

Test report

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Further evaluation on Versalis polystyrene decontamination technology for enlarging evaluated scenarios

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The results refer solely to the tested samples.

1 Situation and Aim of the Study

Versalis has developed a decontamination technology for post-consumer polystyrene (PS). The determination of the cleaning efficiency of the investigated polystyrene decontamination technology has been studied by Fraunhofer IVV test report issued on 05.12.2023.

Aim of the present study is to increase the number of evaluated scenarios.

The decontamination technology and cleaning efficiency is considered unchanged; therefore, no further sampling has been carried out.

With respect to the 05.12.2023 study, the present study considers settled the here below paragraph:

Paragraph 2: Sample Material,

Paragraph 3: Sample Material,

Paragraph 4: Method,

Paragraph 5.1: Challenge Test

Paragraph 5.2: Safety Evaluation of the Decontamination Technology

The present study is an addendum of the Fraunhofer test report from 05.12.2023, addressing new exposure scenarios.

5.3 Safety Evaluation of the Decontamination Technology on further Scenarios

Diffusion models provide a scientific tool for establishing a correlation between the migration into contact media and the corresponding concentration $C_{p,0}$ of a migrant (surrogates) in the final product of the super-clean recycling process. In this way maximum surrogate concentrations in PS can be established which would not lead to exceeding a certain migration value of interest.

All calculations were based on the modelling parameters for HIPS ($A_p' = 1.0$ and $\tau = 0$ K). In addition, all calculation were done for a food package with 1 l volume and 600 cm² surface area ("EU cube"), a density of 1.04 g/cm³ and high solubility for the surrogates (partition coefficient $K_{\text{Polymer/Food}} = 1$).

Remark: The input material of the recycling process is PS, mainly high impact polystyrene (HIPS), because most of the yogurt cups are made from HIPS. However, the sorting processes might not distinguish between general purpose polystyrene (GPPS) and therefore also GPPS might be also in the input stream. From a migrational point of view, GPPS shows a lower diffusivity compared to HIPS. For both polymers, modelling parameters are available. We choose the modelling parameters of HIPS, because these parameters are the worst-case compared to GPPS.

In 05.12.2023 study the following rPS scenarios have been evaluated, concluding that the investigated application can be considered as safe up to 100% recycle:

- Scenario 1: pot for cold filled yogurt, 250 g yogurt per day for a toddler, storage for 40 d at 6 °C
- Scenario 2: pot for hot filled yogurt, 250 g yogurt per day for a toddler, 2 h 70 °C followed by 40 d at 6 °C
- Scenario 3: tray for meat, fish or cheese, 150 g meat, fish or cheese per day for a toddler, 30 d at 6 °C
- Scenario 4: tray for fruit or vegetables, 500 g fruit or vegetables per day for a toddler, 30 d at 25 °C
- Scenario 5: cup for cold drinks, 750 ml cold drinks per day for a toddler, 1 d at 25 °C (cold drinks)
- Scenario 6: cup for hot drinks, 750 ml hot drinks per day for a toddler, 2 h at 70 °C (hot drinks)

Within this study the following additional rPS scenarios have been evaluated:

- Scenario 7: packaging for solid and liquid food, 150 g per day for a toddler, hot filling at 95 °C for 10 min, stored 18 months (540 d) at 25 °C
- Scenario 8: packaging for solid and liquid food, 150 g per day for a toddler, 12 months (365 d) at 25 °C
- Scenario 9: packaging for solid and liquid food, 150 g per day for a toddler, 6 months (180 d) at 25 °C
- Scenario 10: packaging for solid and liquid food, 500 g per day for a toddler, 10 d at 40 °C
- Scenario 11: packaging for solid and liquid food, 250 g per day for a toddler, 80 d at 8 °C
- Scenario 12: packaging for solid and liquid food, 250 g per day for a toddler, 10 d at 40 °C
- Scenario 13: packaging for solid and liquid food, 250 g per day for a toddler, 12 months (365 d) at 25 °C
- Scenario 14: packaging for solid and liquid food, 500 g per day for a toddler, 12 months (365 d) at 25 °C
- Scenario 15: packaging for solid and liquid food, 1000 g per day for a toddler, 10 d at 40 °C
- Scenario 16: packaging for solid and liquid food, 250 g per day for a toddler, hot filling at 95 °C for 10 min, stored 18 months (540 d) at 25 °C
- Scenario 17: packaging for solid and liquid food, 500 g per day for a toddler, hot filling at 95 °C for 10 min, stored 18 months (540 d) at 25 °C

Daily assumption is connected to the specific typology of food. As a general approach may refer to 95th percentile consumption as per EFSA Food Consumption Database (available online: <https://www.efsa.europa.eu/en/data-report/food-consumption-data>).

Scenario 7: rPS in packaging for solid and liquid food (as reference for processed fruit or meat jelly juices)

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **150 g** food per day (as reference for processed fruit or meat jelly juices). This leads to a maximum migration of $0.167 \mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.150 = 0.167$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **$0.833 \mu\text{g per kg}$** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **$3 \text{ mg}/\text{kg}$** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done under hot fill conditions of **$95 \text{ }^\circ\text{C}$ for 10 min** followed by a maximum shelf life of **540 d at $25 \text{ }^\circ\text{C}$** .

The results are visualized in Figure 1 and Figure 2. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

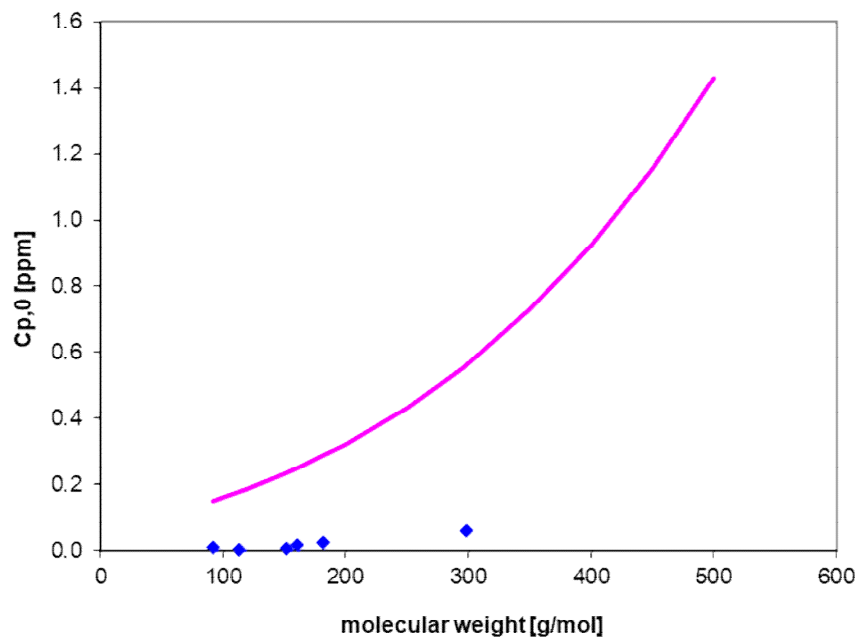


Figure 1: Residual concentrations corresponding to a migration of **$0.833 \mu\text{g}/\text{kg}$** of surrogates adjusted to **$3 \text{ mg}/\text{kg}$** initial concentration, storage conditions: **$95 \text{ }^\circ\text{C}$ for 10 min followed by 540 d at $25 \text{ }^\circ\text{C}$** . pink line: maximum concentration, blue dots: experimental data (C_{res})

