Sixth Report on the Novel Technology

“INEOS Styrolution Twin Screw Degassing Extrusion”

According to Article 13(4) of the Commission Regulation (EU) 2022/1616

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Contents

1. Description of the novel technology

The INEOS Styrolution super-clean recycling process for polystyrene (PS), which began operating before the entry into force of Commission Regulation (EU) No. 2022/1616, consists of the following main process steps:

- Step 1: Oversorting of available PS Bales (waste specification DSD 331; > 94% article content PS) Grinding of collected post-consumer PS containers into flakes followed by an intensive wash process and drying (remark: step 1 is made by the flake suppliers).

- Step 2: Extrusion of the washed flakes using a twin screw extruder with vacuum degassing.

INEOS STYROLUTION is buying washed flakes derived from post-consumer PS trays and containers from green dot systems and curbside collections in Europe. The flakes suppliers use state of the art oversorting and washing processes. Oversorting ensures that non-PS and non-food articles are sorted out of the remaining recycled material to ensure that the feedstream consists of > 95% PS articles having food contact origin. After oversorting, the PS feedstock is cut into flakes.

The PS flakes are then washed using a caustic hot washing process that contains surfactants to assist in the removal of undesirable residues.

The hot washing process is followed by rinsing with water and surface drying of the PS flakes. The flakes are sorted again with NIR technology in order to ensure that foreign materials from labels and closures, that were formerly attached to the PS container, are removed.

The washed flakes are then extruded using a twin screw extruder with vacuum degassing. Potential contaminants are removed during this melt degassing. The decontaminated melt is subsequently pelletized. The twin screw extruder design allows for control over the following critical decontamination parameters:

- Temperature
- Vacuum
- Residence time

The key components of the super-clean recycling process are shown in Figure 1.

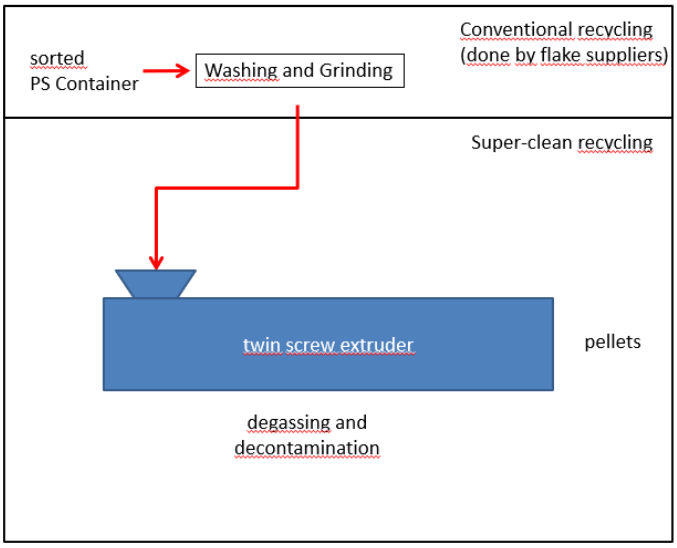

Fig. 1 Schematic of the investigated super-clean recycling process

The final pellets are intended for use in manufacturing new food contact articles with a recyclate content of up to 100%, including containers for dairy products, trays for packaging food, and beverage cups.

The novel technology developer has assessed the polystyrene (PS) recycling process in a fashion similar to that utilized in the EFSA Scientific Opinion on the *criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food* (EFSA, 2011). As discussed in the initial novel technology development report, the recycling process has been evaluated by applying the cleaning efficiency of the recycling process, obtained from a challenge test with surrogate contaminants at highly exaggerated levels, to a conservative reference contamination level for misuse contaminants in PS to calculate the residual concentration of contaminants in recycled PS (Cres). The resulting residual concentration for each contaminant is then compared to an “allowable” concentration of each contaminant in the PS that is derived using diffusion modeling (Cmod) and by considering the conditions of use of the articles manufactured with recycled PS. Specifically, this Cmod is calculated using generally recognized conservative migration models and it corresponds to a migration which cannot give rise to a dietary exposure exceeding the threshold below which the risk to human health would be negligible. Therefore, when Cres is not higher than Cmod, it is considered that the process is able to produce an output which is not likely to be of safety concern for the defined conditions of use. Consistent with Commission Regulation (EU) 2022/1616, the notifier monitors substances in the input and output to ensure that contaminants that may be retained in the recycled output material are not expected to migrate to contacted food at levels that would present health or safety concerns.

