

Via delle Industrie 10/12 20864 Agrate Brianza (MB) - Italia

tel. +39 039.94.57.100 - fax +39 039. 94.51.996 www.capsol-spa.com - capsolsales@capsol-spa.com

P.IVA 00723610960 - C.F. 01778690154

PRODUCT CONFORMITY DECLARATION

GENERAL INFORMATION

DECLARATION Nr.	24-096
DATE OF DECLARATION	2024, 7 th June
MANUFACTURER	CAPSOL S.p.A.
CUSTOMER	RETAL PLASTEC SRL
CAPSOL CODE	02148BIA; 02148AZA; 02148BLC;
	02148RSA; 02148VEA
CUSTOMER CODE	

DECLARATION IN COMPLIANCE WITH

EUROPEAN REGULATION
Regulation 1935/2004/CE - Materials and objects intended for contact with food
Regulation 1895/2005/CE – Restriction of the use of certain epoxy derivatives in materials and objects intended in
contact with foods
Reg. 10/2011/UE – and its following amendments – Concerning plastic materials and objects intended in contact
with foods
Reg. 2023/2006/CE - GMP
Reg. 1907/2006/CE – and its following amendments - REACH
Reg. 2022/1616/CE - Recycled plastic
Reg. 94/62/CE – Packaging and packaging waste
Reg. 1223/2009/CE – Cosmetics products
Reg. 2019/904 – Reduction the impact of certain plastic products on the environment
ITALIAN REGULATION
DM 21/03/1973 - and its following amendments – Hygiene regulations for packaging intended in contact with food substances
DL 10/02/2017 n.29 – Sanctions for violations of the provisions of Regulations concern materials and object intended in contact with food
DPR 777/82 - and its following amendments – Implementation of Dir. (EEC) 76/893 relating to materials and objects
intended in contact with food
DM 360/2022 – Environmental labeling
AMERICAN REGULATION
PROP 65



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STATEMENT ON RAW MATERIALS

The plastic item covered by this declaration has been manufactured only with virgin monomers, additives and other starting substances authorized under Regulation (EC) n. 10/2011.

The items are manufactured in Agrate Brianza plant with the following raw materials:

02148BLC TAPPO A SIGILLO	20PL.02	POLITENE (HD) ALTA DENSITA'	LUMICENE M5220M	TOTAL
SATINATO BLU TETHERED			ELTEX B 4020 N 1331 (Alternative)	INEOS (Alternative)
	10BL.448	BLU LIQUIDO	FZ51050095	AVIENT
02148RSA TAPPO A SIGILLO SATINATO ROSSO	20PL.02	POLITENE (HD) ALTA DENSITA'	LUMICENE M5220M	TOTAL
TETHERED			ELTEX B 4020 N 1331 (Alternative)	INEOS (Alternative)
	10RS.288	Rosso LIQUIDO	FZ33050055	AVIENT
02148AZA TAPPO A SIGILLO SATINATO	20PL.02	POLITENE (HD) ALTA DENSITA'	LUMICENE M5220M	TOTAL
AZZURRO TETHERED			ELTEX B 4020 N 1331 (Alternative)	INEOS (Alternative)
	10AZ.195	Azzurro LIQUIDO	FZ53050096	AVIENT
02148VEA TAPPO A SIGILLO SATINATO VERDE	20PL.02	POLITENE (HD) ALTA DENSITA'	LUMICENE M5220M	TOTAL
TETHERED			ELTEX B 4020 N 1331 (Alternative)	INEOS (Alternative)
	10VE.524	VERDE LIQUIDO	FZ63050050	AVIENT
02148 TAPPO A SIGILLO SATINATO BIANCO	20PL.02	POLITENE (HD) ALTA DENSITA'	LUMICENE M5220M	TOTAL
TETHERED			ELTEX B 4020 N 1331 (Alternative)	INEOS (Alternative)
	10BI.70	Bianco LIQUIDO	FZ00050022	AVIENT

ENVIRONMENTAL CODE (Comm. Dec. 97/129/EC)

	ENVIRONMENTAL CODE				
ITEM CODE	O1 PET	O2 PE-HD	O4 PE-LD	05 PP	ۿ
02148		Х			



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COMPLIANCE WITH SPECIFIC MIGRATION LIMIT

		The material	doesn't	contain	substances	subject t	to restriction	according	to the	above-mentioned	l regulation
_	_	THE IHALEHAI	uocan t	Contain	30D3tarice3	Jubject (to restriction	according	to the		i iegulation.

The overall migration limits, together with the other specific restrictions of the monomers and/or additives present in the material, are respected at the using condition described above. The statement is supported by analytical tests carried out in compliance with the **Reg.** (UE) N.10/2011 (and its following amendments) or based on calculations made considering the content of the substances subject to migration limits. The calculations are made with the assumption that 1 kg of food is in contact with 6 dm² of packaging material.