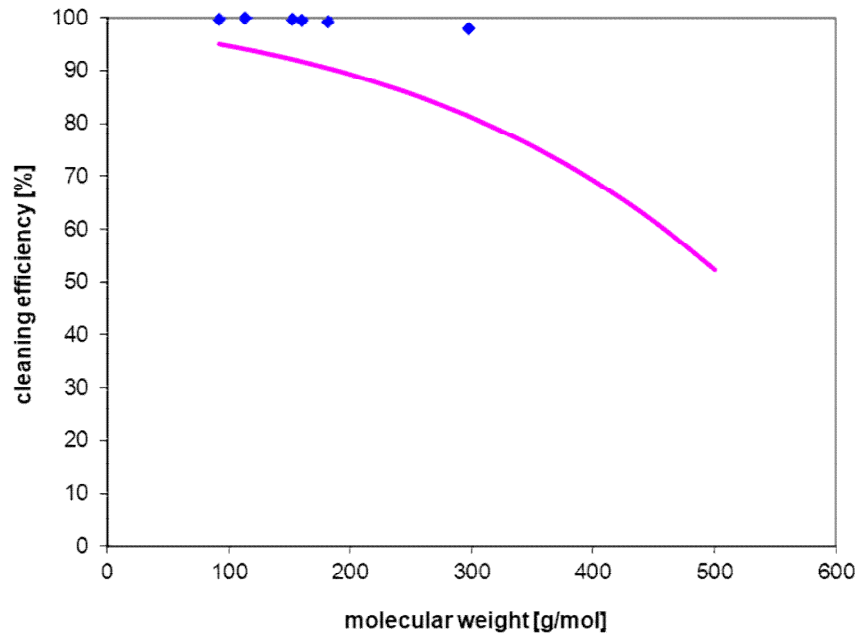


Figure 2: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 8: rPS in packaging for solid and liquid food (as reference for butter)

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **150 g** food per day (as reference for butter). This leads to a maximum migration of 0.167 µg/kg ($0.0025 \cdot 10 / 0.150 = 0.167$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.833 µg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a maximum shelf life of **365 d at 25 °C**.

The results are visualized in Figure 3 and Figure 4. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

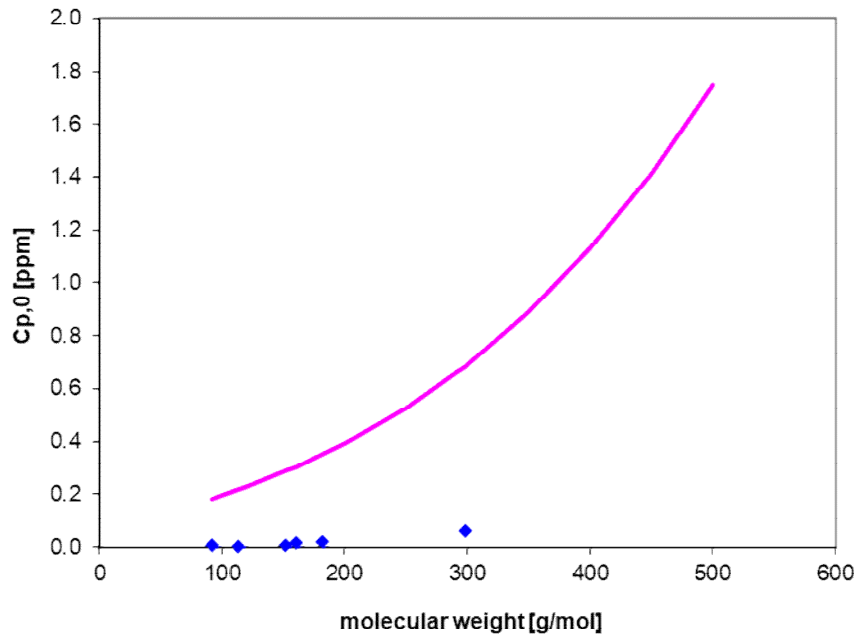


Figure 3: Residual concentrations corresponding to a migration of **0.833 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **365 d at 25 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

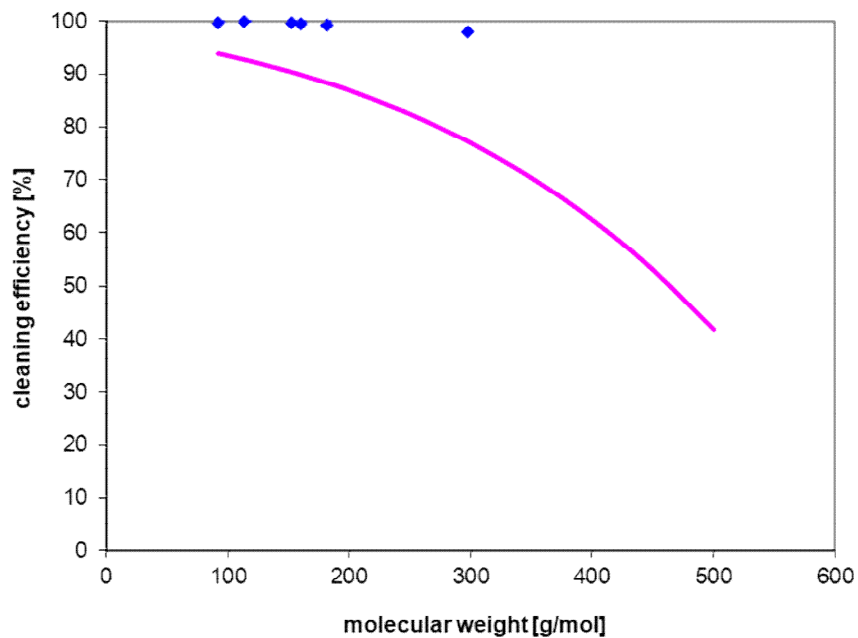


Figure 4: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 9: rPS in packaging for solid and liquid food (as reference for creamer)

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **150 g** of food per day (as reference for creamer). This leads to a maximum migration of $0.167 \mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.150 = 0.167$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.833 μg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recycle content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a maximum shelf life of **180 d at 25 °C**.

