


EVIOSYS Packaging Switzerland GmbH

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Declaration of Compliance of EVIOSYS Closures Products Lined with Compound N61

EVIOSYS Packaging Switzerland GmbH located in Baarermatte, CH-6340 Baar, Switzerland is issuing the present declaration of compliance relevant for all closures manufactured by the plants:

EVIOSYS Packaging Italia S.r.l.

Via Nettunense 118 - 04011 Aprilia (LT) - Italy - Tel. +39 069 21 511

EVIOSYS Packaging Closures Spain S.L.

Poligono Industrial Carretera de La Isla - Turdetanos

No. 1 C.P. 41703 DOS HERMANAS, Sevilla- Spain - Tel. +34 954 97 95 00

EVIOSYS Packaging Polska Sp. z o. o.

ul. Maszewska 20 - 72-100 Goleniow - Poland - Tel. +48 914 69 78 01

EVIOSYS Packaging Foodcan GmbH

Werk Seesen - Fritz-Züchner Strasse 8 - 38723 Seesen - Germany - Tel. +49 538 17 81 224

EVIOSYS Packaging España S.A.U.

Pol. Ind. Silvota, 33420 Llanera, Asturias - Spain - Tel. +34 985 732 030

Products:

Out of the range between 33 mm to 110 mm closures (including, but not limited to, profiles DTO - DTP/B - DWO/B - MTP/B - RTO/B - RTS/RSB - RTP/B - ECO/B - FTS/FSB - FTO/B - TNV/B - MTP/B - OBT) lined with the ESBO not-intent PVC based N61 compound forming the sealing gasket.

Application:

Food categories: All aqueous, acidic and oily products listed in the Annex III of the Commission Regulation (EU) No. 10/2011 as amended but particularly indicated for the ones in sub-column D2, including pesto, vegetables in oil and sauces.

Conditions of use: Cold fill, hot fill and pasteurisation up to 100°C for 60 minutes.

Limitations on use: Migration values will be dependent on food type, process/storage conditions, jar size and shelf life. As these factors are outside Eviosys' control, it is the filler's responsibility to ensure compliance through use of appropriate jar size and setting an appropriate shelf life. Migration data provided in annex 1 may be used as a guide to acceptable jar sizes.

CAPq-CLO-DOC-008.doc N61 Version 16

Written By:	AVOLIO, Salvatore	Authorised By:	J AUSLIN, Richard	Lang.:	English
Checked By:	SULLIVAN, Kathryn	Date:	14 Apr 2022	Page:	1/8

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A) General Compliance Statement

The metal vacuum closures specified above manufactured by the Eviosys packaging plants have been produced in accordance with the appropriate EU and US legislation with respect to food contact materials and articles currently in force including:

- EU Regulation (EC) No. 1935/2004 relating to materials and article intended to come into contact with food and particularly with articles 3, 11(5), 15 and 17.
- EU Regulation (EC) No. 1895/2005 relating to the use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- EU Regulation (EU) 2018/213 regarding Bisphenol A from varnishes and coatings.
- EU Regulation (EC) 2023/2006 regarding Good Manufacturing Practice for materials and articles intended to come into contact with food.
- EU Regulation (EC) No. 1169/2011 regarding the absence of substance or products causing allergies or intolerances (allergens).
- EU Regulation (EU) No. 2019/1021 regarding the absence of persistent organic pollutants.
- EU Directive 78/142/EEC relating to materials and articles which contain vinyl chloride monomer and which are intended to come into contact with food.
- With respect to the sealing gasket only, EU Regulation (EC) No 10/2011 as amended.
- 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.
- With respect to the sealing gasket, California Proposition 65 (US California Safe Drinking Water and Toxic Enforcement Act) related to the content of chemicals known to cause cancer or birth defects or other reproductive harm. With regards to the coating, BPA containing specifications may require “clear and reasonable warnings” for consumers.

