

Pano Blueseal[®]-Compound T

Migrationdata according VO EU 10/2011

Designation: Provalin[®] **Manufacturer:** Actega DS GmbH, Bremen, Germany

Description: Sealing-gasket based on thermoplastic elastomers (TPE).

1. Closure-specific global migration

For closures types: RUP, RUB, T, Ts, TWS, TSB, DTO, DOB

Conditions: 1 h 100°C and 10 d 60 °C

Closure type	Diameter [mm]	Simulant A 10% ethanol		Simulant B 3 % acetic acid		Simulant D1 50% ethanol	
		Average global migration [mg]	Mimumum jar volume 60 mg/kg [ml]	Average global migration [mg]	Mimumum jar volume 60 mg/kg [ml]	Average global migration [mg]	Mimumum jar volume 60 mg/kg [ml]
RUP/RUB	38	n.d.	>5	n.d.	>5	n.d.	>5
T/Ts	45	n.d.	>5	n.d.	>5	n.d.	>5
TWS/TSB DTO/DOB	48	n.d.	>5	n.d.	>5	n.d.	>5
	53	n.d.	>5	n.d.	>5	n.d.	>5
	58	n.d.	>5	n.d.	>5	n.d.	>5
	63	n.d.	>5	n.d.	>5	n.d.	>5
	66	n.d.	>5	n.d.	>5	n.d.	>5
	70	n.d.	>5	n.d.	>5	n.d.	>5
	77	n.d.	>5	n.d.	>5	n.d.	>5
	82	n.d.	>5	n.d.	>5	n.d.	>5

n.d.: with the current Limit of Quantification (LOQ) of 0,06 mg/kg **no migration** could be analyzed.

For no jar size it can be expected that the migration-limit may be exceeded.

The values for the lid-diameters are calculated based on compound-contact-areas.

Conditions: 3 h 60°C and 10 d 60 °C

Closure type	Diameter [mm]	Simulant 95% ethanol	
		Average global migration [mg]	Mimumum jar volume 60 mg/kg [ml]
RUP/RUB	38	0,09	>5
T/Ts	45	0,12	>5
TWS/TSB DTO/DOB	48	0,11	>5
	53	0,13	>5
	58	0,14	>5
	63	0,16	>5
	66	0,16	>5
	70	0,17	>5
	77	0,20	>5
	82	0,21	>5

The simulant D2 olive-oil was replaced with ethanol 95% .

For no jar size it can be expected that the migration-limit may be exceeded.

The values for the lid-diameters are calculated based on compound-contact-areas.

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2. Specific migration

Blueseal[®]-Compounds do not contain PVC and no phtalates.

Substances with a specific migration limit

The compound contains following substances with w specific migration limit

FCM	PM-Ref	substance	CAS-No.	restriction
264	22660	1-octene	111-66-0	SML = 15 mg/kg
402	96240	zincoxide	1314-13-2	SML = 5 mg/kg as Zn
433	68320	octadecyl-3-(3,5 Di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	SML = 6 mg/kg
661	95360	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazin-2,4,6(1H,3H,5H)-trione	27676-62-6	SML = 5 mg/kg

The compound contains furthermore components where the generic SML of 60 mg/kg according art. 11 (2) can be applied. The identity of these components is confidential but may be communicated to independent testing institutes in necessary cases.

Based on the amount of substances in the compound even in cases of a total migration it is not expected that the specific limit may exceed.

3. Final Evaluation of the migration results

Under the test conditions there were no global migration confirmed with simulants A, B and D1.

Assumed that the compound will be used for a closure with a diameter of 66 mm on a 200 ml size jar with a total inside surface of 195 cm² and a food contact area of 5 cm² will be used following data can be calculated

Conditions: 1h 100°C und 10 d 60°C

Simulant	mg/ closure	mg/dm ²	mg/kg food
A 10% ethanol	n.d. (LOQ <0,06)	not applicable	not applicable
B 3% acetic acid	n.d. (LOQ <0,06)	not applicable	not applicable
D1 50 % ethanol	n.d. (LOQ<0,06)	not applicable	not applicable

Conditions: 3h 60°C und 10 d 60°C

Simulant	mg/ closure	mg/dm ²	mg/kg food
95% ethanol	0,16	0,03	0,3

n.d.: not detectable; LOQ: Limit of Quantification

In general every type of compound has to be tested on its suitability for the individual food.

4. DUAL USE Additives

The compound contains according its formulation following substances which may also be used as food-ingredients

FCM	PM Ref	designation	CAS-No.	E-No.
106	89040	sodium-, potassium- and calciumsalts of fatty acids	--	E470a
615	92080	talc	14807-96-6	E553b