The results are visualized in Figure 5 and Figure 6. In conclusion the above mentioned application can be considered as safe up to 100% recycle.

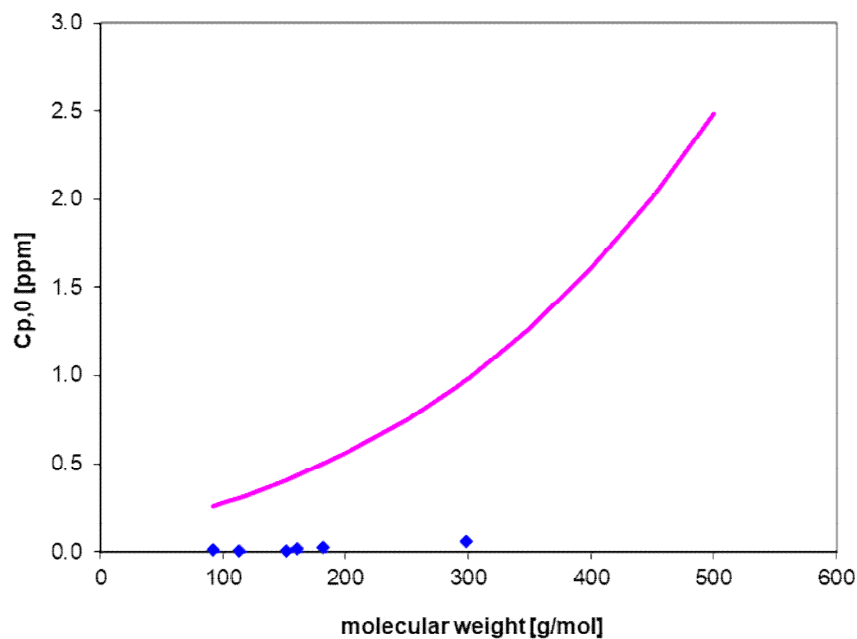


Figure 5: Residual concentrations corresponding to a migration of **0.833 $\mu\text{g}/\text{kg}$** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **180 d at 25 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

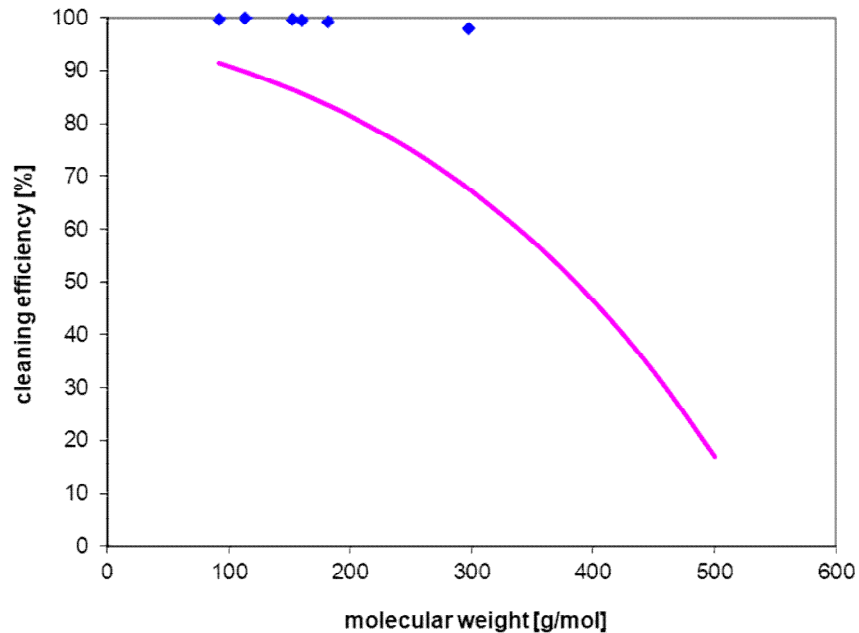


Figure 6: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 10: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **500 g** food per day. This leads to a maximum migration of $0.05 \mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.500 = 0.105$).
- Due to the fact, that migration models for a low diffusive polymer like HIPPS overestimated the migration by at least a factor 5 the maximum migration was set to **$0.250 \mu\text{g per kg}$** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **$3 \text{ mg}/\text{kg}$** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a storage conditions of **10 d at 40 °C**.

The results are visualized in Figure 7 and Figure 8. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

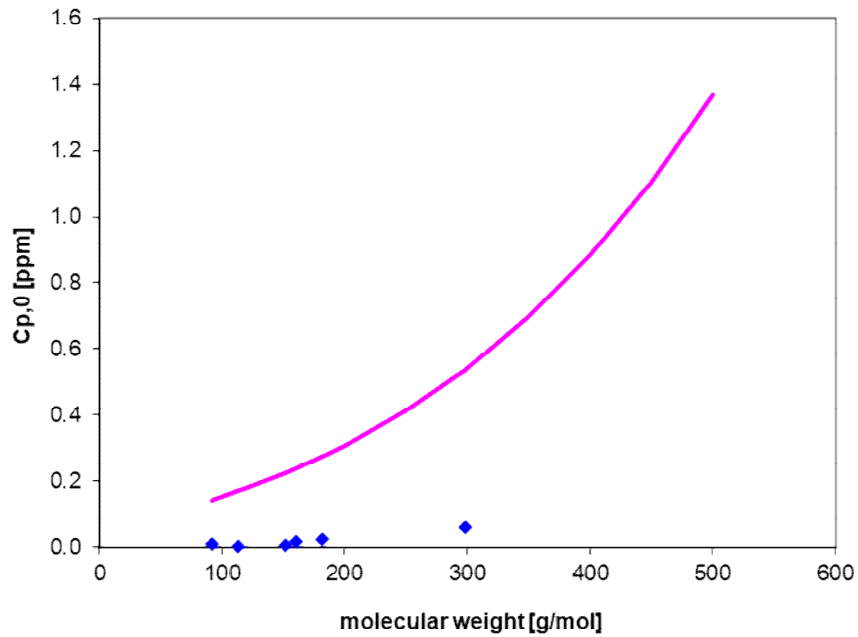


Figure 7: Residual concentrations corresponding to a migration of **0.250 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **10 d at 40 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

