

CROWN Closures Italy
Via Nettunense, 118
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Declaration of Compliance of CROWN Closures Europe Products

Crown Closures Italy Srl located in Aprilia (LT) Via Nettunense 118 - 04011-Italy on behalf of the metal closures businesses of its affiliates, Crown Embalajes España S.L.U., Crown Verschlusse Deutschland GmbH, Crown Packaging UK plc, Crown Packaging Polska, all of which are subsidiaries of Crown European Holdings S.A. in the metal closures business of the Crown European Division, is issuing the present declaration of compliance.

Product: 38 - 110 mm closures lined with B15 compound (including profiles RTO/RTB - RTS/RSB - ECO/ECOB - FTS/FSB - FTO/FTB - DWO/DWB - TNO/TNB)

Application:

Food categories: All products listed in the Annex to the Council Directive 85/572/EEC, replaced by the provisions reported in Annex III of the Commission Regulation (EU) No 10/2011 as of 1 January 2013, but particularly indicated for the ones in any DRF category re. including pesto, vegetables in oil and sauces.

Conditions of use: Cold fill, hot fill and pasteurisation up to 100°C for 60 minutes and typical shelf-life up to 3 years.

A) Compliance Statement

The metal vacuum closures specified above supplied by Crown Closures Europe comply with the appropriate EU legislation with respect to food contact materials and articles currently in force:

- EU Regulation (EC) No. 1935/2004
- EU Regulation (EC) No. 2023/2006 "Good Manufacturing Practice"
- EU Regulation (EC) No. 1895/2005
- With regards to the sealing gasket: EU Regulation No 10/2011 and amendments.
- The sealing gaskets are formulated in accordance with US FDA CFR21 177.1210 (Closures with sealing gaskets for food containers), and satisfy the overall migration requirements in this regulation.
- All internal coatings are formulated in accordance with US FDA CFR21 175.300 (Resinous and polymeric coatings), and satisfy the overall migration requirements in this regulation.

Sede Legale / Legal Address: CROWN Closures Italy S.r.l. Strada Ugozzolo, 100/A - 43122 Parma (PR)
Cap. Soc. € 30.263.320 i.v. - C.F., P.I. e nr iscrizione del Registro delle Imprese di Parma 01554960599 - iscrizione al REA di Parma al n.254465 -
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B) Confidential Information

(i) The following constituents (monomers and additives) of the sealing gasket are subject to restrictions or specifications in Commission Regulation (EU) No 10/2011 as amended:

FCM Substance No	Ref No	CAS No	Name	Restriction / Specification (i)
127	26050	0000075-01-4	Vinyl Chloride	Q _m = 1mg/kg; SML = ND Specifications in Annex I of EU Reg. 10/2011 & am.
532	88640	0008013-07-8	Epoxidised Soyabean Oil	SML = 60mg/kg (infant food SML = 30mg/kg) Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
73	76866	--	Polyadipate	SML = 30mg/kg) Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
575	76721	0063148-62-9	Polydimethylsiloxane (Silicone Oil)	Restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
--	--	0000557-05-1	Zinc stearate	SML = 25mg/kg (expressed as Zn) Restrictions in Annex II of EU Reg. 10/2011 & am.

Note:

(i) ND indicates that the substance shall not migrate in detectable quantities

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(ii) The following constituents (additives) of the sealing gasket listed without specific restriction or specification in Commission Regulation (EU) No 10/2011 as amended:

FCM Substance No	Ref No	CAS No	Name	Restriction / Specification
--	--	0000144-55-8	Sodium Bicarbonate	No specific restrictions; Generic SML = 60 mg/kg
138	93760	0000077-90-7	Tributyl acetyl citrate	No specific restrictions; Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
670	56800	0030899-62-8	Glycerol monolaurate diacetate	No specific restrictions; Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
242	85360	0000109-43-3	Sebacic acid, dibutyl ester	No specific restrictions; Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
--	--	0001592-23-0	Calcium stearate	No specific restrictions; Generic SML = 60 mg/kg
610	93440	0013463-67-7	Titanium dioxide	No specific restrictions; Generic SML = 60 mg/kg
335	68960	0000301-02-0	Oleamide	No specific restrictions; Generic SML = 60 mg/kg
271	52720	0000112-84-5	Erucamide	No specific restrictions; Generic SML = 60 mg/kg

NB: Our declaration of compliance with regulations concerning overall and specific migration is based on the use of statutory simulants and test conditions as laid out in EU Directives 82/711/EEC as amended and 85/572/EEC, that will be replaced by the provisions reported in Annex III of the Commission Regulation (EU) No 10/2011 as of 1 January 2013. Actual migration levels of materials from the closure into food are dependent on the composition of the food product, the volume of the jar, the method of processing the food in the jar, and the storage conditions in which it is held, and may be higher. It is the packer's responsibility to ensure that migration levels remain within permitted limits, and to carry out any necessary testing to establish this, since CROWN Closures Europe has no control over the actual conditions of use, or of the composition, processing and storage conditions of the final product.

