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www.silgan-closures.com
on behalf of Silgan Closures GmbH

Technical Center – R&D

Supporting Documentation

Closure Migration Simulation (CMS)

Closure	Nominal Size	Nominal Type	Compound Type
	082	**DWB-DWO-HSB-HSP-KDB-KDO-RSB-RTA-RTS**	**469**

Basic closure / application information:		
Food contact area - compound	**4.30 cm²**	Silgan engineering drawings (CPS, WGF)
Food category: aqueous acidic (pH < 4.5) alcoholic milk products, cloudy drinks etc. fatty/oily	 Simulant A (10% ethanol) Simulant B (3% acetic acid) Simulant C (20% ethanol) Simulant D_1 (50% ethanol) Simulant D_2 (vegetable oil)	Commission Regulation (EU) No 10/2011 as amended
Processing conditions	Pasteurisation	Silgan Product Data Sheet (PDS) and Silgan Customer Cap Information (CCI)

Confirmation of Compliance(*)

Based on the simulation test conditions and calculations described in this document the closure type defined above meets the requirements with regard to the migration limits of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with foodstuffs as amended

- **if glass jars are filled with more than**

22	**g**	**aqueous,**
22	**g**	**acidic,**
22	**g**	**alcoholic,**
70(**)	**g**	**milk products, cloudy drinks etc. or**
717	**g**	**fatty/oily foodsimulant.**

- **or if the total food contact surface of closure and sealed container is larger than**

13	**cm²**	**for aqueous,**
13	**cm²**	**for acidic,**
13	**cm²**	**for alcoholic,**
42	**cm²**	**milk products, cloudy drinks etc. or**
430	**cm²**	**fatty/oily foodsimulant.**

With reference to Article 18(6) of Regulation (EU) No 10/2011 please note that the results of specific migration testing obtained in food shall prevail over the results obtained in food simulants. This Confirmation of Compliance refers to the closure, considering prescribed simulation test conditions. Therefore the food business operator is required to ensure compliance of the finished packaging (filled container) under actual food processing conditions. Compliance of the finished packaging with overall and specific migration limits depends on various factors which are beyond the control of Silgan White Cap.

(*) This confirmation does not consider the **reduction factors** according to Chapter 4 of Annex V of Commission Regulation (EU) No 10/2011 which shall be applied when comparing specific and overall migration test results with the migration limits in certain cases. When applying the reduction factors the Minimum Filling Quantities (V_{min}) and Minimum Total Food Contact Surfaces (A_{min}) will decrease accordingly. Furthermore the specific **application for baby food** is not considered in this table but it is part of the supporting information (see page 3ff).

(**) "Worst case" assumption based on overall migration value even though it is formal not applicable

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Supporting Information

- **based on Compound Migration Simulation Test results**

Simulation Test Conditions (worst-case assumption)			
Processing conditions High temperature applications up to 100°C + any long term storage at room temperature or below	Simulants A, B, C, D_1, D_2	Simulation test conditions **I** Overall migration – OM4+OM2 1h 100°C + 10d 40°C **II** Specific migration 1h 100°C + 10d 60°C	Regulation (EU) No 10/2011 Annex V, Chapter 3, Table 3 Annex V, Chapter 2, Table 1 and 2

Compound Migration Simulation Test Results				**Source / remarks:**
Overall Migration	Simulant	[mg/cm²]	Simulation test cond.	Test report: CME-GRP46Xf-2020A
	A	0.16	I	
	B	0.06	I	
	C	0.19	I	
	D_1	0.98	I	
	D_2	4.3	I	
Additional Migration*	Simulant	[mg/cm²]	Simulation test cond.	Test report: IN_46915_1850-320-00
	A	0.08	II	
	B	0.09	II	
	C	0.09	II	
Specific Migration:	Simulant	[mg/cm²]	Simulation test cond.	Test report: CME-GRP46Xf-2020A
Soybeanoil, epoxidised (ESBO)	D_1	0.41	II	
Soybeanoil, epoxidised (ESBO)	D_2	10.0	II	
Zinc	B	0.006	II	
Zinc	D_1	0.003	II	
Zinc	D_2	< 0.004	II	

***** additional overall migration tests in order to determine the migration potential into simulants under consideration of the more severe time/temperature conditions for specific migration simulation testing (worst-case approach)

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Calculation of Minimum Filling Quantities (V_{min}) and Minimum Total Food Contact Surfaces (A_{min})

Simulant A	**Migration** (1) [mg/closure]	**Restrictions** (2) (Silgan: CPI-46915)		V_{min} (3) [g]	A_{min} (4) [cm²]
Overall Migration	**0.7**	60 mg/kg simulant (6)	OML	11	
		10 mg/dm² surface area (7)	OML		7
Soybeanoil, epoxidised (5)	**0.3**	60 mg/kg food or simulant (8)	SML	6	
		30 mg/kg babyfood or simulant (9)	SML	11	
		10 mg/dm² surface area (10)	SML		3
Zinc	not analysed, see simulant D_1 („worst case“)	5 mg/kg food or simulant (11)	SML	3	
		1 mg/dm² surface area (10)	SML		1