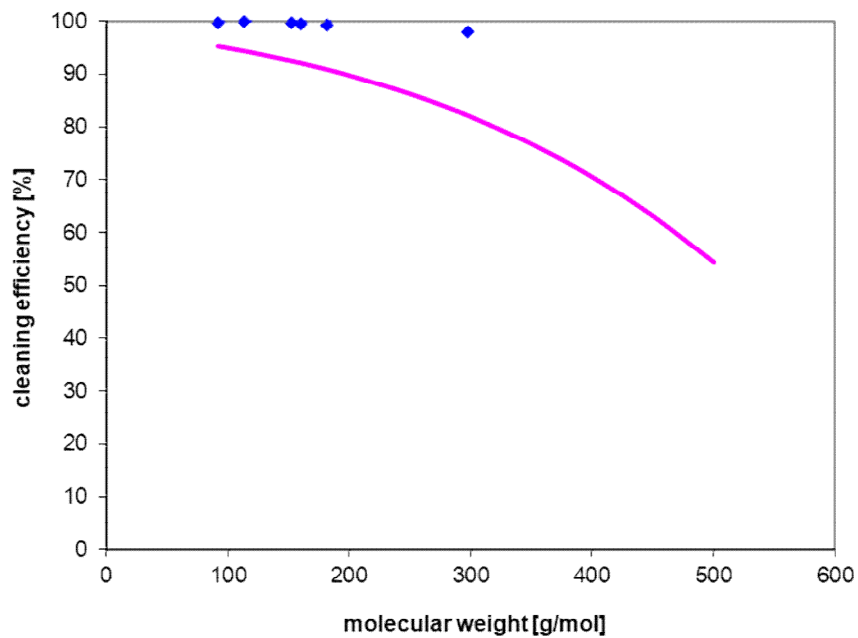


Figure 8: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 11: rPS in packaging for solid and liquid food (as reference for yogurt)

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **250 g** food per day (as reference for yogurt). This leads to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.250 = 0.1$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.500 μg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a maximum shelf life of **80 d at 8 °C**.

The results are visualized in Figure 9 and Figure 10. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

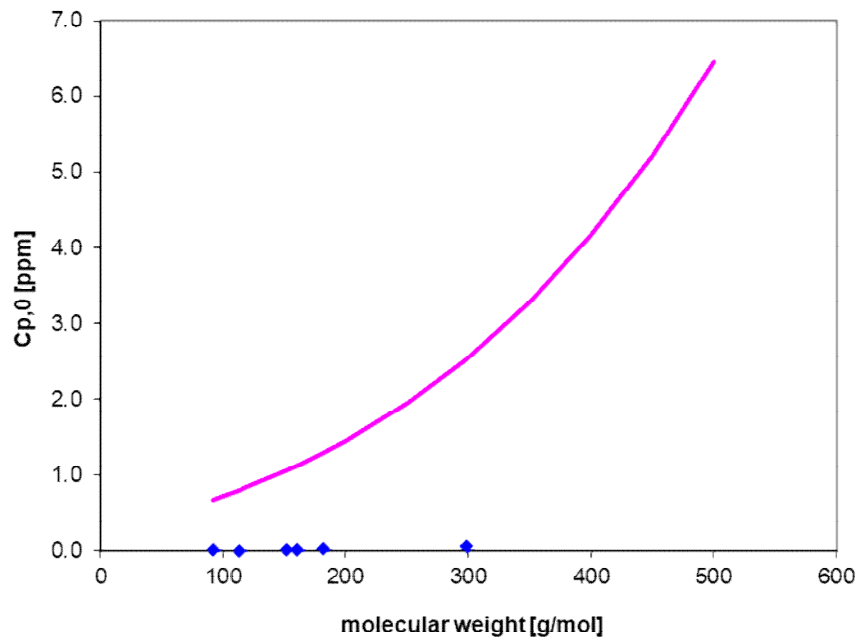


Figure 9: Residual concentrations corresponding to a migration of **0.500 $\mu\text{g}/\text{kg}$** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **80 d at 8 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

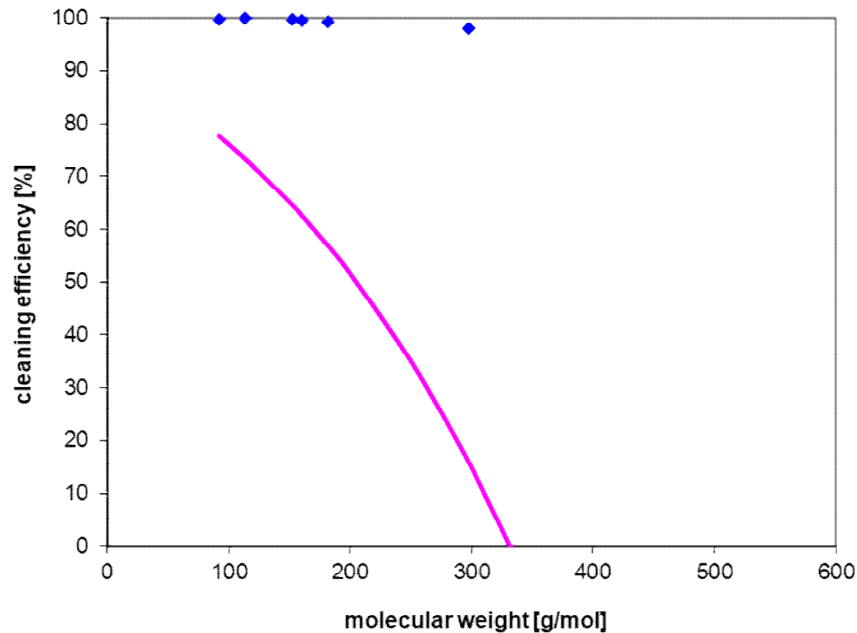


Figure 10: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 12: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **250 g** food per day (as reference for yogurt). This leads to a maximum migration of 0.1 µg/kg ($0.0025 \cdot 10 / 0.250 = 0.1$).
- Due to the fact, that migration models for a low diffusive polymer like HIPPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.500 µg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%
- The calculation was done for a storage conditions of **10 d at 40 °C**.