2. Compliance with Article 3 of Regulation (EC) No 1935/2004

INEOS Styrolution prepared an initial report on its novel polystyrene recycling technology in accordance with Article 10 of Commission Regulation (EU) No. 2022/1616. That report included extensive reasoning, scientific evidence, and studies that demonstrated that the recycled polystyrene produced under the INEOS Styrolution process complies with Article 3 of Regulation (EC) No. 1935/2004. The report summarized the results of a challenge test that was used to establish the decontamination efficiency of the process for commonly utilized surrogate contaminants. The initial report also included an industry study that evaluated the residual contaminant concentration in the recycled input based on samples of post-consumer PS flake samples obtained throughout Europe (Guazotti and Welle 2025). This study demonstrated that a conservative estimate of contaminants in the input stream is unlikely to exceed 1 mg/kg. The initial report also included a migration estimate for contaminants based on various use scenarios for the applications under which the recycled PS will be marketed.

The initial report demonstrated that the cleaning efficiency for the INEOS Styrolution polystyrene recycling process was sufficient to ensure that an exposure of 0.0025 µg contaminant/kg bw/day would not be exceeded. The 0.0025 µg contaminant/kg bw/day exposure threshold value is the level that EFSA has determined is safe even for chemicals with structural alerts raising concern for potential genotoxicity. Generally, this threshold value is low enough to address all toxicological concerns. Thus, the initial report demonstrated that any unknown contaminant potentially present in the recycled polystyrene would not result in risk of harm to consumers consuming food packaged in the modelled applications.

INEOS Styrolution published its first semi-annual report in October 2023. The first report included sampling data demonstrating that although some impurities in the recycled PS output exceeded the 1 mg/kg assumed contaminant level, many of the substances are also present in virgin polystyrene. Additionally, several of the compounds were suspected to be artifacts of the analytical method used to analyze the samples, and likely were not true contaminants in the recycled plastic output. Based on the toxicity profiles of the detected substances and the expected migration of the detected substances to food, the first report demonstrated that the potential presence of the contaminants in the recycled PS did not present any health or safety concern, and the recycled PS may be considered compliant with Article 3 of Regulation (EC) No. 1935/2004.

As discussed in previous reports, INEOS Styrolution has refined the analytical methodologies used for the evaluation of contaminant chemicals in the recycled PS input and output to confirm that the observation of certain oxygenated species in prior analyses was attributable to decomposition of the test samples during analysis, rather than their actual presence in the recycled PS. In previous reports, this was primarily accomplished by sparging the headspace of Gas Chromatography (GC) vials with nitrogen in an attempt to avoid the oxygen-induced degradation of the samples. INEOS Styrolution has then used an additional analytical methodology, similar to the nitrogen method, by sparging the headspace of the GC vials with argon (argon method). As was shown in the fourth report of April 2025, the argon method is a similar method compared to the nitrogen method. For the current report both methods were applied again due to an ongoing reorganization of the developer's own lab facilities. Once the lab facilities are available again all batch samples shall be analyzed with the argon method again.

2.1 Characterization of contaminant levels in the plastic input and the recycled plastics

As described in the initial report, critical contaminants in post-consumer polymers might be chemicals from possible misuse of packaging containers, contaminants from containers used in non-food applications such as non-authorized additives, as well as degradation products generated during recycling (Barthélémy et al. 2014).

In a study conducted by the Fraunhofer Institute for Process Engineering and Packaging, the authors analyzed 49 washed post-consumer PS flake samples obtained throughout Europe to assess whether chemicals originating from the misuse of PS containers used to store solvents, household, or garden chemicals were present in the recycled polystyrene samples (Guazzotti and Welle 2025). Each sample (containing approximately 35.1 flakes/gram/sample) was analyzed 6 times. Overall, 10,310 individual post-consumer PS flakes were analyzed. One substance, identified as α- and/or β-pinene, was detected in one rPS flake sample at a concentration of 16.9 mg/kg and was attributed to consumer misuse. The study authors assumed that only one flake in the 35.1 ± 7.0 flakes were contaminated with α- and/or β-pinene, the misuse concentration was calculated to be 475 - 711 mg/kg, which is a factor of 10 lower than the maximum concentration measured in PET. Additionally, the incidence of misuse was calculated to be no more than 0.0097% (1 ÷ 10,310), and thus, recycled polystyrene containers are not likely to be used by consumers to store hazardous substances after the first food contact-use.