Simulant B	**Migration** (1) [mg/closure]	**Restrictions** (2) (Silgan: CPI-46915)		V_{min} (3) [g]	A_{min} (4) [cm²]
Overall Migration	**0.3**	60 mg/kg simulant (6)	OML	4	
		10 mg/dm² surface area (7)	OML		3
Soybeanoil, epoxidised (5)	**0.4**	60 mg/kg food or simulant (8)	SML	6	
		30 mg/kg babyfood or simulant (9)	SML	13	
		10 mg/dm² surface area (10)	SML		4
Zinc	**0.03**	5 mg/kg food or simulant (11)	SML	5	
		1 mg/dm² surface area (10)	SML		3

Simulant C	**Migration** (1) [mg/closure]	**Restrictions** (2) (Silgan: CPI-46915)		V_{min} (3) [g]	A_{min} (4) [cm²]
Overall Migration	**0.8**	60 mg/kg simulant (6)	OML	14	
		10 mg/dm² surface area (7)	OML		8
Soybeanoil, epoxidised (5)	**0.4**	60 mg/kg food or simulant (8)	SML	6	
		30 mg/kg babyfood or simulant (9)	SML	13	
		10 mg/dm² surface area (10)	SML		4
Zinc	not analysed, see simulant D_1 („worst case“)	5 mg/kg food or simulant (11)	SML	3	
		1 mg/dm² surface area (10)	SML		1

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Simulant D_1	**Migration** (1) [mg/closure]	**Restrictions** (2) (Silgan:CPI-46915)		**V_{min}** (3) **[g]**	**A_{min}** (4) **[cm^2]**
Overall Migration	**4.2**	60 mg/kg simulant (6)	OML	**70**	
		10 mg/dm² surface area (7)	OML		**42**
Soybeanoil, epoxidised	**1.8**	60 mg/kg food or simulant (8)	SML	29	
		30 mg/kg babyfood or simulant (9)	SML	59	
		10 mg/dm² surface area (10)	SML		18
Zinc	**0.01**	5 mg/kg food or simulant (11)	SML	3	
		1 mg/dm² surface area (10)	SML		1

Simulant D_2	**Migration** (1) [mg/closure]	**Restrictions** (2) (Silgan:CPI-46915)		**V_{min}** (3) **[g]**	**A_{min}** (4) **[cm^2]**
Overall Migration	**18.5**	60 mg/kg simulant (6)	OML	308	
		10 mg/dm² surface area (7)	OML		185
Soybeanoil, epoxidised	**43.0**	60 mg/kg food or simulant (8)	SML	**717**	
		30 mg/kg babyfood or simulant (9)	SML	1433	
		10 mg/dm² surface area (10)	SML		**430**
Zinc	**< 0.02**	5 mg/kg food or simulant (11)	SML	3	
		1 mg/dm² surface area (10)	SML		2

(1) Migration per closure = compound food contact area (page 1) x compound migration value (test results on page 2)

(2) Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, for further information see Silgan Compound Information (CPI)

(3) V_{min}= Migration value per closure (column 2) x 1000 (unit conversion factor) / relevant restriction (column 3)

(4) A_{min}= Migration value per closure (column 2) x 100 (unit conversion factor) / relevant restriction (column 3), not applicable for closures intended to be brought into contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC (= baby food)

(5) not analysed, it is assumed that the specific migration corresponds to the "migration value" analysed as overall migration value using the more severe time/temperature test conditions of the specific migration test protocol (worst-case assumption)

(6) overall migration limit (OML) related to food simulant, only applicable for closures intended to be brought into contact with baby food

(7) overall migration limit (OML) related to total food contact surface of closure and sealed container, not applicable for baby food

(8) specific migration limit (SML) related to food or food simulants. **Exception:** For articles brought into contact **with baby food: SML=30 mg/kg** food or food simulants (see (9)).

(9) specific migration limit (SML) related to baby food or baby food simulants

(10) specific migration limit (SML) related to total food contact surface of closure and sealed container derived from SML as given in Commission Regulation (EU) No 10/2011 by application of the EU-cube model (1 kg/6 dm²)

(11) specific migration limit (SML) related to food or food simulants

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Further Supporting Information

- **based on Extraction Test results and Total Migration assumption (worst-case approach)**

Compound Extraction Test Results			
Vinyl chloride	Headspace GC-MS	< 0.005 mg/dm² compound (detection limit)	Test report: CME-GRP46Xf-2020A

Calculation of Minimum Filling Quantities (V_{min}) and Minimum Total Food Contact Surfaces (A_{min})				
For all food categories	**Value** [mg/closure]	**Restrictions** (Regulation (EU) No 10/2011, Annex I) (see Silgan: CPI-46915)	**V_{min} [g]**	**A_{min} [cm^2]**
Vinyl chloride	**< 0.00022**	ND = not detectable (< 0.01 mg/kg food) SML	**22**	**13**

This document is valid until submission of an updated version. It replaces all previous Migration Simulation Information (MSI) and Closure Migration Simulation (CMS).

The information given about the type of substances used and migration values is strictly confidential. However, you are entitled to make this information available to authorities, institutes and your customers to the extent as needed for assessing compliance and measuring migration as required by law. In this case, you must require that the recipient also treats the information as strictly confidential. Passing on this information to others, in particular to our competitors, is not permitted.

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