The results are visualized in Figure 11 and Figure 12. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

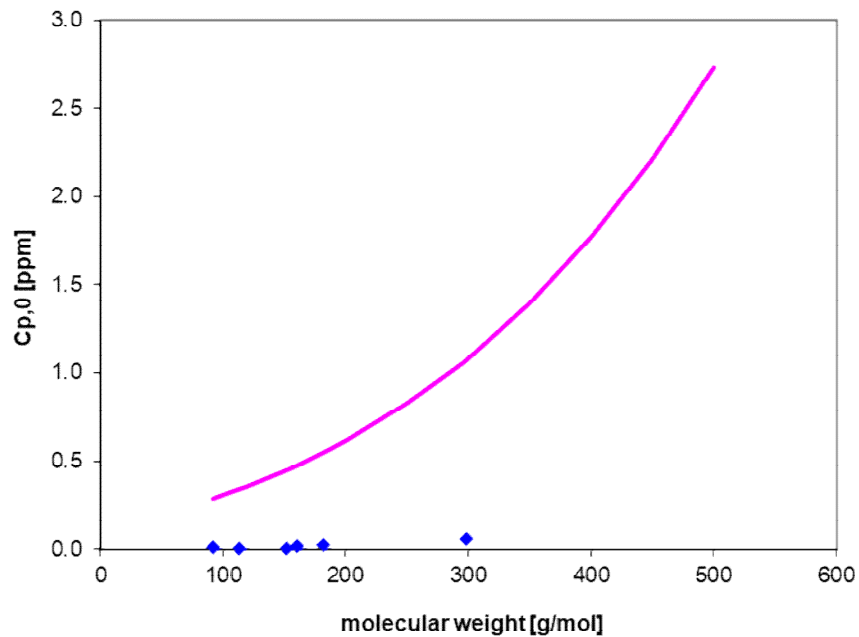


Figure 11: Residual concentrations corresponding to a migration of **0.500 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **10 d at 40 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

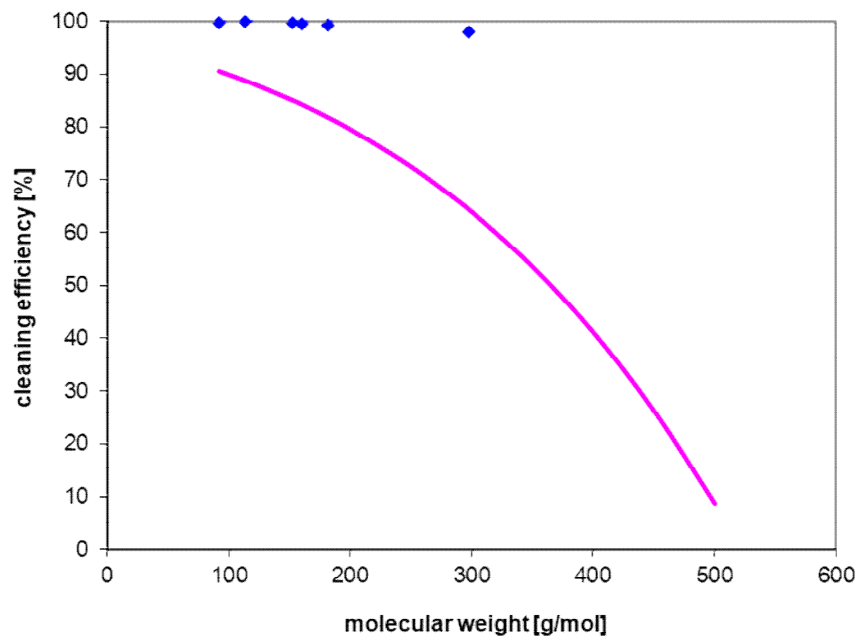


Figure 12: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 13: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **250 g** food per day. This leads to a maximum migration of $0.1 \mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.250 = 0.1$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **$0.500 \mu\text{g per kg}$** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **$3 \text{ mg}/\text{kg}$** in conventionally recycled PS flakes before super-cleaning.
- The recycle content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a storage conditions of **$365 \text{ d at } 25 \text{ }^\circ\text{C}$** .

The results are visualized in Figure 13 and Figure 14. In conclusion the above mentioned application can be considered as safe up to 100% recycle.

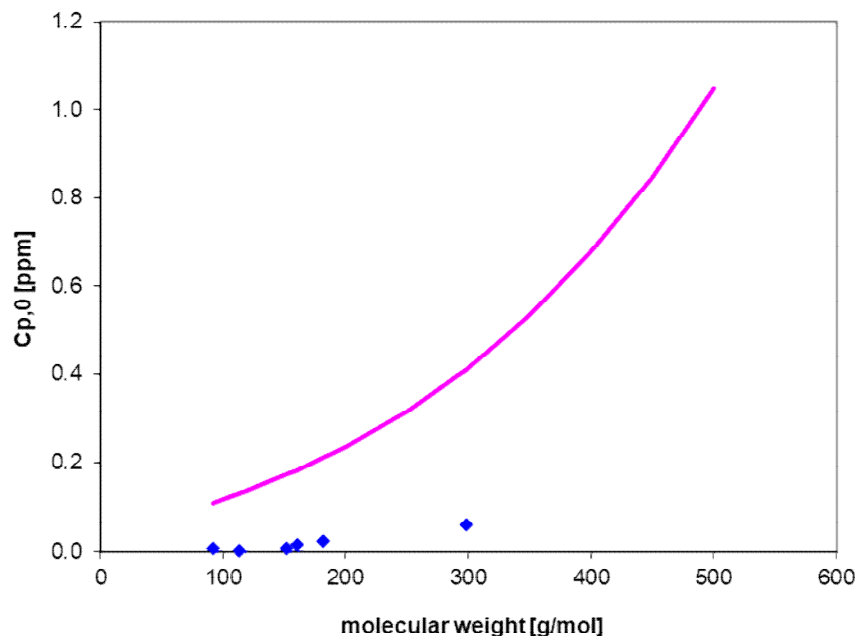


Figure 13: Residual concentrations corresponding to a migration of **$0.500 \mu\text{g}/\text{kg}$** of surrogates adjusted to **$3 \text{ mg}/\text{kg}$** initial concentration, storage conditions: **$365 \text{ d at } 25 \text{ }^\circ\text{C}$** . pink line: maximum concentration, blue dots: experimental data (C_{res})