■ LUMICENE M5220M – TOTAL

Substances as mentioned in the Regulation (EU) No 10/2011 Annex I, Annex II and/or Annex IV (6) ¹				
Substances	Maximal Residual Level (ppm)	FCM Reference No or CAS RN	Specific Migration Limit or Restriction (ppm)	
1-hexene	25	356	3	
Poly(4-hydroxy-2,2,6,6-tetramethyl-1- piperidine ethanol-alt-1,4-butanedioic acid)	1300	716	30	
ethylene oxide	traces*	129	ND (LD 10 ppb)** 1 ppm in final product	
propylene oxide	traces*	135	ND (LD 10 ppb)** 1 ppm in final product	
4-tert-butylphenol	traces*	186	0.05	
2,6-di-tert-butyl-4-ethylphenol	traces*	477	4.8	

■ ELTEX B4020 N1331- INEOS

Adequate information on the substances used for which restrictions are set out No monomers subject to Specific Migration Limit (SML) are used.

No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

■ BLU LIQUIDO FZ51050095 - AVIENT

Restrictions and Limitations

Information on substances contained for which a restriction and/or specifications are set out in Annex I and Annex II:

Aluminium: SML = 1 mg/kg food or food simulant

■ ROSSO LIQUIDO FZ33050055 - AVIENT

Information on substances contained for which a restriction and/or specifications are set out in Annex I and Annex II:

· Aluminium: SML = 1 mg/kg food or food simulant



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AZZURRO LIQUIDO FZ53050096 – AVIENT

Information on substances contained for which a restriction and/or specifications are set out in Annex I and Annex II:

- Aluminium: SML = 1 mg/kg food or food simulant
- Copper: SML = 5 mg/kg food or food simulant

■ VERDE LIQUIDO FZ63050050 – AVIENT

Information on substances contained for which a restriction and/or specifications are set out in Annex I and Annex II:

- Aluminium: SML = 1 mg/kg food or food simulant
- Copper: SML = 5 mg/kg food or food simulant

■ BIANCO LIQUIDO FZ00050022 - AVIENT

Information on substances contained for which a restriction and/or specifications are set out in Annex I and Annex II:

- Aluminium: SML = 1 mg/kg food or food simulant
- Poly(12-hydroxystearic acid) stearate, SML = 5 mg/kg

INFORMATION ABOUT "DUAL-USE" ADDITIVES IN THE PRODUCT

In the material there aren't substances called additive "dual use" according to experimental data and/or theoretical calculations provided by raw materials supplier.	
In the material there are substances called additive "dual use" according to experimental data and/or theoretical calculations provided by raw materials supplier, these substances are in accordance with the provisions of Regulation 10/2011/UE, Art.11, comma 3:	

■ LUMICENE M5220M – TOTAL

Dual Use Additives as listed in Regulations (EC) No 1333/2008 ⁴ and No 1334/2008 ⁵					
Substances	Maximal Residual Level (ppm)	FCM Reference No or CAS RN	Restriction in Food (ppm)		
E 470a Sodium, potassium and calcium salts of fatty acids	1950	9	Quantum satis		
E 526 Calcium hydroxide	traces*	394	Quantum satis		
E 570 Fatty acids	traces*	9	Quantum satis		
		4 1 4 4 4 4			

■ ELTEX B4020 N1331- INEOS

7. Adequate information relative to the substances which are subject to a restriction in food. Calcium Stearate (E470) (CAS nb 1592-23-0) is approved as food additive (dual-use additive). It is present, as additive, in the above grade.



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■ BLU LIQUIDO FZ51050095 — AVIENT

Information on dual-use-additives contained:

FCM number	Name of the additive	Content of the additive (given in range)
414	sorbitan monolaurate	5% -10%
84	Silicates	30% - 40%
	Polyethyleneglycol sorbitan	20% - 30%
	monolaurate	

■ ROSSO LIQUIDO FZ33050055 – AVIENT

Information on dual-use-additives contained:

AMEGINATION ON CO.	uar-use-accitives contained.	
FCM number	Name of the additive	Content of the additive (given in range)
414	sorbitan monolaurate	5% - 10%
575	Polydimethylsiloxane (Mw > 6800	< 0.1%
	Da)	
	Polyethyleneglycol sorbitan	10% - 20%
	monolaurate	
9	acids, C2-C24, aliphatic, linear,	0.25% - 0.5%
	monocarboxylic from natural oils and	
	fats, and their mono-, di- and	
	triglycerol esters (branched fatty acids	
	at naturally occuring levels are	
	included)	

■ AZZURRO LIQUIDO FZ53050096 - AVIENT

Information on dual-use-additives contained:

