

Dear Customer → cover letter
Attention: Mr. / Mrs → cover letter
Reference products codes → cod. id. as listed in the cover letter

Declaration of conformity and specification for using plastic materials, which come in contact with food



You receive the following material from us:

- *Crown cork pry-off (closure) CODE *401**
- *Food contact plastic: TPE PVC FREE best quality compound*
- *NEW BOX S.P.A. internal validation codes: TC002 – TC003 - TC004 – TC005 - TC 006 – TC011 – TC 012–TC014-TC015*

I. Materials description:

- Metal plate: Electrolytic tin plate or tin free steel – EN 10202
- Plastic compound: The product is a mixture consisting of thermoplastic elastomer (TPE), polyolefin and additives.
- Plastic compound application process: Hot extrusion and cold moulded
- Plastic compound supplier: selected by New Box S.P.A.

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The product is conform to the following regulations and the subsequent amendments, which are currently (at date of this conformity) enacted.

II. European general regulations:

- ✓ EU Framework regulation article 3 (EC) No. 1935/2004 on food contact materials
- ✓ Regulation (EC) 2023/2006

III. European specific regulations:

- ✓ Plastics Regulation (EU) 10/2011
- ✓ Italian rule DM 21/03/1973 and following updates and amendments
- ✓ German Law Book on Foodstuff and Feeds (LFGB) §§30 and §§31

IV. Non-European regulations:

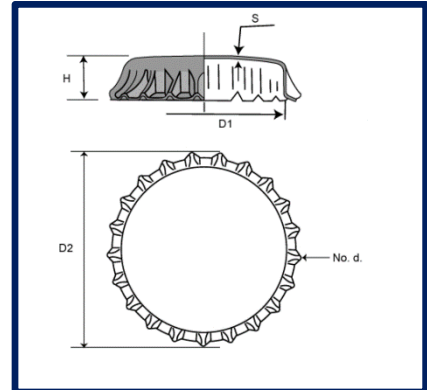
- ✓ 21 CFR 177.1210 of the US FDA Regulation
- ✓ Switzerland - Ordinance on Materials and Articles in Contact with Food of 23.11.2005 (817.023.21), including subsequent amendments

V. Dimension and composition of the product:

The dimension are according to the last DIN 6099

❖ NEW BOX Technical data Sheets: "PDS PRY FREE"

- H - height: $6,00 \pm 0,15$ mm
- D1 - internal \varnothing : $26,75 + 0,15$ mm
- D2 - outside \varnothing : $32,10 \pm 0,20$ mm
- No. d. – number of teeth: 21
- S - Metal thickness (*): $0,20 \pm 5\%$ (NEW BOX STANDARD)
 - Possible metal thickness: $0,210 \pm 5\%$ / $0,200 \pm 5\%$ / $0,190 \pm 5\%$ / $0,180 \pm 5\%$



(*) as per last EN 10202, but not according to last DIN 6099 and last STL B (Germany) - The delivered thickness can be found in the delivery note or in the supply agreement.

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- Liner profile of the plastic compound:

- "P 916"; "P 912"



VI. Composition of the product (description top to down)

1. outside paint (lacquer + inks + lacquer)
2. metal plate as functional barrier
3. inside paint adhesion of the compound
4. liner compound in direct food contact



VII. Provided application / restriction:

Suitable filling goods:

The closures are suitable for **Beers, and Soft drinks (carbonated and not carbonated)**, the compliance of which has to be assessed using simulants "B" and "C" according to annex III (EU) 10/2011. It is recommended to check the level of migration.

Provided application:

- ✓ Usable for cold filling
- ✓ Usable for pasteurisation, but only in tunnel Pasteur (Max. 75°C)
- ✓ Usable for hot filling
- ✓ Processing typical temperature 15°C ÷ 30°C
- ✓ Lacquer dust (depend on the lithography in Max. 35 mgr for 25 closures)
- ✓ Internal pressure regarding the last STL B (Germany)

Applications which bring the down gauged crown corks in extreme conditions (for example: packaging and stacked in the tray, pasteurization, hot fill etc.) must be particularly qualified by the bottler separately.

Closing:

The closing rings should have a diameter of \varnothing 28,25 mm (ceramic rings are to be preferred)

For down gauged material we recommend the follow diameter:

0,210 mm => \varnothing 28,20 ÷ 28,25

0,200 mm => \varnothing 28,20 ÷ 28,25

0,190 mm => \varnothing 28,15 ÷ 28,20

0,180 mm => \varnothing 28,15 ÷ 28,20

- The top load of the machine should be Min. 250 kg
- The typical closing diameter on the closed bottle should be between \varnothing 28,6 ÷ 28,8 mm
- To prevent corrosion it is necessary to rinse and blow-dry the crowns after closing, and use bottle with Maximum coverage 20 CTU in the finishing treatment of the mouths (bottles mouths HOT END).
- The crowns are usable for bottles according to DIN 6094-1
- A good quality of the bottle mouth is a prerequisite for a good sealing

We suggest the customer to confirm the qualification for the different applications with their own packaging tests. For any questions, please feel free to contact us.

