Ref. Ares(2025)2566867 - 31/03/2025

PRIMUS

WP1. Fridge Plastics: (N)IAS Quantification, Exposure Scenario Development, and Risk Assessment

Task 1.3

Beyond general product safety towards Food Contact Material Status

Deliverable 1.3

Concept for modelling tool or a custom-made software for quantification of (non-)intentionally added substances and substances risk assessment

Funded by the European Union's Horizon Europe Programme under Grant Agreement No. 101057067

DISCLAIMER

ACKNOWLEDGEMENT

The PRIMUS project is funded by the European Union’s Horizon Europe research and innovation programme under grant agreement N° 101057067.

Project Data	
Project Acronym	PRIMUS
Project Title	Reforming Secondary Plastics to Become the Primary Raw Material Choice for Added Value Products
Grant Agreement number	101057067
Call identifier	HORIZON-CL4-2021-RESILIENCE-01
Topic identifier	HORIZON-CL4-2021-RESILIENCE-01-10 Paving the way to an increased share of recycled plastics in added value products
Funding Scheme	RIA – Research and Innovation Actions
Project duration	36 months (From 1 May 2022)
Coordinator	VTT
Website	https:// primus-project.eu

Deliverable Document Sheet			
Deliverable No.	D1.3		
Deliverable title	Concept for modelling tool or a custom-made software for quantification of (non-)intentionally added substances and substances risk assessment		
WP No.	WP1		
Related task	T1.3 – Beyond general product safety towards Food Contact Material Status		
Lead Beneficiary	PRE		
Author(s)	Patrick de Kort, Mathilde Taveau		
Contributor(s)	COR, UEF		
Type	Report		
Dissemination L.	Public		
Language	English – GB		
Due Date	31/03/2025	Submission Date	DD/MM/YYYY

Version	Action	Owner	Date
V.0.1	First Draft	PRE	26/02/2025
V.0.2	Reviewed	UEF	11/03/2025
V.1.0	Reviewed (coordinator)	VTT	28/03/2025

Table of Contents

List of Figures

List of Tables

EXECUTIVE SUMMARY

The PRIMUS project, funded by the European Union's Horizon Europe research and innovation program, aims to enhance the quality and safety of recycled plastics in the European market. Deliverable D1.3, part of Work Package 1 (WP1), focuses on the quantification of (Non-)Intentionally Added Substances ((N)IAS) in high impact polystyrene (HIPS) Fridge recyclate and the development of a comprehensive risk assessment model to evaluate its suitability for food contact materials (FCM).

Objectives and Scope

The primary objective of this deliverable was to develop a standardized methodology to assess the safety of HIPS Fridge recyclate for reuse in new refrigerator. This included:

- Quantification of (N)IAS present in the recyclate.
- Development of an exposure scenario specific to refrigeration applications.
- Implementation of a migration model to estimate potential consumer exposure.
- Conducting a risk assessment to determine the safety of the recyclate in FCM applications.

Methodology and Implementation

A detailed (N)IAS screening was conducted using gas chromatography-mass spectrometry (GC-MS) and flame ionization detection (FID) techniques. A migration model was developed based on established European Food Safety Authority (EFSA) guidelines to estimate the migration of substances into food under worst-case conditions. A risk characterization ratio (RCR) approach was applied to compare measured concentrations with tolerable limits.

Key Findings

- The study identified several (N)IAS, including styrene oligomers, antioxidants, and plasticizers.
- All detected substances were found to be within safe limits, with RCR values demonstrating a substantial margin of safety.
- A sensitivity analysis confirmed that even under conservative assumptions, the recyclate does not pose a health risk.

Conclusion and Future Directions

The findings demonstrate that HIPS Fridge recyclate can be safely reused in new refrigerator linings without significant health risks. The developed methodology and accompanying Excel-based risk assessment tool provide a robust framework for future evaluations. While empirical migration testing under real-use conditions remains an avenue for further validation, the current results support the potential regulatory acceptance of this material for FCM applications.

