

Investigation Report

Investigation of the migration behaviour of a seal material for packed glands

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Test period: 17.09.2019 - 30.09.2019

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Sample:	No.	Specification
	1	TP 30 dry (not tested)
	2	TP 30 with Silfar (not tested)
	3	TP 30 with Optileb (not tested)
	4	TP 30 with Silfar (not tested)
	5	TP 30 with Optileb

1. Introduction

Aim of this investigation was the determination of the migration behaviour of a seal for packed glands, to be used on shafts for pumps and agitators in food production. The seal is intended to come into repeated contact with food during the production.

2. Experimental

The following investigations were performed:

Sample	Investigation	Method of analysis	Simulant	Conditions time/ temp.
5	„10 ppb“-Screening *	GC/MS and GC/FID (07.02A00501 dated on 18.09.2019)	Ethanol 95%	2 hours/ 100°C)
5	Determination of overall migration *	Gravimetric (07.02A00401 dated on 18.09.2019)	Ethanol 95% Isooctane Acetic acid 3%	3 x 2 hours/ 100°C First and third migrate (“repeated use”)

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* Accredited method

2.1 „10 ppb“-Screening

For the migration investigation the samples were placed into migration cells and covered with the food simulant ethanol 95%. The samples were stored at the time/temperature conditions mentioned above and the migration solutions were worked-up. After addition of an alkane standard (Tridecane) and an analytical standard the solutions were analysed by means of gas chromatography coupled to a mass spectrometer (GC/MS) and by gas chromatography with flame ionisation detection (GC/FID).

The substances were quantified semi quantitatively via the alkane standard (07.02A00501 dated on 18.09.2019).

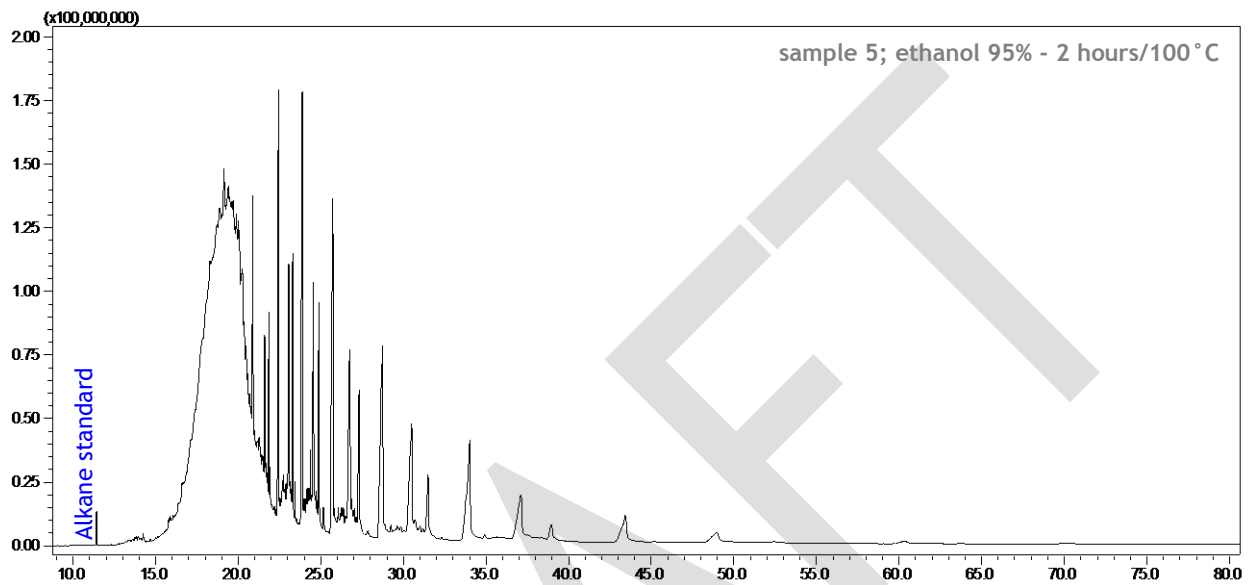
2.2 Determination of overall migration

For the determination of the overall migration the samples were placed into migration cells and covered with the adequate food simulants. After the time/temperature conditions mentioned above the migration solutions were evaporated to dryness and the residues weighed (07.02A00401 dated on 18.09.2019).

3. Results

3.1 „10 ppb“-Screening

In the following the GC/MS-chromatogram and the table with the qualitative and semi quantitative results of the screening, are shown. Aliphatic hydrocarbon compounds (AHC) and alcohols, as well as oligomers from the Poly(ethylenpropylene)glycole are not listed.



Substance	Rt-MS	Results *	
	[min.]	[$\mu\text{g}/\text{dm}^2$]	[$\mu\text{g}/\text{kg}$] ¹⁾
Alkane standard (Tridecane)	11,4	27,2	10

¹⁾ 1000 kg of food are in contact with 1 metre (362 g) seal-material.

* Accredited method

3.2 Determination of overall migration

In the following table the results of the determination of the overall migration are listed.

Sample	Simulant	Conditions time/ temperature	Results *	
			[mg/g]	[mg/kg] ¹⁾
5	Ethanol 95%	2 hours/100° C first migrate	65,7	24
		2 hours/100° C third migrate	5,0	2
5	Acetic acid 3%	2 hours/100° C first migrate	5,7	2
		2 hours/100° C third migrate	2,1	< 1
5	Isooctane	2 hours/100° C first migrate	72,7	26
		2 hours/100° C third migrate	1,9	< 1

¹⁾ EU-convention: 1000 kg of food are in contact with 1 metre (362 g) seal-material.

* Accredited method

4. Conclusions

For the assesement it is assumed, that 1 metre (362 g) of seal material are used in a packed gland which is in contact with 1000 kg of food. It is assumed as a worst-case that the complete surface of the seal material is in contact with the food.

Migration evaluation of repeated use articles and materials has to be performed as follows: Compliance shall be checked on the basis of the level of the migration found either in the third migration test concerning substances with a SML or in the first migration test concerning substances which shall not be detectable and NIAS. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test. The decrease of migration amount has to be proved.

The contribution of the measurement uncertainty arising from the sampling procedure of the test sample from the totality of the test object was not considered.

In case of accredited quantitative determinations the measurement uncertainty, if available, is considered in the evaluation.

4.1 „10 ppb“-Screening

- A number of aliphatic hydrocarbons could be detected. These are oligomers of the white oil, which is in accordance to requirements of the European Pharmacopoe and EU-Regulation 10/2011 (by statement of the manufacturer). The limit of overall migration (OML: 10 mg/dm² and 60 mg/kg food respectively) is not exceeded in the worst-case scenario assumed.
- Additionally a number of oligomers of the poly(ethylene propylene)glycol could be detected. The substance is in accordance to requirements of FCM 551 of the EU-Regulation 10/2011 (by statement of the manufacturer). The limit of overall migration (OML: 10 mg/dm² and 60 mg/kg food respectively) is not exceeded in the worst-case scenario assumed.

4.2 Determination of overall migration

The quantitative results of overall migration tests (gravimetric) are below the stipulated migration limit of 10 mg/dm² and 60 mg/kg food respectively (commission regulation (EU) No. 10/2011 and its amendments) as of the worst case conditions.

Summary:

Concerning the results of the migration studies performed, the provided sample can be assessed as **conform** with the European legal stipulations for food contact materials for the foreseen use as seal material in gland nuts used in food production.

The results of the investigations and their assessment are limited to the submitted test samples and to the information provided till date of signature of this report. Retained samples are stored for six months.

Munich, 13.11.2019

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