There is no active substances or Intelligent substances, therefore the regulation does not apply
Alls raw materials	Directive 94/62, Article 11 (amended by directive 2004/12/EC)	All raw materials are in compliance in respect to the Heavy metal content of the sum of lead, cadmium, mercury and chromium-VI of < 100 ppm
Alls raw materials	EU Regulation n°528/2012 - Annexe I	We confirm you that the raw materials used for the production that we provide you are formulated without any voluntary introduction of biocide.
Film in contact with product	Regulation (EU) n°1223/2009 - Annexe I et II	The residual level of 1,1-dichloroethylene ; vinylidene chloride (CAS # 75-35-4) in the film is max < 0.0001 % wt. Supplier Information not controlled by MGJ

● Specific regulation

- FDA

Film in contact with product	U.S. FDA 21 CFR 177.1350, 175.105 174.5, 177.1350,178.3860,177.1350, 176.170,177- U.S. FDA 21 CFR Prior Sanction - 181.1	Complies
------------------------------	--	----------

- Prop 65

Film in contact with product	California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)	This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute as of the effective date of this letter
------------------------------	---	--



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

- European Pharmacopoeia

Ldpe in direct contact with product	European Pharmacopoeia, 7 th Edition (7.0 – implemented 1 /01/2011),	The polyethylene material complies with the compositional requirements Paragraph 3.1.3 “polyolefines”. Regarding the European pharmacopoeia, the specifics tests are in user charge
-------------------------------------	--	---

- 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/srresults.asp?lang=e&c=1&msg=&q=OENOSEAL&sub=SOUMETTRE>

Overall Migration tests

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.
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 40°C during 10 days.

Tests conditions	Simulant	Mean value in mg/dm ² - rounded to the nearest 0.1
10 days 40°C	Acetic acid 3% (w/v)	1.6
2 days 20°C	Isooctane	1
10 days 40°C	Ethanol 95% (w/v)	2.2

SML SUBSTANCES

	PM/ Ref	No. Component	CAS Nr.	Restriction	Laboratory Tests results
Film	46640	2,6-Di-tert-butyl-p-cresol (BHT)	128-37-0	SML=3ppm	Analysis by reverse phase HPLC/DAD (280nm), with isocratic mode Acetic acid 3% - 10 days 40°C < LQ / 95% Ethanol – 10 days 40°C < LQ
Film		Vinylidene Chloride	75-35-4	SML=nd (LOD=50ppb) or QM=5ppm	XP ENV 13130-6 – GC/MS < 0.5 mg/Kg
Film		Epoxised soy bean oil	8013-07-8	SML =60ppm (LOD=10ppb) And QM=1ppm	Compliance is confirmed by supplier



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

This film contains a monomer with imposed SML. The information on the Monomer is our supplier proprietary and cannot be disclosed. It was shown by modelling that the SML cannot be exceeded for this film thickness. Results of tests performed in our supplier laboratory, on a 50µm sample made in the laboratories on a single surface exposure (pe side) showed that the above-mentioned film complies with these overall and specific migration limit requirements imposed by the EU Commission Regulation (EU) N° 10/2010.

Dual Use Additives (Additives Having Multiple Functions)

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

(*)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 t

● 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 of 2008/10/28 and 2010/01/20.

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.

Derived from animal origin

Our film supplier certify that animals derivated materials are not used in the manufacturing of.



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

GMO

The level of the substance is <0.6 %wt

Based on information from our supplier, the Epoxidized soybean oil (ESO) may contain detectable amounts of GMO

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.

The film does, however, contain a substance derived from soy (< 0.6%wt) and a substance derived from lactate (< 0.7%wt).

● 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 :

CAS N° or référence	Chemical name
37953-21-2	(methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer
95-50-1	1,2-DICHLOROBENZENE
01675-54-3	2,2-Bis(phenyl-4-glycidoxy)propane - / Bisphenol A diglycidyl ether;
134-84-9	4-methylbenzophenone / 4MeBP
98-83-9	Alpha-Méthyl-Styrène
	Aromatic amines
	Azodicarbonamide
119-61-9	Benzophenone (C ₆ H ₅) ₂ CO, generally abbreviated Ph ₂ CO
	biostables polyurethanes
117-82-8	Bis(2-methoxyethyl) phtalate
054208-63-8	Bisphenol F-DIGLYCIDYL ETHER - BFDGE
80-05-7	Bisphenol-A
	Brominated compounds



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

85-68-7	Butyl Benzyl Phthlate (BBP)
117-81-7	Di(2-ethylhexyl) Phthalate (DEHP, DOP)
117-84-0	Di(n-octyl) Phthalate (DNOP)
84-74-2	Dibutylphthalate (DBP)
84-66-2	Diethyl Phthalate (DEP)
26761-40-0	Diisodecyl Phthalate (DIDP)
28553-12-0	Diisononyl Phthlate (DINP)
131-11-3	Dimethyl Phthalate (DMP) Dioxins
110-05-4	Di-tert-Butyl peroxyde (DTBP)
67-68-5	Dyméthyl sulfoxide DMSO
624-49-7	fumarate de diméthyle Hydroxybenzophenone INAL
9016-00-6	LATEX
<u>91-20-3</u>	NAPHTALENE Nitrites - Nitrozamines Nonylphenoethoxilate(NPE) Nonylphenols (NP) NOVOLAC GLYCIDYL ETHER - NOGE Phtalates and derivates polycarbonate Polychlorinated Biphenyls (PCBs)
7782-50-5	POLYCYCLIC AROMATIC HYDROCARBONS - PAH - Hydrocarbures polycycliques aromatisés
25608-63-3	polyether sulfone
9003-07-0	Polypropylene Polyvinyl chloride, commonly abbreviated PVC
57-56-7	semicarbazide (SEM)



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

100-42-5	Styrene (Vinyl benzene; cinnamene; styrol; phenylethene; diarex HF 77; styrolene; styropol; vinylbenzene; phenylethylene)
85-86-9	SUDAN - 85-86-9 THIAZOLINE, ISOTHIAZOLINE
16545-54-3	thiodipropionic acid, ditetradecyl ester Tribromophénol TBP - Tribromoanisoole TBA Trichloroanisoles (TCA)
57-13-6	Urea

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.
This guaranty shall not extend to any subsequent modification of the product composition or any working likely to lead to material distortion.
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.

● INFORMATION

We obtained some information from our suppliers.

This guaranty shall not extend to any subsequent modification of the product composition or any working likely to lead to material distortion.

Be informed that the user must check:

- The compatibility container - contents.
- The integrity of the properties, particularly the organoleptic characteristics.

We specify that our food contact declaration do not guarantee anything in the organoleptics field. Considering the possibility of smell developing during various steps of storage, converting and manufacturing, the user must check the organoleptics properties at any relevant step.

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](#)

03/2013	EU Regulation (EC) No n° 450/2009
04/2013	Azodicarbonamide / 1282/2011 et 1183/2012
06/2013	Standard presentation - Prop 65
07/2013	Règlement n°1223/2009 - Annexe I et II



37, rue clos chapuis - b.p 6 - 69380 chazay d'azergues - France
☎ 33 / 04.72.54.70.50 - télécopie 33 / 04.78.43.78.94
e-mail mgj@mgj.fr

08/2013	Polypropylene
08/2013	substance 100-42-5
09/2013	EU Regulation n°528/2012
10/2013	GMO
01/2014	REGULATION (EC) No 1005/2009
10/2013	GMO

Isabelle AUBRIOT – QD

FEDERFIN