Storage and storage life:



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www.new-box.com - info@new-box.com

Capitale Sociale € 5.200.000,00 int. vers. - Via Industriale, 11 - 36043 Camisano Vicentino (VI) - Tel. +39 0444 419500 (ric. aut.) Fax. +3 9 0444410123
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- ✓ Storage life of 12 month in rooms with relative humidity of Max. 60%
- ✓ Storage temperature of 5°C ÷ 35°C with good air circulation
- ✓ Do not expose to direct sunlight, protected from humidity and smell influence
- ✓ The product has to be used according to the "FiFo" (first in – first out) principle

VIII. Limit value for the food contact plastic liner compound:

REG. (EU) 10/2011 - annex I and II

The formulation complies with the compositional requirements as set forth in annex I and II of Regulation (EU)

10/2011, including amendments (EU) 321/2011 and (EU) 1282/2011.

Further to the requirements of adhering to the limit of overall migration, the product contains the following components with specific restriction to be observed.

FCM	Ref. N°.	Designation	CAS N°.	Rstriction	Remarks
223	13630	Butadien	106-99-0	SML = ND	Qm = 1mg/kg in finished product
315	46640	2,6 Di-tert-butyl-p-kresol	128-37-0	SML = 3 mg/Kg	na
384	4000	2,4-Bis-(octylmercapto)-6-(4-hydroxy-3,5-di-tert-utylanilino)-1,3,5-triazin	991-84-4	SML = 30 mg/Kg	na
433	68320	Octadecyl (3,5-di-tert-butyl-4-hydroxyphenyl) propionat	2082-79-3	SML = 6,0 mg/Kg	na

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The sealing material contains components, for which the generic SML of 60mg/kg according to article 11 (2) is applicable. The identity of these components is generally confidential.

There are components in the sealing, about which the suppliers state the presence of substances with SML / Qm. The identity is their confidential know how. If desired, we could arrange a non-disclosure agreement between the supplier and an independent laboratory for evaluation.

REG. (EU) 10/2011 – Substance with restriction in food

According to article 11 (3) of Regulation (EU) 10/2011, the following direct food additives are present in the formulation and / or are present in the raw material used for the sealing.

FCM	Ref. N°.	Designation	CAS N°.	Rstriction	Max %
106	89040	Calciumstearat	106-99-0	E 470 a	na
315	46640	2,6 Di-tert-butyl-p-kresol	128-37-0	E 321	na
504	86240	Siliciumdioxid	7631-86-9; 112945-52-5	E 551	na
610	93440	Titandioxide	1346-67-7	E 171	1%

Overall migration

The overall migration are ascertained which a 200 ml bottle and a food contact area of 6,2 cm²



Simulants	t and T conditions	Dry residue of migrates mg/l	Calculated with 200 ml filling capacity
B – Acetic acid 3 % (p/v)	10 days @ 40°C	0,4 mgr. / crown cork (*)	2.0 mg/l
C - Ethanol 20 % (v/v)	10 days @ 40°C	0,4 mgr. / crown cork (*)	2.0 mg/l

Method ME348; EN 1186-5

(*) crown corks liner food contact surface it' about 0,05 dm²

Evaluation of the overall migration:

Taking into account the small amount of lining gasket applied to one cap the overall migration data are:

- They are lower than the limits mentioned in Regulation (EU) 10/2011
- They are lower than the limits mentioned in Italian rule DM 21/03/1973 and following updates and amendments
- They are lower than the limit of 60 mg/l according to the German Bedarfsgegenständeverordnung.
- They are lower than the limits mentioned in 21 CFR 177.1210 of the US FDA Regulation concerning lining gaskets.

We suggest the customer, to confirm the qualification for the different applications with their own packaging tests. For questions, please feel free to contact us.

This confirmation is valid for the closure as described. If the food contact conditions are observed, the closures fulfil these requirements.

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We would like to draw your attention to the responsibility of the industrial food packer to make sure that the levels of global as well as specific migration are below their stipulated limits.

IX. Summary

- ✓ The mentioned closures are in compliance if they are used under the conventional conditions according to the regulation (EG) N°. 1935/2004.

The information about the migration results are based on the statement form the Liner supplier.

The listed using and closing parameter are valid for the complete closure.

The declaration is valid for the product delivered by us as specified above.

The Directives 82/711/EEC and 85/572/EEC provide a guideline for the selection of test conditions to be used for various food products.

According to that and under consideration of the food contact conditions stated, the product complies with the stipulations of this Directive regarding the packaging of food products to be packed. The user shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Directive.

This declaration will be valid for three years. With the release of this declaration, all others lose their validity.



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Date 19/04/2016

New Box S.P.A.
Food Safety
Christian Zanarella

New Box S.P.A.
Business Operator
Ottaviano Lucatello
(" Business Operator " pursuant to Art. 2, paragraph 1, letter d) of Regulation 1935/2004/EC)

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