Wherever this document refers to Regulation (EU) No. 10/2011 as amended, this includes all amendments as described in a separate Eviosys document “European Regulation (EU) No. 10/2011 and Amendments”. Each amendment is carefully evaluated by Eviosys Food Contact Regulatory group to identify and act on any relevant changes. The document will be updated with every amendment.

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Furthermore:

- Internal protective coatings are not currently in the scope of material specific EU legislation, however they comply with the requirements of the council of Europe Resolution AP (2004)1 and the CEPE European Coatings Code of Practice.
- All external coatings and decoration are specified and formulated specifically for use on the non-food contact surface of food packaging in conformance with the EuPIA Guidelines and are applied under good manufacturing practice such that compliance of the finished closures with Regulation (EC) 1935/2004 is not compromised.
- Although ESBO is not intentionally used in the closure sealing gasket, trace contamination cannot always be avoided. Such traces do not in any way impact on the safety or compliance of the closure.
- Phthalate ester plasticizers are not intentionally used by Eviosys packaging.
- With respect to the sealing gasket, bisphenol A (BPA) is not intentionally used in the formulation.

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B) Confidential Information

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

FCM Number	Ref No	CAS No	Name	Restriction / Specification (*)
127	26050	0000075-01-4	Vinyl Chloride	Qm = 1 mg/kg; SML = ND Specifications in Annex I of EU Reg. 10/2011 & am.
73/ 797	76866/ 76807	--/ 0007328-26-5	Polyadipate	SML = 30 mg/kg Group restrictions and specifications in Annex I of EU Reg. 10/2011 & am.
138	93760	0000077-90-7	Tributyl acetyl citrate	No specific restrictions; Group 32 restrictions in Annex I of EU Reg. 10/2011 & am. (iv)
242	85360	0000109-43-3	Sebacic acid, dibutyl ester	No specific restrictions; Group 32 restrictions in Annex I of EU Reg. 10/2011 & am. (iv)
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 = 5 mg/kg (expressed as Zn) Restrictions in Annex II of EU Reg. 10/2011 & am.

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

The gasket material may contain traces of bis(2-ethylhexyl) adipate, FCM 207, Ref. 31920, SML = 18 mg/kg. This material is not intentionally added during the gasket production but it could be contained as side product of one of the materials intentionally used and listed in the table above.

(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 Number	Ref No	CAS No	Name	Restriction / Specification
335	68960	0000301-02-0	Oleamide	No specific restrictions;
271	52720	0000112-84-5	Erucamide	No specific restrictions;

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(iii) The following constituents (dual-use additives) of the sealing gasket are listed without specific restriction or specification in Commission Regulation (EU) No 10/2011 as amended. These additives are authorized by Regulations (EC) No 1333/2008 and (EC) No 1334/2008 as amended:

E-Number/ FCM Number	Ref No	CAS No	Name	Restriction / Specification
E500ii/ --		000144-55-8	Sodium bicarbonate	No specific restrictions;
E470a/ --		001592-23-0	Calcium stearate	No specific restrictions;
E171/ 610	93440	013463-67-7	Titanium dioxide	No specific restrictions;
E900/ 575	76721	0063148-62-9	Polydimethylsiloxane (Silicone Oil)	Restrictions and specifications in Annex I of EU Reg. 10/2011 & am.

NB: *Our declaration of compliance to regulations concerning overall and specific migration is based on the use of statutory simulants and test conditions as laid out in Commission Regulation (EU) No 10/2011 as amended. 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.*

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 the closure manufacturer has no control over the actual conditions of use, or of the composition, processing and storage conditions of the final product.

Issue 16 dated 14th April 2022

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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 as amended.

Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Annex V, Commission Regulation (EU) No. 10/2011 as amended. Before comparing specific and overall migration test results with the migration limits the correction factors in Chapter 4 of Annex V of EU Regulation 10/2011 as amended shall be applied in accordance with the rules set out therein.