For comparison, the incidence of misuse found for post-consumer PET bottles was 0.03% to 0.04%. Toluene (at a concentration of 6750 mg/kg in the contaminated PET flake) has been identified as an example of the sort of substances that are most likely filled into these misused PET bottles. In terms of consumer behavior, PET bottles are much more suitable for storage of liquids, because the bottles can be re-sealed with a closure. PS cups or trays cannot be re-sealed and are therefore not suitable for storage of liquid chemicals. In addition, solvents such as toluene dissolve PS and destroy the container. Therefore, the incidence for misuse of PS cups or trays for storage of hazardous chemicals is most likely much lower than that for PET, which was confirmed by the "misuse" study discussed above.

Using the data from the Guazzotti and Welle (2025) study noted above, the input concentration chemicals attributed to the misuse of the PS can be calculated by multiplying the “misuse” concentration level of 475 – 711 mg/kg by the incidence of contamination approximated in the misuse study (0.0097%). Thus, the contaminant concentration of recycled PS input is estimated to be no more than 0.1 mg/kg (711 mg/kg x 0.0097% = 0.069 mg/kg, or 0.1 mg/kg). Therefore, it would be conservative to assume a worst-case input contamination of the input flake is significantly less than the 0.5 mg/kg level assessed in previous reports of this novel technology development.

Other contamination, such as microbiological or viral contamination, can be excluded because of the high temperatures used to process the polymer (Barthélémy et al. 2014).

3. List of substances in plastic input and recycled plastic output

Tables 1 and 2 below list the substances found in the plastic input and in the recycled polystyrene output, sorted in descending order of the concentration in the samples.

The tentative identity of each substance was determined by matching the fragmentation pattern for each substance with a library of known compounds. The concentration of each substance was semi-quantified using calibration data for a limonene external standard. Substances identified with an asterisk (“*”) following the chemical name were quantified using external reference calibration data for that substance (rather than using the limonene standard).

Substances highlighted in blue were also identified in virgin polystyrene samples evaluated using the same analytical method. Because these substances are present in virgin samples, they are not considered contaminants and are not further discussed in this report.

Table 1: Substances identified in Source (INPUT)

Substance Name	CASRN	Average Conc. (mg/kg)
Styrene *	100-42-5	147.33
Ethylbenzene *	100-41-4	24.70
1,2-Ethanediol	107-21-1	22.35
Ethoxy ethene	109-92-2	10.95
2-Propenal	107-02-8	10.37
Acetophenone *	98-86-2	8.58
Limonene *	138-86-3	7.01
Acetic acid	64-19-7	5.22
Xylene	1330-20-7	5.18
Cumene	98-82-8	4.78
1-Octene-3-one	4312-99-6	4.28
1-Octene	111-66-0	4.28
Benzaldehyde	100-52-7	4.00
Decane	124-18-5	3.51
Isobutene	115-11-7	3.49
Anisole	100-66-3	3.32
Styrene dimers	-	3.10
2-heptanone	110-43-0	3.06
n-Propylbenzene	103-65-1	3.03
2-Ethylhexanol	104-76-7	2.60
Toluene	108-88-3	2.39
Butylated Hydroxytoluene	128-37-0	2.26
2,2,4,6,6-Pentamethylheptane	13475-82-6	1.91
2-Nonen-1-ol, (Z)-	41453-56-9	1.76
Cyclohexane, 1-methyl-4-(1-methylethyl)-, trans-	1678-82-6	1.52
Cyclohexane	110-82-7	1.42
2-Nonanone	821-55-6	1.26
Trimethylbenzene	108-67-8	1.24
α-methylstyrene	98-83-9	1.21
Dimethyl disulphide	624-92-0	1.20
Branched alkane	-	1.16
Hexanal	66-25-1	1.16
Octane	111-65-9	1.15
1-Octanol, 2,7-dimethyl-	15250-22-3	1.12
Not identified	-	1.10