PRIMUS PROJECT

PRIMUS project is dedicated to significantly contribute to the goals of the European Strategy for Plastics and enhance the amount of quality and safe recycled plastics that enter the European markets. PRIMUS is a project funded by the Horizon Europe in the following call: *HORIZON-CL4-2021-RESILIENCE-01-10: Paving the way to an increased share of recycled plastics in added value products (RIA)*. PRIMUS is a 3-year project with a total budget of 7 M€. PRIMUS has 10 partners[1], and 2 affiliated entities[2].

PRIMUS will actively engage with the plastics value chain stakeholders and innovatively develop novel methods and technologies to significantly increase the circularity, and production and use of sustainable, safe and quality recyclates in added value products. The main technological focuses are on advanced mechanical recycling coupled with broad analytics and novel pretreatment methods for removal of hazardous substances and counteracting degradation. PRIMUS will produce 4 demonstrations where new added value products will be made from recycled and upgraded non- or underutilized plastic waste streams from waste electronics and electrical equipment (WEEE) and end-of-life vehicles (ELV). The four demo products will be automotive interior parts, automotive cooling circuits and its elements, a food contact application refrigerator, and a closed-loop demonstration of washing machine seals.

The project aims at establishing EU widely accepted and transparent procedures to control quality and safety of recyclates, especially for the waste streams containing hazardous substances like brominated flame retardants. The framework related work will include broad engagement of the European plastics sector and recyclers, but also the society, citizens and communities as well as consumers. Safety and trackability back to origin, traceability, are consistent and overlapping themes in PRIMUS. PRIMUS will not only technically and industrially support the uptake of recyclates in products but will also address and support the concerns of the society and enhance the uptake of products that have recycled content.

1 INTRODUCTION

All material that: *(a) are intended to be brought in contact with food, or (b) are already in contact with food and where intended for that purpose, or (c) can reasonably be expected to be brought in contact with food or to transfer their constituents to food under normal or foreseeable conditions of use* are regulated by the framework regulation on food contact material (1935/2004) and are considered "food contact material" (FCM). The general requirements in this regulation state that such FCM may not under normal or foreseeable conditions of use, transfer their constituents to food in quantities which could: *(a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof.*

Under the framework regulation, the European Commission is empowered to adopt specific regulation to further elaborate these general requirements, and it has done so by adopting Commission Regulation (EU) No 10/2011 on plastic materials and Commission Regulation (EU) 2022/1616 on recycled plastic materials. The former is largely setting requirements on plastics materials placed in contact with food while the latter is more process-oriented to set requirements on what needs to be done to control contamination that might have occurred during the use phase of the articles that are being recycled[1].

The requirements in the regulation on plastics material (10/2011), amongst other things, include that intentionally added substances must be risk assessed for the intended application. To aid such risk assessment, there is a positive list of substances which have been approved for use in food contact materials which frequently include specific migration limits (SMLs) that are set based on Tolerable Daily Intake (TDI) values that are derived by a panel of experts hosted by the European Food Safety Authority (EFSA) following a petition by the producer of the substance. In this TDI derivation all publicly available- and petitioner supplied- toxicological evidence of the substance is evaluated.

This regulation also recognises that there might be Non-Intentionally Added Substances (NIAS) by defining them as: *an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product*. Such substances are to be *assessed in accordance with internationally recognised scientific principles on risk assessment*. Such risk assessment is normally done by a combination of migration modelling and empirical (accelerated) testing on the final product. In general, the use phase can contribute, at least partially, to the number and quantity of NIAS in the input of plastics recyclers.

