

A/S Gunnar Haagensen
CUSTOM ENGINEERED SEALS & SEALING SOLUTIONS

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Date 28th February 2020
Subject Supplier declaration regarding material compliance

We confirm that compound **PTFE PEW10659 = PTFE TFM 1705** is compliant to the below mentioned regulations and legislation.

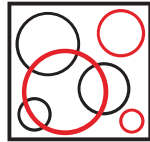
To European regulation EC 1935/2004
To European regulation No. 10/2011
To European regulation EC 2023/2006
To Danish Ministerial order No. 1248 of October 2018
To FDA regulation CFR 21§177.1550
To USP Class VI - 121 °C
ADI (Animal Derived Ingredient free)
TSE/BSE free

This compound is in compliance with regulation EC 1935:2004 (Commission regulation on materials and articles intended to come in contact with food) and regulation EC 2023:2006 (Commission regulation on Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food). This compound is also in compliance with FDA regulation CFR 21§177.1550 and USP Class VI - 121 °C as well as being ADI and TSE/BSE free.

We confirm that the applicable law in Denmark referred to by Order No. 1248 of October 2018 regarding food contact materials and subsequent amendments thereto, is in compliance with regard to machines or machine parts. This implies in particular laws regarding GMP as well as materials and articles, which is intended for direct contact with food. All materials in direct contact with food must be suitable for use repeated use with foodstuffs. We also confirm that supplied articles comply with technical requirements regarding food legislation and EU regulations.

The customer is asked to examine relevant documentation regarding supplied item application, limitations and performed tests as well as employment with regard to the type of foodstuff. It remains the customers responsibility to determine compliance with any applicable legislation for the final product with regard to contact with foodstuff.

Details on performed tests and conditions for such tests can be found on the following declaration pages.



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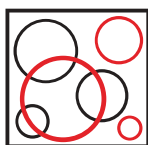
Information with regard to Dual Use additives in articles and materials for direct contact with food is enclosed in technical datasheets in connection to the performed sale. Information regarding chemical content/CAS-numbers, raw material designation or identity of active and intelligent components will also be enclosed in the datasheets. Information with regard to functional barriers for articles in direct contact with food is likewise included in technical datasheets.

A/S Gunnar Haagensen confirms that our PTFE PEW10659 compound is employed and delivered for items specified in the list of articles on the following page.

If in doubt, please contact A/S Gunnar Haagensen.

Best regards,
A/S Gunnar Haagensen

Rasmus Lage
Quality Manager



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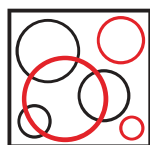
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Date 28th February 2020
Subject List of PTFE PEW10659 articles

A/S Gunnar Haagensen confirms that the following articles is employed and delivered in our PTFE PEW10659 compound. Country of origin (COO) is listed for each article:

310055-4 (MEMBRANE PTFE PEW10659) - COO Italy
320055-4 (MEMBRANE PTFE PEW10659) - COO Italy
400055-9 (MEMBRANE PTFE PEW10659) - COO Italy
850055-4 (MEMBRANE PTFE PEW10659) - COO Italy
860055-6 (MEMBRANE PTFE PEW10659) - COO Italy
870055-4 (MEMBRANE PTFE PEW10659) - COO Italy
890055-3 (MEMBRANE PTFE PEW10659) - COO Italy
895531-1 (MEMBRANE PTFE PEW10659) - COO Italy
895532-1 (MEMBRANE PTFE PEW10659) - COO Italy
333255-1 (MEMBRANE PTFE PEW10659) - COO Italy
333155-1 (MEMBRANE PTFE PEW10659) - COO Italy
260167-1 (MEMBRANE PTFE PEW10659) - COO Italy



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Date 28th February 2020
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EC 1935:2004 and EU regulation No. 10/2011

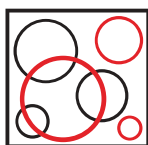
Overall and specific migration tested for PTFE PEW10659 material as per EU regulation.

Compound PTFE PEW10659 white			
Method	Parameter	Principle	Limit
EN 1186-2	Overall migration	Exposure to olive oil by total immersion. Gravimetric + GC/FID determination.	2,0 mg/dm ²
EN 1186-3	Overall migration	Exposure to 3% acetic acid and 10% ethanol by total immersion. Gravimetric determination.	1,0 mg/dm ²
EN 1186-14	Preparation for specific migration	Exposure to isooctane by immersion.	-
EN 13130	Heptafluoropropyl trifluorovinyl ether	Migration simulant analysed by Headspace-GC/MS	0,05 mg/kg
Internal	Tetrafluoroethylene (residual content)	Solvent dissolution and analysis by Headspace-GC/MS.	0,5 mg/kg
Calculation	Tetrafluoroethylene	Worst case calculation of the specific migration based on residual content	-
Tests have been executed by Eurofins, DK. Full report available on request.			