With respect to Vinyl Chloride, compliance was verified by worst case calculation.

Use of migration information: Overall and specific migration data expressed in mg/lid can be used to evaluate compliance with limits dividing the value reported in the table by the pack size in (kg or dm² to get results in mg/kg or mg/dm²). Values in mg/kg need to be corrected for S/V in accordance with paragraph 2 of art. 17 of Reg. (EU) 10/2011 as amended.

Correction of migration into food simulant D2 [Reg. (EU) 10/2011, Annex V, point 4.2]: The migration test results expressed in mg/dm² or mg/kg (where relevant) generated into food simulant D2 shall be divided by the D Reduction Factor (DRF) indicated in Reg. (EU) No. 10/2011, Annex III, Table 2, sub-column D2 of column 3 before comparing the results with the migration limits.

Simulant D1: As simulant D2 is conventionally considered worst case for fatty foods, D2 data may be used in place of D1 data [ref (EU) 10/2011 Annex III section 4 and Annex V section 2.1.2].

1.1 Overall migrations (OM) expressed as mg/lid:

Cap Size (mm)	Process Conditions	Simulant (i)	OM	Minimum Total Food Contact Surface (dm ²) (ii)	Ref.
33	2 h @ 100°C	D2	2.1	0.2	E01-21
38	2 h @ 100°C	D2	5.8	0.6	E86-20
43	2 h @ 100°C	D2	5.2	0.5	E05-21
48	2 h @ 100°C	D2	8.4	0.9	E06-21
53	2 h @ 100°C	D2	6.5	0.7	E01-20
53	10 d @ 40°C	D1	18.0	1.8	E97-21
58	2 h @ 100°C	D2	9.3	0.9	E97-20
58	10 d @ 60°C	E	2.0	0.2	21L14206/1
63	2 h @ 100°C	D2	7.8	0.8	E47-18
63	10 d @ 40°C	D2	7.3	0.7	E08-21
63	15 min @ 49 °C	n-heptane	3.4	na	E28-19
66	2 h @ 100°C	D2	10.0	1.0	E105-20
70	2 h @ 100°C	D2	9.6	1.0	E96-19
82	2 h @ 100°C	D2	7.7	0.8	E20-20
110	1 h @ 100°C + 10 d @ 60°C (iii)	A	3.5	0.4	E75-20

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110	1 h @ 100°C + 10 d @ 60°C (iii)	B	3.3	0.3	E76-20
110	1 h @ 100°C + 10 d @ 60°C (iii)	C	8.4	0.8	E77-20

1.2 Specific migrations (SM) expressed as mg/lid:

Cap Size (mm)	Process Conditions	Simulant (i, v)	Specific Migration (iv)				Minimum Total Food Contact Surface (dm ²) (vi)	Minimum Filling Quantity (g) (vi)	Ref.
			PAD	DBS	ATBC	Zn			
33	1 h @ 130°C + 10 d @ 60 °C	D2	NA	0.7	2.8	NA	0.4	59	E111-20
53	1 h @ 100°C + 10d @ 60°C	B	NA	NA	NA	<0.1	0.01	1.7	18L06544/3
53	1 h @ 100°C + 10 d @ 60°C	D2	<1.0	2.3	10.2	NA	1.4	225	1327\FPM\FD C\20
58	1 h @ 100°C + 10 d @ 60°C	D2	1.5	2.3	9.4	NA	1.3	220	284FPM\FDC\ 20
58	1 h @ 100°C + 10 d @ 60°C	B	NA	NA	NA	<0.1	0.01	1.7	20L05588
58	10 d @ 60°C	E	<0.5	<0.01	<0.01	NA	0.05	8.7	21L14206/1
63	1 h @ 100°C + 10 d @ 60°C	D2	2.8	2.1	10.0	NA	1.5	248	19L04918
63	10 d @ 40°C	D2	NA	1.6	4.4	NA	0.6	100	E08-21