The EU's Directive (2012/19/EU) on waste electrical and electronic equipment (WEEE Directive) ensures the separate collection of fridges and freezers and establishes targets for the recycling and recovery of WEEE. The High Impact Polystyrene (HIPS)

[1] The classical example here is the misuse of PET bottles in garages to store automotive fluids (eg gasoline and engine oil), which subsequent to such use are discarded and may contaminate the PET Bottle recycling stream. The regulation ensures that PET bottles go through a process known colloquially as "super-cleaning" where typically under vacuum and higher temperatures contamination is removed.

contained in the fridges and freezers as part of the internal lining is currently recycled at scale and utilised in new electrical and electronic equipment or other applications. The plastic that lines the interior of fridges and freezers *can reasonably be expected to be brought in contact with food* and is therefore a FCM, albeit a less traditional example. To allow the use this HIPS Fridge recyclate back into the lining of new fridges and freezers, there needs to be an evaluation of the (N)IAS content and risk assessment.

In this paper, the result of an untargeted quantification of (N)IAS is presented, an exposure model for the use of plastics in fridges and freezers is elaborated, and finally a risk assessment is performed to determine if HIPS Fridge recyclate can be used safely in new fridge and freezer linings.

This report can be useful for those who wish to learn about the safety of using HIPS Fridge Recyclate into new refrigeration appliances.

1.1 Contributions of partners

The following Table 1 depicts the main contributions from participant partners in the development of this deliverable.

Table 1 Partners´ contributions

Participant short name	Contributions
COR	Prepared Fridge HIPS Recyclate.
UEF	Analytical work of the (N)IAS Screening of the Fridge HIPS Recyclate. Contributed to drafting this report.
PRE	Report writing. Development of Exposure Scenario, Migration Model, and Risk Assessment (D1.3).

1.2 Relation to other activities in the project

The following Table 2 depicts the main relationship of this deliverable to other activities (or deliverables) developed within the PRIMUS project and that should be considered along with this document for further understanding of its contents.

Table 2 relation to other activities in the project

Deliverable Number	Contributions
D1.3	This report and accompanying Excel tool fulfil the requirements of deliverable D1.3.

1.3 Structure

- **Section 1:** Contains an overview of this document, providing its Scope, Audience, and Structure.
- **Section 2:** Contains the objectives and expected impacts of the project.
- **Section 3:** presents the results of the (N)IAS Screening and provides an evaluation of the toxicological benchmarks used for the identified (N)IAS.
- **Section 4:** contains a reasonable worst-case exposure scenario for the use of fridge and freezer plastics with defined parameters based on desk research.
- **Section 5:** outlines a migration model that is used to calculate a tolerable concentration of the (N)IAS based on the toxicological benchmarks defined in section 3 and the exposure scenario outlined in section 4.
- **Section 6:** compares the measured concentration of (N)IAS with the tolerable concentration to determine if the Fridge HIPS recyclate can be used safely in new food fridge and freezer food contact applications.
- **Section 7:** Discusses uncertainties inherent to the analysis
- **Section 8:** Concludes that Fridge HIPS recyclate can be used safely in new FCM applications and discusses the relation to continued developments as well as deviations to the plan

2 OBJECTIVES AND EXPECTED IMPACT

2.1 Objective

The objective of this task 1.3 was to go beyond general product safety towards Food Contact Material status by:

- Quantifying (Non-)Intentionally Added Substances in Fridge HIPS recyclate.
- Performing a Substances Risk Assessment.
- Drafting of Guidance on how to perform risk assessment of Fridge HIPS recyclate to evaluate whether the material is suitable for use in new fridges and freezers, and finally.
- If successful to submit a dossier to EFSA to petition them to write an opinion on the application.

The deliverable associated with this task was: *D1.3 Concept for modelling tool or a custom-made software for quantification of (non-)intentionally added substances and substances risk assessment*

2.2 Expected Impact

This report provides a first systematic methodology to evaluate the safety (N)IAS in fridge and freezer plastics applications and is accompanied by a software tool developed in Excel.

3 (N)IAS SCREENING

3.1 Method

HIPS fridge plastics recyclate was cryogenically using a 0.5 mm sieve, and dried overnight in an oven at 60 °C. 0.2 g of the HIPS was extracted with 4 ml of solvent mixture (n-hexane and 2-propanol 1:1) for 1 hour at 70 °C under ultrasound, similar to previously described methods for the extraction of brominated flame retardants [1]. After extraction toluene internal standard was added to the extract, supernatant filtered through a 0.2 µm PTFE syringe filter to a GC vial.