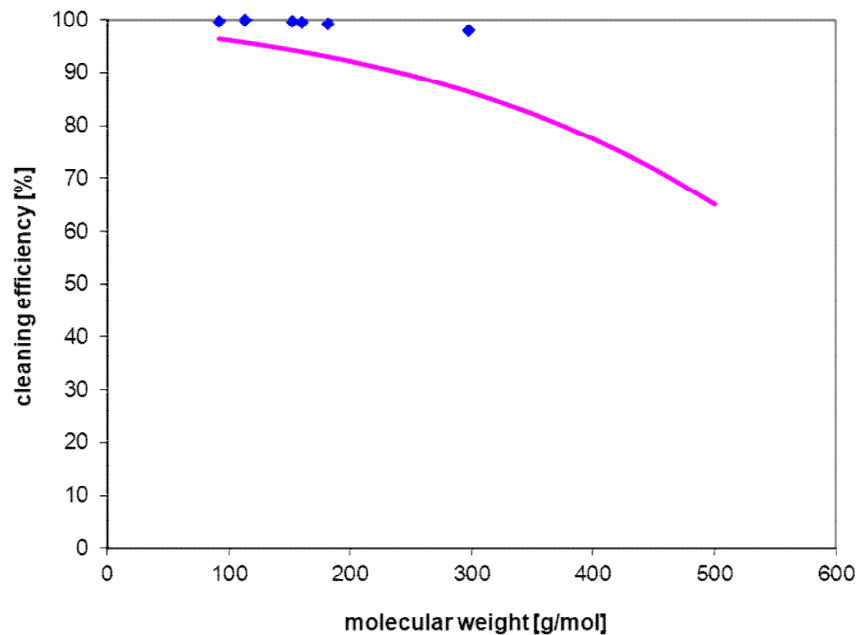


Figure 14: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 14: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **500 g** food per day. This leads to a maximum migration of 0.05 µg/kg ($0.0025 \cdot 10 / 0.500 = 0.05$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.250 µg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recycle content in the packaging material is 100%, 75%, 50%, 25%
- The calculation was done for a storage conditions of **365 d at 25 °C**.

The results are visualized in Figure 15 and Figure 16. In conclusion the above mentioned application can be considered as safe up to 100 % recycle.

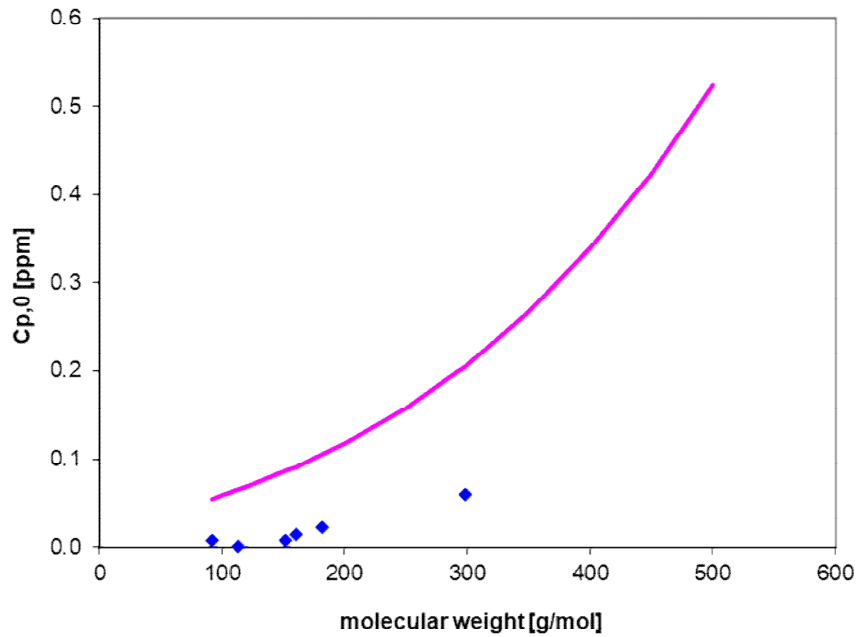


Figure 15: Residual concentrations corresponding to a migration of **0.250 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **365 d at 25 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

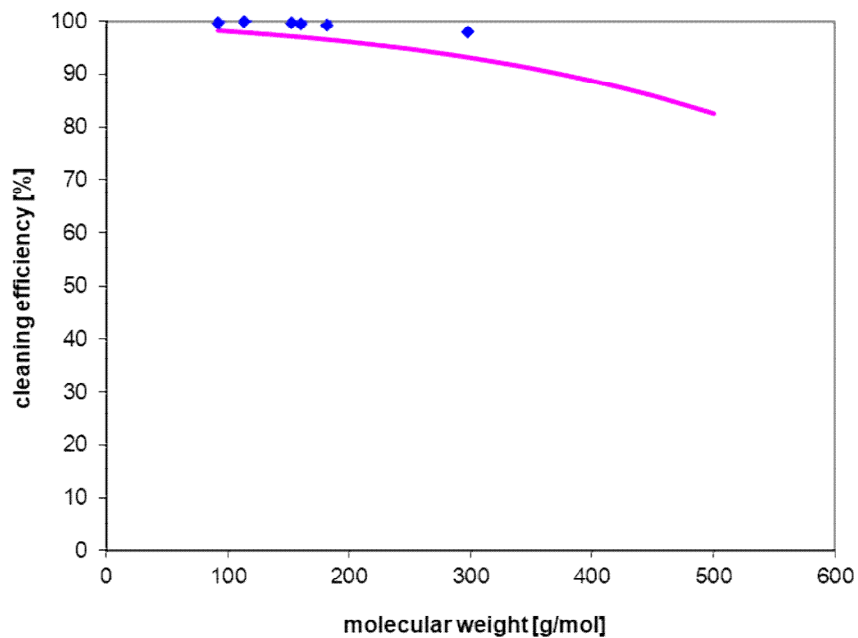


Figure 16: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 15: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **1000 g** food per day. This leads to a maximum migration of 0.025 µg/kg ($0.0025 \cdot 10 / 1.000 = 0.025$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.125 µg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recycle content in the packaging material is 100%, 75%, 50%, 25%
- The calculation was done for a storage conditions of **10 d at 40 °C**.

The results are visualized in Figure 17 and Figure 18. In conclusion the above mentioned application can be considered as safe up to 100% recycle.