FCM number	Name of the additive	Content of the additive (given in range)
414	sorbitan monolaurate	1% - 5%
575	Polydimethylsiloxane (Mw > 6800	< 0.1%
	Da)	
	Polyethyleneglycol sorbitan	20% - 30%
	monolaurate	

■ VERDE LIQUIDO FZ63050050 – AVIENT

Information on dual-use-additives contained:

FCM number	Name of the additive	Content of the additive (given in range)
414	sorbitan monolaurate	5% - 10%
575	Polydimethylsiloxane (Mw > 6800	< 0.1%
	Da)	
	Polyethyleneglycol sorbitan	20% - 30%
	monolaurate	
9	acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and	< 0.1%
	triglycerol esters (branched fatty acids	
	at naturally occuring levels are included)	



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■ BIANCO LIQUIDO FZ00050022 – AVIENT

Information on dual-use-additives contained:

FCM number	Name of the additive	Content of the additive (given in range)
414	sorbitan monolaurate	1% - 5%
	Polyethyleneglycol sorbitan monolaurate	5% - 10%
575	Polydimethylsiloxane (Mw > 6800	0.1% 0.25%
373	Da)	0.176 - 0.2376

COMPLIANCE WITH GLOBAL MIGRATION in aqueous food simulants

As per **DM 21/03/73** to demonstrate compliance with the migration in all types of food, the test is carried out in food simulants:

The product was tested with following simulant by total immersion at the following conditions:

Food simulant	Contact conditions	Surface/vol. ratio	Limits (Reg. EU 10/2011) [mg]/[kg]	Result
Α		24		
В	10 days at 60°C	6 dm²/Kg	≥ 95	OK
D2				

The test has confirmed that the product covered by this declaration is in conformity with the migration as per DM 21/03/73.

COMPLIANCE WITH SPECIFIC MIGRATION OF METALS

To guarantee the compliance to **Reg (UE) 10/2011**, plastic materials and articles shall not release the mentioned metals beyond the limits expressed in **Reg. (UE) 10/2011**. This declaration is issued basing on the latest updated of the metals' list (and their associated migration limit) in Reg (UE) 10/2011.

The product was tested with following simulant by total immersion at the following conditions:

Food simulant	Contact conditions	Surface/vol. ratio	Element	Limits (Reg.EU 10/2011) [mg]/[kg]	Result
			Al	1	OK
			Sb	0.04	OK
			Ва	1	OK
			Со	0.05	OK
			Fe	48	OK
			Li	0.6	OK
			Mn	0.6	OK
			Ni	0.02	OK
_	40 1	6 1 2/4	Cu	5	OK
В	10 days at 60°C	6 dm ² /Kg	Zn	5	OK
			As	0.01	OK
			Cd	0.002	OK
			Cr	0.01	OK
			Hg	0.01	OK
<u> </u>		Danie C	Pb	0.01	OK



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Eu	0.05	OK
Gd	0.05	OK
La	0.05	OK
Tb	0.05	OK

The product covered by this declaration is in conformity with the specific migration limits associated with metals listed in Reg (UE) 10/2011.

COMPLIANCE WITH SPECIFIC MIGRATION OF PRIMARY AROMATIC AMINES

To guarantee the compliance to **Reg. (CE) 1935/2004** and **Reg (UE) 10/2011**, plastic materials and articles shall not release primary aromatic amines, except for those listed in Table I Annex I, in quantities detectable in foodstuff or food simulants. The limit of detection is 0.002 mg of substance per kg of food product or food simulant. The limit of detection is applied to the sum of the primary aromatic amines released.

Food simulant	Contact conditions	Surface/vol. ratio	Limits (Reg. EU 10/2011) [mg]/[kg]	Result
В	10 days at 60°C	6 dm²/Kg	0.002	OK

The product covered by this declaration is in conformity with the specific migration limits associated with primary aromatic amines.

IN COMPLIANCE WITH:

To guarantee the compliance to Reg (UE) 10/2011, plastic materials and articles, CAPSOL S.p.A. also certifies:

- Based both on the declarations issued by our suppliers and on laboratory tests results, our products are compliant for Food Contact use.
- Additives as Bisphenols and Phthalates are not intentionally used in the product manufacturing process.
- Allergen Substances as listed in Dir. 2007/68/CE and Annex II of Reg. (EU)1169/2011 are not intentionally used.
- NIAS as like GMO, CMR, Flame retardants, Substances of animal origins, Nanomaterials, Endocrine Disruptors and Ethanol are not intentionally used.
- Substances listed in the Regulation (EU) 2019/1021 of the European Parliament and of the Councils of 20 June 2019 on persistent organic pollutants (POPs), including PFOA, PFOS and its derivatives, are not used as raw materials or intentionally used.
- PVC, LATEX and EPS are not intentionally used.
- Forbidden mineral oils (MOSH and MOAH) are in compliant with the Reg. (UE) 10/2011.