Principle

Olive oil: The sample was exposed (2 dm² to 100 ml) for 2 hours at 175 °C by total immersion. At test end, the samples was removed from the food simulant. The sample was weighed and extracted with pentane by means of Soxhlet extraction for 16 hours. The amount of extracted olive oil was determined by gaschromatography with flame ionisation detection (GC/FID). The loss of weight was adjusted the excessive oil extracted from the sample and the calculated loss equals the total migration.

3% acetic acid and 10% ethanol: The sample was exposed (2 dm² to 100 ml) for 4 hours at 100 °C (80 °C for 10% ethanol). At test end, the sample was removed from the food simulant. The simulant was then evaporated and the dry matter determined by weighing.



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Subject Declaration Page 2-5

EC 1935:2004 and EU regulation No. 10/2011

Overall and specific migration tested for PTFE PEW10659 material as per EU regulation.

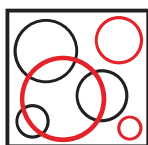
Principle (continued)

Isooctane: The sample was exposed (2 dm² to 100 ml) for 4 hours at 60 °C. At the end of the test period, the samples was removed from the food simulant.

Specific migration: An aliquot of the food simulant is analysed for the specific compound as listed on prior page.

Results

The results for the specific migration are below the specific migration limit. The threshold values for overall migration is 10 mg/dm² and the results show that the product tested complies with the requirements in EU regulation No. 10/2011/EC as amended by regulation No. 321/2011/EC, No. 1282/2011/EC, 1183/2012/EC and No. 202/2014/EC on plastic material and articles intended to come into contact with food for the mentioned test conditions.



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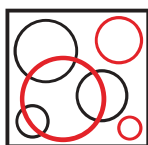
Date 28th February 2020
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FDA regulation CFR 21§177.1550

As per CFR 21§177.1550, total extractives and fluoride extractables of perfluorocarbon resins are determined by extraction testing.

Compound PTFE PEW10659 white			
Test	Extraction solvent	Norm FDA CFR 21§177.1550	Test result
Total Extractives	Heptane	max. 0,2 mg/inch ²	< 0,1 mg/inch ²
	50% Ethanol	max. 0,2 mg/inch ²	< 0,1 mg/inch ²
	Distilled Water	max. 0,2 mg/inch ²	< 0,1 mg/inch ²
	Ethyl Acetate	max. 0,2 mg/inch ²	< 0,1 mg/inch ²
Fluoride Extractives calculated as Fluorine	Heptane	max. 0,3 mg/inch ²	< 0,01 mg/inch ²
	50% Ethanol	max. 0,3 mg/inch ²	< 0,01 mg/inch ²
	Distilled Water	max. 0,3 mg/inch ²	< 0,01 mg/inch ²
	Ethyl Acetate	max. 0,3 mg/inch ²	< 0,01 mg/inch ²

Tests have been executed by NAMSA, USA. Full report available on request.



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USP Class VI - USP Systemic Toxicity Study

Summary

The test article, PTFE PEW10659, was evaluated for systemic toxicity in mice. This study was conducted in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted alcohol saline, polyethylene glycol, 0,9% sodium chloride USP solution, and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on day 3. There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.

Study was performed by NAMSA, USA. Full test report available on request.

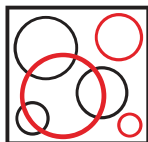
USP Class VI - USP Intracutaneous Study

Summary

The test article, PTFE PEW10659, was evaluated for the potential to cause irritation following intradermal injection in rabbits. The study was conducted based on the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted in 0,9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG). A 0,2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of the two animals. Similarly, the corresponding control was injected at the left side of the back of each animal. Observations for erythema and edema were conducted at 24, 48 and 72 hours after intracutaneous injection.

There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements.

Study was performed by NAMSA, USA. Full report available on request.



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Subject Declaration Page 5-5

USP Class VI - USP Muscle Implantation Study

Summary

The test article, PTFE PEW10659, was implanted in muscle tissues of rabbits to evaluate the local tissue response. The study was conducted based on the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo.

Implant test article and negative control article were sterilized by steam. The test article and negative control were intramuscularly implanted and animals were euthanized 7 days later. Muscle tissue were excised and the implant sites examined macroscopically. The macroscopic reaction was not significant as compared to the negative control articles. The implanted test article met the USP requirements.

Study was performed by NAMSA, USA. Full test report available on request.