GC-MS/FID analysis was conducted using a Bruker Scion 456 GC equipped with a Rxi-5Sil MS column by Restek (30 m × 0.25 mm × 0.25 µm). The GC was coupled to a high-resolution timsTOF PRO mass spectrometer by Bruker via an atmospheric pressure chemical ionization (APCI) interface. Additionally, the GC was also equipped with FID detector, allowing both detectors to be used simultaneously. Measurements were conducted in a split injection mode using a split ratio of 1:10. The identification of analytes was done based on their accurate masses, fragmentation patterns and Kovats retention indices. The quantification was done using FID signal areas by assuming 1:1 response between toluene internal standard and all analytes. The reported results are average values of triplicate measurements.

3.2 Recovery Study

To determine the recovery of the method for the compounds it was designed to identify, a sample of the primary HIPS (Ineos Styrolution , ESCRimo) was compounded with TBBPA, the concentration of TBBPA was determined by measuring the compounded material by XRF and assuming all measured bromine was due to TBBPA. Subsequent analysis by the method described in section 3.1 resulted in an estimated recovery of 81%. Quantification was performed based on GC-FID peak areas using experimentally determined relative response factor, with 1,4-dibromobenzene acting as an internal standard.

While the extraction of such higher molecular weight substances such as brominated flame retardants is considerably more difficult than lower molecular weight substances, a small validation study was performed to determine that lower molecular weight substances would also be recovered using this method. A non-volatile polar substance (benzophenone) and a non-volatile non-polar substance (tetracosane), taken from US FDA Guidance [2], were dissolved along with HIPS in toluene followed by evaporation of the solvent. This resulted in recoveries of 79 and 92% for benzophenone and tetracosane, respectively.

Given the recoveries were around or exceeding 80%, the measured toluene equivalent concentrations were multiplied by a factor 100/80 to calculate recovery corrected concentrations for risk assessment.

3.3 **Results**

The raw data can be found in annex I and the recovery corrected concentrations can be found in Table 3. Details and calculations can be reviewed in the accompanying excel workbook (sheets: "(N)IAS_Identification" and "(N)IAS_Quantification").

Table 3 Recovery corrected measured concentration of (N)IAS in HIPS Fridge recyclate expressed as mg toluene equivalent per kg (mg tol. eq./kg).

Compound	CAS	**Concentration** (mg tol. eq./kg)
Butylated hydroxytoluene	128-37-0	93
Palmitic acid	57-10-3	78
Stearic acid	57-11-4	40
Butyl stearate	123-95-5	62
DEHP	117-81-7	81
Styrene dimer 1		46
Styrene dimer 2		331
Styrene trimer 1		611
Styrene trimer 2		900
Styrene trimer 3		1371
Styrene trimer 4		435
Styrene trimer 5		486
Styrene trimer 6		226
Styrene trimer 7		82

3.4 **Toxicological Evaluation**

Butylated hydroxytoluene (BHT) is a well-known IAS antioxidant used in the plastics industry which is included in the plastics regulation (10/2011) positive list with a specific migration limit of 3 mg/kg food.

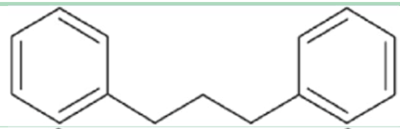
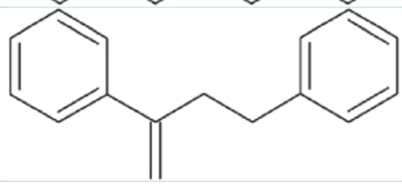
Palmitic acid and stearic acid are fatty acids that are included in the plastics regulation (i.e. IAS) without specific migration limit. The absence of a limit is because these substances are not particularly toxicologically relevant [3]. These fatty acids would form in the digestive tract following consumption of fats (try alkyl glycerol), which are absorbed and either broken down to obtain energy or reaggregated to trialkyl glycerol and stored for later use as an energy source. As such, the most appropriate way to evaluate these substances would be to rule qualitatively that these are of no concern whatsoever. However, to quantitatively include them into the risk assessment, an extremely conservative threshold of toxicological concern (TTC) approach is taken. Both fatty acids qualify for Cramer Class I and therefore have a TTC of 30 µg/kg bw/d, which translates to 1800 µg/kg food assuming an adult of 60 kg consumes 1 kg food per day.