Steve D. Kitchener
 European Materials Manager
 Crown Closures Europe

Issue 12 dated 23rd Feb 2012

Gianmatteo Avancini
 European Quality Manager
 Crown Closures Europe

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Annex 1. Supporting Documentation

Migration Test Data

The following data was generated in accordance with Commission Regulation (EU) No 10/2011 and associated directives 82/711/EEC as amended and 85/572/EEC.

Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC as amended and 85/572/EEC (or Annex V, EU Regulation 10/2011 as of the 1st Jan 2013). Before comparing specific and overall migration test results with the migration limits the correction factors in Directives 82/711/EEC, 85/572/EEC as well as in Chapter 4 of Annex V of EU Regulation 10/2011 and amendments shall be applied in accordance with the rules set out therein.

1.1. Global and specific migration expressed as mg/lid.

Cap Diameter (mm)	Process/Storage Conditions	Simulant (i)	Migration	ESBO	PAD	DBS	ATBC	AMG L	Ref.
38	1 hr.@100°C + 10d @ 40°C	D	3.4			0.3	0.4	0.7	E1608
48	1 hr.@100°C + 10d @ 40°C	D	6.4			0.2	0.7	0.7	E2808
53	1 hr.@100°C + 10d @ 40°C	D	5.2			0.5	1.1	2.5	E0208
58	1 hr.@100°C + 10d @ 40°C	D	5.0			0.4	1.0	1.9	E0108
63	1h @60°C + 2d @ 20°C	Iso-octane	2.8						E2208
63	30 min @ 49°C	n-heptane	1.9						E2008
63	1 hr.@100°C + 10d @ 40°C	D	5.1						E0808
63	30 mins.@90°C + 10d @ 40°C	D	--	2.1	< 1.5	0.9	0.7	< 0.7	2008L06324 CW3606D
66	1 hr.@100°C + 10d @ 40°C	D	5.8			< 0.8	0.9	1.7	E0308
66	1 hr.@100°C + 10d @ 40°C	B	0.2						E1208
70	1 hr.@100°C + 10d @ 40°C	D	6.8			0.4	1.0	1.7	E1908
82	1 hr.@100°C + 10d @ 40°C	D	6.7						E3509
110	1 hr.@100°C + 10d @ 40°C	D	11.3			1.1	1.3	1.5	E3009
110	1 hr.@100°C + 10d @ 40°C	B	1.8						E2909

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1.2. Specific migration on food expressed as mg/kg

Cap Diameter (mm)	Process/ Storage Conditions	Product	Jar size (ml)	ESBO	PAD	AMG L	DBS	ATBC	Ref.
66	Pasteurisation +3 months RT	Vegetables in oil	314	10	nd	nd	2.6	2.8	08L15844
66	Pasteurisation +6 months RT	Vegetables in oil	314	<10	<10	nd	3	5	08L24269
66	Pasteurisation +9 months RT	Vegetables in oil	314	15	<10	10	3	nd	08L35242
66	Pasteurisation +12 months RT	Vegetables in oil	314	<10	<10	nd	<2	3	09L05460
66	Pasteurisation +18 months RT	Vegetables in oil	314	12	<10	34	6	nd	09L26069
66	Pasteurisation +24 months RT	Vegetables in oil	314	<10	nd	13	4	4.5	10L08396
66	Pasteurisation +30 months RT	Vegetables in oil	314	17	<10	11	4.5	12	10L32908
66	Pasteurisation +36 months RT	Vegetables in oil	314	15	<10	26	7.0	18	11L09734
58	Pasteurisation +2 months RT	Pesto sauce	212	nd	nd	18	9.9	13	08L13288
58	Pasteurisation +6 months RT	Pesto sauce	212	<10	nd	nd	3	6	08L24266
58	Pasteurisation +9 months RT	Pesto sauce	212	16	<10	<10	4	nd	08L35283
58	Pasteurisation +12 months RT	Pesto sauce	212	<10	nd	<10	4	7	09L05461
58	Pasteurisation +18 months RT	Pesto sauce	212	<10	<10	20	6	6	09L26070
58	Pasteurisation +24 months RT	Pesto sauce	212	<10	nd	13.5	4.5	5.5	10L08397
58	Pasteurisation +30 months RT	Pesto sauce	212	21	nd	nd	nd	3.5	10L32907
58	Pasteurisation +36 months RT	Pesto sauce	212	12	<10	25	5.5	15	11L09735

Notes:

(i) Simulant "B" = 3% acetic acid; simulant "D" = rectified olive oil; n-heptane is used according CFR 21 §177.1210