Notes

(i) Simulant “A” = 10% Ethanol (v/v); simulant “B” = 3% acetic acid (w/v); simulant “C” = 20% ethanol (v/v); simulant “D1” = 50% ethanol (v/v); simulant “D2” = vegetable oil; simulant “E” = poly(2,6-diphenyl-p-phenylene oxide) (MPPO, TENAX®); *n*-heptane and DI Water are used according to FDA CFR 21 §177.1210;

(ii) The value is indicative, based on 10 mg/dm² overall migration limit (OML); The minimum volume/surface does not consider the reduction factors according to Chapter 4 of Annex V of Commission Regulation (EU) No 10/2011 as amended which shall be applied when comparing specific and overall migration test results with the migration limits when applicable;

(iii) With water-based simulants A, B and C this represents the worst case condition;

(iv) List of acronyms used: PAD = Polyadipates; DBS = Dibutyl sebacate; ATBC = Acetyl tributyl citrate; Zn = Zinc; ND = not detectable; NA = data not available;

(v) The specific migrations were mainly evaluated with simulant D2. For simulants A and B it is assumed that the specific migration corresponds to the overall migration value measured under test conditions at least as severe as for specific migration (worst case);

(vi) Based on the sum of the specific migration of the group No. 32 restricted substances (SML(T) of 60 mg/kg); for filling volumes <500 mL or >10 L, the minimum total food contact surface (jar + closure) is shown for which compliance can be assured in accordance with Article 17 of (EU) 10/2011 as amended. For filling volumes ≥500 mL or ≤10 L, the minimum filling quantity is shown

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for which compliance can be assured in accordance with Article 17 of (EU) 10/2011 as amended calculated using the real filling quantity. The density is assumed to be 1 g/cm³. A separate document explaining how migration should be expressed is available.

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November 2021

Phthalates in Cans, Ends, and Closures Supplied by Eviosys

Phthalates¹, including but not restricted to:

Name	CAS #
Butyl Benzyl Phthalate (BBP)	000085-68-7
Di-Butyl Phthalate (DBP)	000084-74-2
Di-2-Ethylhexyl Phthalate (DEHP)	000117-81-7
Di-isoButyl Phthalate (DIBP)	000084-69-5
Di-(2-Methoxyethyl) Phthalate (DMEP)	000117-82-8
Di-basic Lead Phthalate	069011-06-9
n-Pentyl Isopentyl Phthalate (nPiPP)	776297-69-9
Di-isoPentyl Phthalate (DiPP)	000605-50-5
Di-Pentyl Phthalate (branched and linear – mixed isomers (DPP))	084777-06-0
Di-Alkyl Phthalate C6-8 branched (DIHP)	071888-89-6
Di-Alkyl Phthalate C7-C11 branched and linear	068515-42-4
Di-Hexyl Phthalate (DHP)	000084-75-3
Di-isoNonyl Phthalate (DINP)	028553-12-0
Di-isoDecyl Phthalate (DIDP)	026761-40-0
Di-n-Octyl Phthalate (DNOP)	000117-84-0
Di-Ethyl Phthalate (DEP)	000084-66-2
Di-cycloHexyl Phthalate	000084-61-7

are not intentionally used as plasticisers in the manufacture of cans, ends, or closures produced by Eviosys, nor are they intentionally used in the manufacture² of the constituents of the cans, ends, or closures. However there are two limited non-plasticiser applications (which fully comply with all relevant EU legislation) where very low levels of Phthalates are used either:

- as a co-monomer in one of the PVC resins used in some PT closures,
- as a technical support agent in catalyst systems for Polypropylene used in some peelable end foils and some polymer coated metal

K M Sullivan, Regulatory Affairs Manager, EHS & Sustainability, Eviosys

¹ Phthalates referring to di-esters of Phthalic acid typically used as plasticisers

² Based on the assurances of our suppliers