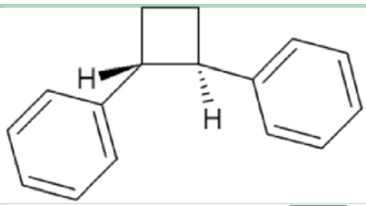
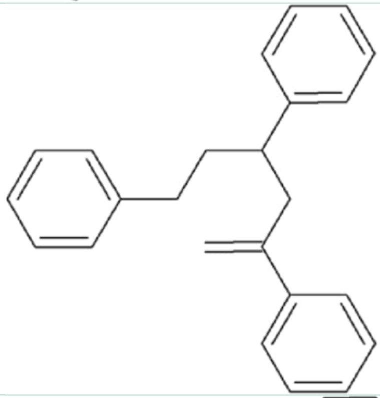
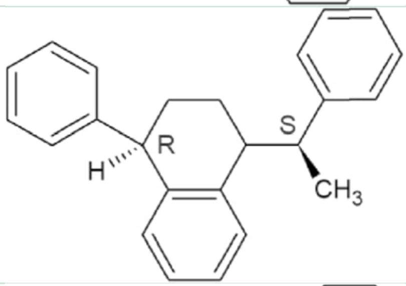
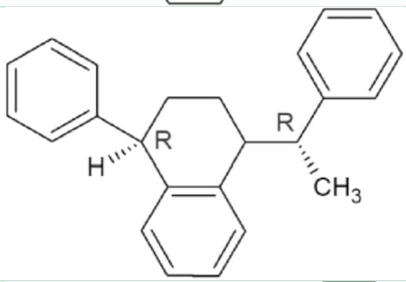
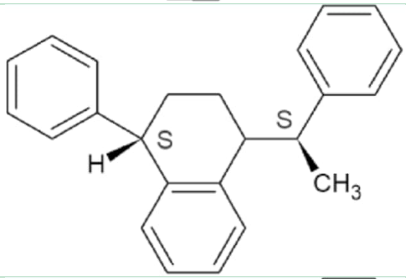
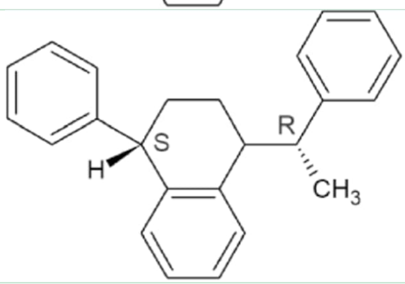
Butyl stearate is also included in the plastics regulation (as stearic acid, butyl ester; 89120) and is therefore an IAS. It is listed without SML and was evaluated in 2007 [4] where it was argued that present use does not present any issue. In general, esters of linear alcohols and saturated carboxylic acids are metabolised to the corresponding alcohols and carboxylic acids, already in the intestines and absorbed as such. Low toxicity can be presumed and the most appropriate way to evaluate these substances would be to qualitatively argue that this substance does not present a risk to human health. However, to include the substance in the quantitative risk assessment, a similar extreme worst-case approach as for the fatty acids is taken and a limit of 1800 µg/kg food is used as butyl stearate is qualifying for Cramer Class I.