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SHELF LIFE, MOSH/MOAH, REACH CONFORMITY AND CONDITIONS OF USE

In accordance with the result of the laboratory tests carried out, Capsol S.p.A. advise:

- We recommend using our products within 12 months from the date of delivery to your warehouses.
- Storage and conservation of the products in their original packaging in a clean, dry, and closed place.
- The place intended for the storage of our products must maintain a temperature between 5°C 35°C and humidity between 45%- 75%.
- The products must be protected from UV rays.
- Before use in the packaging machine, it is recommended to stabilize the products for 24 hours at an ambient temperature between $15 \,^{\circ}\text{C} 35 \,^{\circ}\text{C}$.
- We hereby declare that the products delivered to the Customer, from the date of this declaration, do and will fulfill EC regulation 1907/2006 (REACH, article33) requirements and their updates detailed in Annex XVII of the regulation. https://echa.europa.eu/candidate-list-table.
- The forementioned testing conditions provide a repeated use article and the contact conformity at room temperature (or below)for over 6 months, including heated up to 70°C for 2 hours or up to 100°C for 15 minutes *exclusively* for the following types of food*:

TYPE OF FOOD	TEST SIMULANT	FOOD REPRESENTED
ACIDS	Acetic Acid 3% DM 21.3.1973 and Reg 10/2011	Vinegar, ciders, filtered simple or concentrated fruit of vegetable juices, fruit nectars, lemonades, syrups, bitters, vegetable infusions, coffee, tea, alcoholic, energy and similar drinks, flavored water, liquid coffee extract, preserves, yogurt, feta, mozzarella, mayonnaise, mustard.
ALCOHOLIC	Ethanol 20% Reg. 10/2011	Alcoholic beverages (wines ,spirits, beer), wet sweets, processed fruit in the form of puree, preserves or paste in its own juice or sugar syrup (jams, compote and similar products), processed vegetables in the form of puree, preserves, pasta or in their own juice , fruit and vegetables preserved in alcoholic means, canned fish or meat in aqueous means, eggs (liquid and cooked yolk and egg with) ,sauces with a watery character, ice creams.
DAIRY	Ethanol 50% Reg. 10/2011	Milk and beverages based on whole milk, partially dehydrated, and partially or totally skimmed, fermented milk such as yogurt, buttermilk and similar products, cream, processed cheeses (soft cheeses, cottage cheese and similar), cheeses preserved in aqueous means (feta, mozzarella and similar).



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OILY AND GREASY	DM 21.3.1973 and Reg 10/2011	Bakery, biscuit and dry fresh pastry products with fatty substances on the surface, chocolate and substitutes, sweets with fatty substances on the surface, fruits and vegetables preserved in an oily means, nuts(peanuts, chestnuts, almonds, hazelnuts, nuts, pine nuts and similar)in the form of paste or cream, natural or processed animal and vegetables fats and oils(cocoa butter, lard, melted butter, margarine, other fats consisting of water-in-oil emulsions) fresh, chilled fish, processed, salted or smoked, including fish roe, canned fish and meat in an oily means, crustaceans and mollusks (including oysters, mussels, snails) preserved or cooked without the shell in an oily means, fresh meat, chilled, salted, smoked, processed meat products(ham, salami, bacon, sausages and others) or in the form of paste or cream, meat product marinated in an oily means, natural cheeses without rind or with rind edible(gouda, camembert and similar) and dark cheeses, cheeses preserved in oily means, fried or roasted foods, products with a fatty character(preparations for soups, broths or liquid, solid or powdered sauces; homogenized compound food preparations, ready meals, including yeast and raising agents), sauces with a fatty character(mayonnaise, salad sauces and other and other oil/water emulsions e.g. coconut based sauces), mustards, sandwiches, pizza and toast with substances fat on the surface, cocoa mass, spices and aromas in an oily means(pesto, curry paste).
AQUEOUS	Ethanol 10% Reg. 10/2011	Non-alcoholic drinks or beverages with an alcohol content of less than 5%, sugars and sugar-based products (molasses, sugar syrups, honey and similar), fresh crustaceans and mollusk in the shell, whole fruit, fresh or chilled, unpeeled, vegetables fresh, peeled or in pieces.

(*Ref. Reg. (UE) 10/2011, Annex III, Tab.2)

- Verification of suitability remains with the final user.

<u>Capsol S.p.A.</u> declines all responsibility for any use of its products other than that specified in this declaration.

Capsol S.p.A. operates according to quality standard ISO 9001:2015 (cert. n.IT311356).

Agrate Brianza (MB)

Simone NARDI Capsol Regulatory Affair QM



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