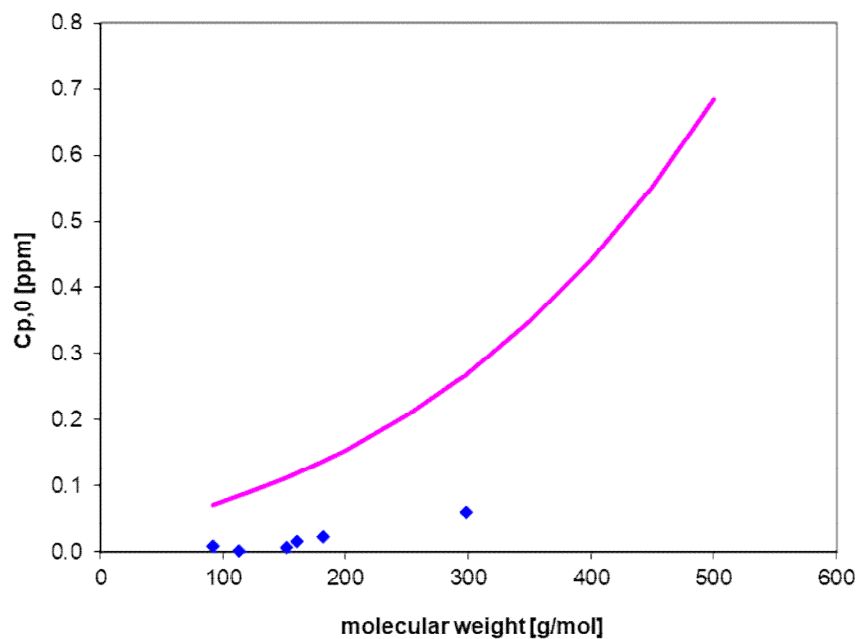


Figure 17: Residual concentrations corresponding to a migration of **0.125 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **10 d at 40 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

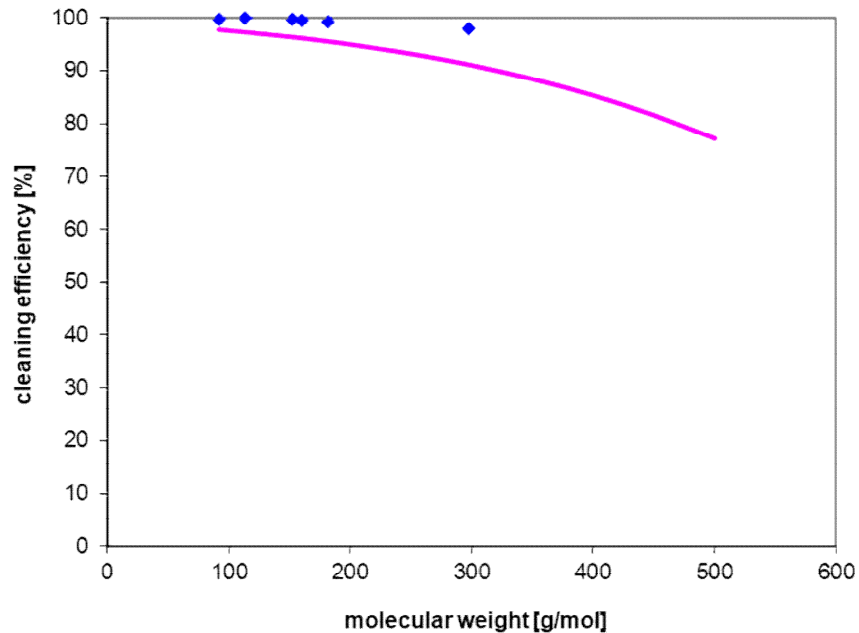


Figure 18: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 16: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **250 g** food per day. This leads to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.250 = 0.1$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **0.500 μg per kg** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **3 mg/kg** in conventionally recycled PS flakes before super-cleaning.
- The recyclate content in the packaging material is 100%, 75%, 50%, 25%.
- The calculation was done for a storage conditions of **95 °C for 10 min** followed by a maximum shelf life of **540 d at 25 °C**.

The results are visualized in Figure 19 and Figure 20. In conclusion the above mentioned application can be considered as safe up to 100% recyclate.

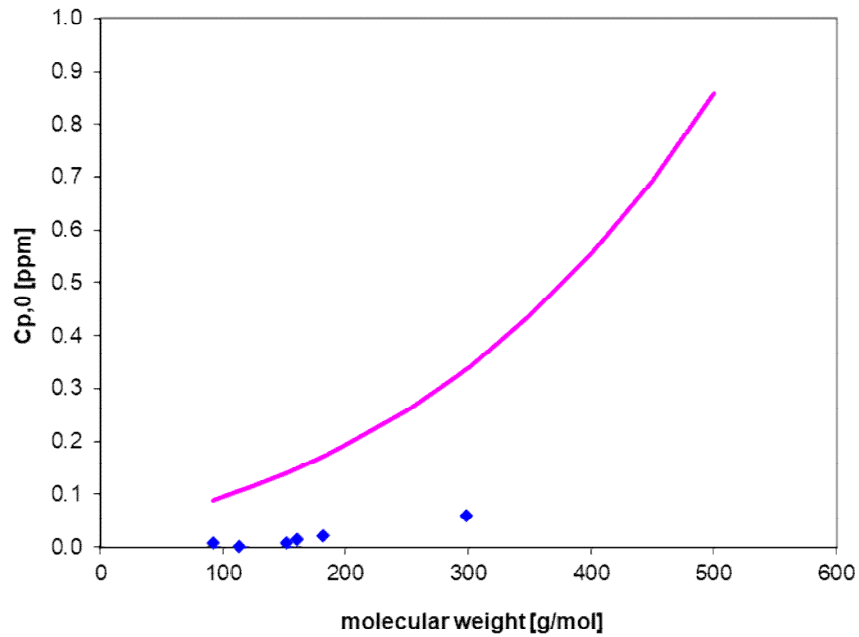


Figure 19: Residual concentrations corresponding to a migration of **0.500 µg/kg** of surrogates adjusted to **3 mg/kg** initial concentration, storage conditions: **10 min at 95 °C followed by 540 d at 25 °C**. pink line: maximum concentration, blue dots: experimental data (C_{res})

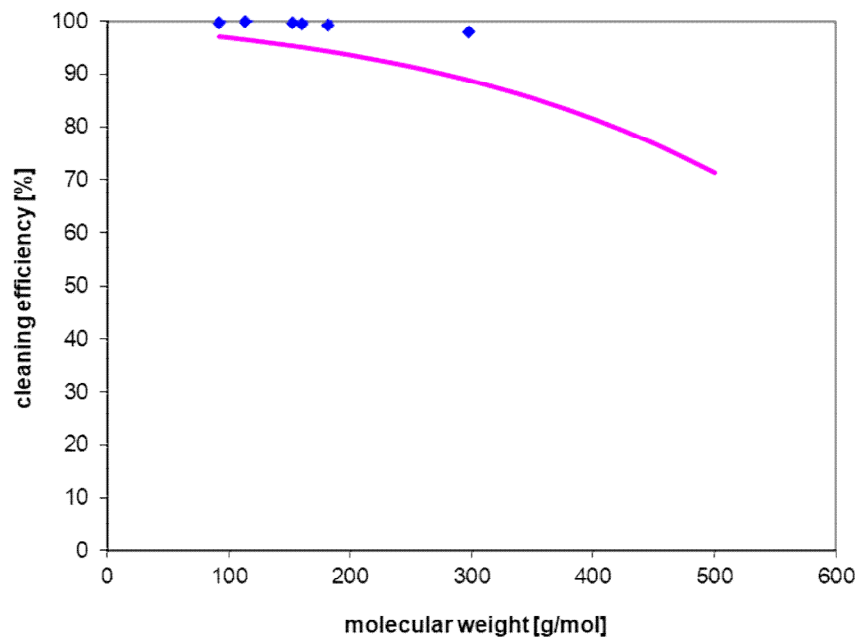


Figure 20: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Scenario 17: rPS in packaging for solid and liquid food