The toxicology of styrene di- and trimers (together styrene oligomers; SO) has been evaluated by several authors [5-8], which concluded that these are not genotoxic nor endocrine disrupting. The most recent of these evaluations [8] indicated that all analogues/databases were more or less the same and the only existing in vitro study into genotoxicity was performed with a mixture of SO and that therefore the substances should be treated as a group for risk assessment and that sum total exposure below 50 µg/kg food does not raise any health concerns. This 50 µg/kg food is based on EFSA Guidance used for petitioning to add a substance to the positive list in the plastics regulation (10/2011) [9], which states that for substances with migration below 50 µg/kg food only a limited dataset is needed that demonstrates that the substance is not genotoxic. An alternative approach, followed in another recent evaluation [6], would be to follow an EFSA Opinion on the Threshold of Toxicological concern [10] which states that substances without structural alerts for genotoxicity falling in the lowest Cramer Class III should be safe if exposure remains below 90 µg/person per day; which would translate to a limit of 90 µg/kg food per day (assuming default 1 kg/day food consumption by adults).

With regards to grouping for risk assessment as proposed in the most recent evaluation [8], simple visual evaluation of the chemical structures of styrene oligomers (see Table 4) shows that indeed there are molecules with strong similarities (ST2, ST3, ST4, and ST5), but also rather large differences between other SO. For much of the *in sillico* work, the authors grouped ST2-ST5, but searched for structural analogues for the other SO, separately. As such it would be somewhat conservative to assume additive effect of all SO oligomers. As such in the main risk assessment a limit value per individual SO will be set at 90 µg/kg food. The sum of the risk characterisation ratio calculated for the SO will be included as a sensitivity analysis, to evaluate the risk if additive effect is assumed for the SO oligomers.

Table 4 Abbreviations, identifier and chemical structures of styrene dimers (SD) and trimers (ST). Axial and equatorial symmetry is indicated by letters “a” or "e”. Taken from: Beneventi et al. 2022 [8]

Abbr	CAS	Name	Structure
SD1	1081-75-0	1,3-diphenylpropane	
SD3	16606-47-6	2,4-diphenyl-1-buten	

Abbr	CAS	Name	Structure
SD4	20071-09-4	*trans*-1,2-diphenylcyclobutane	
ST1	18964-53-9	2,4,6-triphenyl-1-hexen	
ST2	26681-79-6	1a-phenyl-4a-(1-phenylelhyl)-1,2,3,4-tetrahydronaphthalene	
ST3	26681-79-6	1a-phenyl-4e-(1-phenylelhyl)-1,2,3,4-tetrahydronaphthalene	
ST4	26681-79-6	1e-phenyl-4a-(1-phenylelhyl)-1,2,3,4-tetrahydronaphthalene	
ST5	26681-79-6	1e-phenyl-4e-(1-phenylelhyl)-1,2,3,4-tetrahydronaphthalene	

The toxicological benchmarks are summarised in the accompanying Excel workbook (worksheet: "Tox.Benchmarks").

4 EXPOSURE SCENARIO

To the best of our knowledge, no default scenario for the evaluation of food contact plastics in cooling and freezing appliances exists.

While fridge and freezer plastics are nominally food contact material since food may be brought in contact with it, most food that is eaten by the general population will not have been in direct contact with the fridge plastics because:

- Food may be stored outside of cooling appliances (e.g. cooking oil, cereals, or dried fruits), or
- Food may be stored inside of cooling appliances but in a packaged state (e.g. meat and fish, soup, beverages)

To determine the fraction of food items that might be put in contact with fridge and/or freezer plastics, the basket of goods used by the UK to track consumer price fluctuations was evaluated to determine what kind of goods could reasonably be expected to be put in contact with fridge and freezer plastics (see accompanying excel workbook: sheets "UKCPI-Fruits&VegAnalysis" and "UKCPI2024-Basket") [11].

The only food items that were potentially put in contact with the fridge plastics were fresh fruits and vegetables. Eggs were considered, however while these can be placed in trays provided along with fridges, it is deemed unlikely that potential migrants would migrate through the mineral shell. For none of the food items it was considered reasonable to assume that these would be placed in direct contact with freezer plastics.