Table 2: Substances identified in rPS (OUTPUT)

Substance Name	CASRN	Average Conc. (mg/kg)
Styrene *	100-42-5	87.70
Ethylbenzene *	100-41-4	11.37
1,2-Ethanediol	107-21-1	7.39
Acetophenone *	98-86-2	5.66
Ethoxy ethene	109-92-2	4.26
Limonene *	138-86-3	3.87
Benzaldehyde	100-52-7	3.72
Styrene dimers	-	3.00
Acetic acid	64-19-7	2.69
Cumene	98-82-8	2.64
2-Propenal	107-02-8	2.56
Xylene	1330-20-7	2.13
Isobutene	115-11-7	2.00
1-Octene-3-one	4312-99-6	1.84
Decane	124-18-5	1.81
Butylated Hydroxytoluene	128-37-0	1.80
1-Octene	111-66-0	1.80
n-Propylbenzene	103-65-1	1.69
2-Ethylhexanol	104-76-7	1.34
α-methylstyrene	98-83-9	1.28
Anisole	100-66-3	1.24
2-heptanone	110-43-0	1.20
Toluene	108-88-3	1.20
2-Nonen-1-ol, (Z)-	41453-56-9	1.19
Cyclohexane	110-82-7	1.03
2,2,4,6,6-Pentamethylheptane	13475-82-6	0.96
2-Nonanone	821-55-6	0.91
Not identified	-	0.88
Hexanal	66-25-1	0.81
Trimethylbenzene	108-67-8	0.77
Branched alkane	-	0.49
Cyclohexane, 1-methyl-4-(1-methylethyl)-, trans-	1678-82-6	< 1
Dimethyl disulphide	624-92-0	< 1
Octane	111-65-9	< 1
1-Octanol, 2,7-dimethyl-	15250-22-3	< 1

4. List of contaminating materials regularly present in the plastic input

As discussed in INEOS Styrolution' s previous reports, the waste stream from which the source material is obtained consists of PS trays and containers from green dot systems and curbside collection systems in Europe. The waste may originally contain non-food articles such as:

- Video cassettes
- Flower pots
- Hangers
- CD covers
- Clip closures (*e.g.*, freezer bags including metal wire and PS)

These materials are sorted out of the waste stream such that the input material consists predominantly of PS used in contact with food. The specifications for the input to the decontamination process are as follows:

Parameter	**Value**
Moisture	<1%
PS flakes with glue content	<0.5%
Polyolefins content	<1%
Polyamide content	<0.5%
Metals content	<0.1%
Wood, paper, cellulose	<0.5%

5. Analysis of the most likely origin of the identified contaminants

As noted above, testing has demonstrated that many of the substances found in the recycled PS are also found in samples of virgin PS. These substances are generally found at similar concentrations in both virgin and recycled samples.

Several other substances (e.g., limonene) are flavoring substances that may be associated with foods that were stored in the plastic packaging that was in the source material. Other substances could be present in the input and output material from their use as components of the packaging (e.g., labels, printing inks, adhesives, etc.) that was recycled. The levels of these substances are relatively low and are comparable to the levels in other packaging materials.

The utilization of modified analytical techniques, *i.e.*, headspace sampling of contaminants/ impurities in PS flakes in both nitrogen and argon atmospheres, for the analysis of potential contaminants in the recycled material supports the hypothesis that certain substances found when PS samples are analyzed in standard analytical methods (e.g., air) result from the decomposition of the analyzed material, and are not expected to be present in the recycling input or output streams. Hence, a constituent analysis of the recycled PS will be performed under an inert atmosphere (*i.e.*, nitrogen or argon method) moving forward.

6. Measurement or estimation of the migration levels to food of contaminants present

The migration of the contaminants present in the output (recycled polystyrene) was determined using diffusion modeling following the same approach for the various applications covered by the first four reports submitted on this novel technology.