For the evaluation of the recycling process, the following exposure scenario was used:

- A toddler with 10 kg b.w. consumption of **500 g** food per day. This leads to a maximum migration of $0.05 \mu\text{g}/\text{kg}$ ($0.0025 \cdot 10 / 0.500 = 0.05$).
- Due to the fact, that migration models for a low diffusive polymer like HIPS overestimated the migration by at least a factor 5 the maximum migration was set to **$0.250 \mu\text{g per kg}$** foodstuff.
- The maximum contamination level of post-consumer recyclates is assumed to be **$3 \text{ mg}/\text{kg}$** in conventionally recycled PS flakes before super-cleaning.
- The recycle content in the packaging material is 100%, 75%, 50%, 25%
- The calculation was done for a storage conditions of **$95 \text{ }^\circ\text{C}$ for 10 min** followed by a maximum shelf life of **540 d at $25 \text{ }^\circ\text{C}$** .

The results are visualized in Figure 21 and Figure 22. In conclusion the above mentioned application can be considered as safe up to 100% recycle.

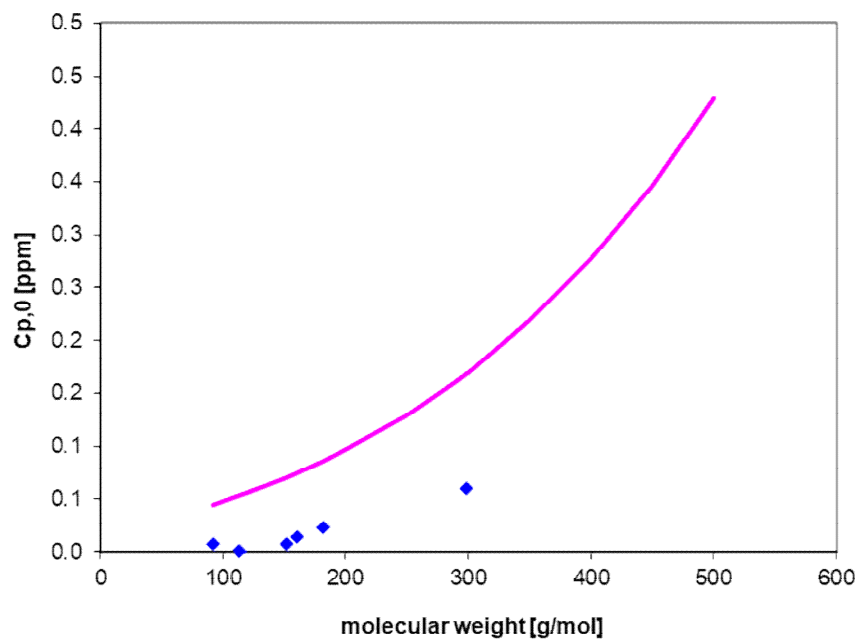


Figure 21: Residual concentrations corresponding to a migration of **$0.250 \mu\text{g}/\text{kg}$** of surrogates adjusted to **$3 \text{ mg}/\text{kg}$** initial concentration, storage conditions: **10 min at $95 \text{ }^\circ\text{C}$ followed by 540 d at $25 \text{ }^\circ\text{C}$** . pink line: maximum concentration, blue dots: experimental data (C_{res})

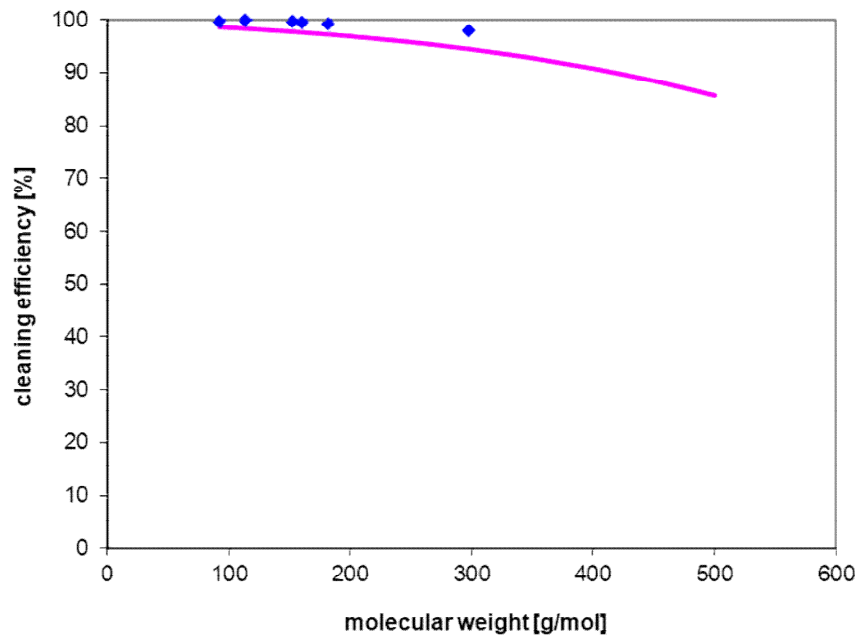


Figure 22: Cleaning efficiencies of surrogates in the challenge test, pink line: Minimum cleaning efficiency, blue dots: experimental data

Compliance with the Relevant Provisions on Food Contact Materials and Articles

From the data provided the following conclusions can be drawn:

- The investigated recycling technology is in a position to reduce the migration of potential contaminants from post-consumer PS to concentration levels which are in compliance with Article 3 of the EU Framework Regulation 1935/2004.
- The investigated recycling technology fulfils the requirements for the specific migration of the applied surrogates according to EU Regulation 10/2011.
- The investigated manufacturing process is in a position to fulfil the requirements of the GMP Regulation (EC) 2023/2006.

Due to the high temperature during PS recycling microbiological contamination is not a problem.

Signatures

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for Process Engineering and Packaging
Freising, May 8, 2025

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(authorized Scientist)