For 9 of the 22 fruit items in the basket, it would not be reasonable to assume that they would be sold and stored unpacked (e.g. blueberries are sold packed, and it would be odd for consumers to unpack these and pour them onto a fridge shelf). Of the remaining 13 food items 8 have an inedible peal (e.g. avocados) which would be removed before consumption of the fruit item, meaning that any migrated substances would also be removed. This leaves just 5 out of the 22 fruit items (=23%) that could be expected to be brought in direct contact with fridge plastics of relevance[2].

12 out of the 30 vegetable products in the basket of goods used to track consumer prices can be expected to be sold unpacked and only one of these (the onion) would have a peel that would be removed before consumption. This leaves 11 out of the 30 vegetable products (=37%) that can be put in contact with fridge plastics. Borderline cases such as the potato, which is mostly eaten without peal and/or stored outside of the fridge are included in this estimate.

For the purpose of the model we will assume that individuals consume 200 grams of fruits and 200 grams of vegetables, which seems to be at the higher side of the

[2] Important to note that in controversial borderline cases such as the kiwi fruit, the conservative assumption is taken that this is eaten with the peal on.

averages reported for different European countries [12], which tends to include fruit juices. Using the factors described above for the fraction of fruits and vegetables that can be brought in contact with fridge plastics, it can be estimated that around 46 grams of fruits and 74 grams of vegetables are consumed daily that have been brought in contact with fridge plastics.

Assuming a density of food of 1 g/cm³ this means that a total of 120 cm³ of food is consumed daily that was brought in contact with fridge plastics. If we assume that this 120 cm³ is a perfect cube that rests on top of the fridge plastics[3], then the contact area becomes: 9.9 cm². If the fridge plastics has a thickness of 3 mm the volume of the polymer becomes 3 cm³. This is reasonably conservative as fruits and vegetables are normally not flush in contact with the fridge and freezer plastics.

When reviewing the food items in the UK CPI basket, very few of the food items were reasonably put in direct contact with the plastics used in freezers. As such, as an extremely conservative approach it will be assumed that there will be a similar contact area, volume of food, and volume of polymer in the freezer scenario as in the fridge scenario.

Under the Ecodesign Directive, specific implementing Commission legislation has been in place since 2009 for household refrigeration appliances (643/2009), which was revised by a new Commission Regulation (2019/2019) in 2019. This EU legislation sets requirements that new refrigerator appliances must meet in terms of temperature (see Table 5). This regulation specifies that the average temperature in fridges should be 4 °C and freezers should maintain a maximum temperature of -18 °C. However, research commissioned by the Netherlands Nutrition Centre, a government subsidised foundation, provided a group of more than 500 households with digital thermometers and requested them to measure the temperature in their fridge. The average temperature was 5.6 °C and 17% of people had a fridge temperature exceeding 7 °C [13], which is largely in line with earlier research [14]. It is reasonable to assume that a similar deviation would exist for freezers and freezing compartments. As such for the purpose of risk assessment, a reasonable worst-case is assumed to be a temperature of 7 °C for the fridge scenario and -12 °C for the freezer scenario.

Table 5 Storage conditions and target temperature per compartment type according to EU Regulation 2019/2019 Ecodesign Requirements for Refrigerating Appliances. Tmin = the minimum temperature inside a compartment during storage testing, Tmax = the maximum temperature inside a compartment during storage testing, Tc = the reference temperature inside a compartment during testing (i.e. the average temperature over time over a set of sensors during testing)

Group	Compartment type	Storage conditions		T_c
		T_{min}	T_{max}	
Unfrozen compartments	Pantry	+14	+20	+17
	Wine storage	+5	+20	+12
	Cellar	+2	+14	+12
	Fresh food	0	+8	+4

[3] A highly conservative assumption, since fruits and vegetables tend to be round and having substantially less contact with the fridge lining then what one would get if the volume of the fruit and vegetable would be considered a perfect square placed on the fridge plastics.