That is, the Piringer-based (i.e., A_P-based) diffusion model was used to estimate migration of the various substances. Because the A_p model exaggerates migration from polystyrene, the migration values were adjusted using the temperature correction factors established by Welle (2023)[1]. As noted in the initial report, the correction factors for polystyrene depend on temperature (the extent of the overprediction of the A_P-based diffusion model increases as temperature decreases), but are also influenced by both molecular weight and polarity. We have used the factor developed for toluene at the specific temperatures of interest (i.e., 4.77 for 60 °C, 11.8 for 40 °C, 22.9 for room temperature conditions, and 20.8 for refrigerated conditions) in determining the estimated migration for each of the contaminants in the various use scenarios for the recycled PS.[2] That is, applications considered here include packaging for yogurt and similar foods (following three different packing scenarios), meat and cheese tray applications, fish boxes, fruit and vegetable tray applications, hot and cold cup applications. The migration values for each contaminant and under each use scenario are reported in Table 3.

Table 3: Calculated migration for substances under various recycled PS use scenarios

			Predicted Migration (µg/kg-food)					
Substance Name	**CASRN**	**Conc. in rPS (mg/kg)**	**Yogurt[3]**	**Meat/ Cheese Tray**	**Fish Boxes**	**Fruit/ Vegetable Tray[4]**	**Cold Cups**	**Hot Cups**
1,2-Ethanediol	107-21-1	7.39	0.74	0.19	0.10	0.06	0.10	1.41
Acetophenone	98-86-2	5.66	0.35	0.09	0.05	0.03	0.05	0.65
Limonene	5989-27-5	3.87	0.21	0.05	0.03	0.02	0.03	0.40
Benzaldehyde	100-52-7	3.72	0.25	0.06	0.03	0.02	0.03	0.48
Acetic acid	64-19-7	2.69	0.28	0.07	0.04	0.02	0.04	0.52
2-Propenal	107-02-8	2.56	0.27	0.07	0.04	0.02	0.04	0.52
1-Octene-3-one	4312-99-6	1.84	0.11	0.03	0.01	0.01	0.01	0.20
Decane	124-18-5	1.81	0.09	0.02	0.01	0.01	0.01	0.18
Butylated Hydroxytoluene	128-37-0	1.80	0.06	0.01	0.01	0.00	0.01	0.11
1-Octene	111-66-0	1.80	0.12	0.03	0.02	0.01	0.02	0.22
2-Ethylhexanol	104-76-7	1.34	0.08	0.02	0.01	0.01	0.01	0.14
α-Methylstyrene	98-83-9	1.28	0.08	0.02	0.01	0.01	0.01	0.15
Anisole	100-66-3	1.24	0.08	0.02	0.01	0.01	0.01	0.16
2-Nonen-1-ol, (Z)-	41453-56-9	1.19	0.06	0.02	0.01	0.00	0.01	0.12
2,2,4,6,6-Pentamethylheptane	13475-82-6	0.96	0.04	0.01	0.01	0.00	0.01	0.08
2-Nonanone	821-55-6	0.91	0.05	0.01	0.01	0.00	0.01	0.09
Trimethylbenzene	108-67-8	0.77	0.05	0.01	0.01	0.00	0.01	0.09

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[1] Welle, F. Recycling of Post-Consumer Polystyrene Packaging Waste into New Food Packaging Applications—Part 1: Direct Food Contact. Recycling 2023, 8, 26. https://doi.org/10.3390/recycling8010026.

[2] As noted above, substances that have been identified in virgin polystyrene resin (and at levels that are similar to that found in the virgin samples) have been excluded from this analysis.

[3] The hot-filled yogurt packaging condition (60°C for 1 hour, followed by 40 days at 6°C) was found to be the worst-case migration condition, and the migration estimate for only that packaging condition is included in this table.

[4] Consistent with the initial report, migration to raw, uncut/unpeeled fruit and vegetables was divided by a 10-fold correction factor as an estimate to this type of food. Prior EFSA opinions noted that the use of trays to transport, store, and display whole fruits and vegetables at room temperature or below involved conditions under which migration was unlikely to occur, noting the solid-solid contact and small surface of contact.

We have concluded that the weight of the evidence indicates that the compounds listed in Table 3 are not genotoxic. Thus, migration can exceed the EFSA-established threshold value for genotoxic compounds of 0.0025 µg/kg bw/day without presenting a health or safety concern.[5] A dietary exposure of 1.5 µg/kg bw/day, which is the human exposure threshold value that has been used by EFSA for Cramer Class III compounds, has been used to assess the safety. Using the same exposure scenarios described in the initial report, including the consumption patterns and assumed body weights described in Table 4 (below), we have calculated the migration levels in foods that will result in exposures to the listed substances of no more than 1.5 µg/kg bw/day under each of the use scenarios.

Table 4: Intended uses and target migration to ensure exposure < 1.5 µg/kg bw/day

Application	rPS content	Representative Time / temperature scenarios	Food Consumption	Body weight	Daily consumption	Acceptable migration in food[6]
Yogurt and similar foods	100%	1 hr @ 60 °C, + 40 days @ 6 °C	12.3 g/kg bw/day	12 kg (toddler)	147.6 g	122 µg/kg
		8 hrs @ 40 °C + 40 days @ 6 °C				
		40 days @ 6 °C				
Meat, poultry, fish, and cheese tray	100%	30 days @ 6 °C	50 g/kg bw/day	12 kg (toddler)	600 g	30 µg/kg
Fish boxes	100%	10 days @ 5 °C	50 g/kg bw/day	12 kg (toddler)	600 g	30 µg/kg
Fruit and vegetable tray	100%	30 days @ 25 °C	50 g/kg bw/day	12 kg (toddler)	600 g	30 µg/kg
Cold cups	100%	1 day @ 25 °C	80 g/kg bw/day	12 kg (toddler)	960 g	18.8 µg/kg
Hot cups	100%	2 hrs @ 70 °C	20 g/kg bw/day	60 kg (adult)	1200 g	75 µg/kg

As demonstrated in Tables 3 and 4, the estimated migration of the contaminants in the recycled PS processed with the INEOS Styrolution novel technology is well below the acceptable migration level noted above (and in most cases less than 1/100th of the level), and clearly these substances in the recycled PS do not present any health or safety concern.

Conclusions

For all use scenarios described above, the estimated migration of substances in the recycled polystyrene results in a dietary exposure below the relevant toxicity threshold for each of the substances. Thus, substances that may possibly be present in the recycled polystyrene will not result in risk of harm to consumers consuming food out of the modelled containers.

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[5] No health or safety concerns are presented from exposures to potentially mutagenic or genotoxic substances at dietary exposures below the genotoxic threshold. Therefore, comprehensive toxicity reviews of substances that may be present in the rPS where diffusion modeling indicates extremely low migration (i.e., that results in a dietary exposure below 0.0025 µg/kg bw/day) were not conducted.

[6] Example calculation:

$<M>_{Target}$ = 1.5 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 122 µg/kg.
$<M>_{Target}$ = 0.0025 µg-contaminant/kg bw/day ÷ 0.0123 kg-yogurt/kg bw/day = 0.20 µg/kg.

7. Description of the applied sampling strategy

The technology developer operates a single recycling facility employing the novel technology. Consistent with Article 13(1) of Commission Regulation (EU) No. 2022/1616, samples from each batch of input flake from the source material and the corresponding batch of the decontaminated plastic output are collected. Each lot size is up to 50 tons maximum.

To date, twenty-nine (29) production batches have been processed using this novel technology (three of which were produced since the last report) and each of these batches were sampled and analyzed using the analytical methods described. Replicate samples of each batch were analyzed.

8. Description of the analytical procedures and methods used

Argon and Nitrogen Methods

A description of the methods was included in the second and third report (nitrogen method) and in the fourth and fifth report (argon method), respectively. No changes have been made to the methods since then.

9. Analysis and explanation of discrepancies

No discrepancies have been observed between the contaminant levels expected in the input and output of the installation and its decontamination efficiency. The data above supports the finding that the decontamination process adequately removes impurities from the waste stream.

10. Discussion of the differences with previous reports

In this report the results of 3 sample batches are discussed. An argon sparge of the headspace vial was used on one sample while a nitrogen sparge was used on the other two samples to remove excess oxygen which may interfere with the identification and quantification of the analytes. The two methods were applied due to a re-organization of the developer’s lab facilities. While the argon method is the preferred method for future analyses as it is performed in-house, the nitrogen method performed by an external lab (Fraunhofer IVV) is equally suitable, as was shown in the fourth report, and is therefore applied temporarily until the developer’s own lab facilities are available again.

11. References

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