Group	Compartment type	Storage conditions		T_c
		T_{min}	T_{max}	
Chill compartment	Chill	-3	+3	+2
Frozen compartments	0-star & ice-making	*n.a.*	0	0
	1-star	*n.a.*	-6	-6
	2-star	*n.a.*	-12	-12
	3-star	*n.a.*	-18	-18
	freezer (4-star)	*n.a.*	-18	-18

The final parameter that needs to be defined for the fridge and freezer scenario is the contact time. The Netherlands Nutrition Centre has a website that provides advice on maximum fridge and freezer storage times for any and all fruits and vegetables. This tool was used to determine the maximum storage times of the items included in the UK CPI Basket that can be put in contact with the fridge and freezer lining. The maximum storage times in the fridge varied from 4 days (plums) to 2 – 4 weeks (apples and pears), as such the worst-case storage time of 28 days is taken forward for risk assessment. The maximum storage time in freezers was 1 year and thus a period of 365 days is taken forwards as a worst-case value for risk assessment.

5 MIGRATION MODEL

The following framework model is used conservatively calculate the maximum concentration of a substance in the HIPS fridge plastics that would not result in unacceptable risk for human health (C_{mod}) [15-17]:

$$C_{mod} = \frac{m_{f,tmax}}{2S \times d_p}\left(1 + \frac{V_p}{V_f \times K_{fp}}\right)\sqrt{\frac{\pi}{D_p \times t}}$$

With:

	Description	Fridge	Freezer	Unit
C_{mod}	Tolerable concentration in polymer	Calculated		mg/kg
$m_{f,tmax}$	Tolerable concentration in food	(N)IAS Dependent		µg/kg
d_p	Density of the Polymer	1.045		g/cm³
S	Contact area	9.9	(9.9)	cm²
V_p	Volume of the polymer	3	(3)	cm³
V_f	Volume of the food	120	(120)	cm³
K_{fp}	Partition of food and polymer at equilibrium	1		-
D_p	Diffusion of the migrant in the polymer	Substance / Scenario Dependent		cm²/s
t	Time	2419200	31536000	s
t	Time	28	365	days

The density of HIPS is between 1.03 and 1.06 [18], a midpoint value of 1.045 is used for the model. The contact area, volume of the polymer, volume of the food, and contact are based on the Exposure Scenario described above. For the partition coefficient, it is assumed that there is good solubility of the migrants into food and the value is set to 1 in line with EFSA Guidance [17].

The diffusion coefficient is calculated based on the molecular weight of the migrant and conservative polymer specific factors with the following formula [19]:

$$D_p = 10000e^{\left(A_p^* - 0.1351 \times MW^{2/3} + 0.003 \times MW - \frac{10454}{T}\right)}$$

And

$$A_p^* = A_p'^* - \frac{\tau}{T}$$

With

	Description	Value		Unit
D_p	Diffusion of the migrant in the polymer	Calculated		cm^2/s
A_p^*	Polymer Conductance Factor	11.5		
MW	Molecular Weight	(N)IAS Dependent		g/mol
T	Temperature	280.15	263.15	K
T	Temperature	7	-12	°C
$A_p'^*$	upper-bound conductance of the polymer	11.5		
τ	Athermal constant	0		

The molecular weight is substance dependent, the temperature is based on the Exposure Scenario, and the polymer specific factors are taken from European Commission Guidance [15].

The migration model is implemented in the accompanying excel workbook (worksheet: "MigrationModel").

6 RISK ASSESSMENT

Risk characterisation ratios (RCRs) were calculated for every individual (N)IAS detected in (N)IAS quantification by dividing the measured recovery corrected concentration in mg tol. eq./kg by the calculated tolerable concentration in the polymer (C_{mod}) in mg/kg for the fridge and freezer scenario. Colour coding was applied to show where the tolerable concentration is >100 times above the measured concentration (blue) or between 10 and 100 times above the tolerable concentration (green).

Table 6 Result of the Risk Assessment of (N)IAS present in Fridge HIPS Recyclate for use in new Fridge and Freezer FCM. Colour coding of RCRs applied: RCR <0.01 are blue and RCR between 0.01 and 0.1 are green.

Compound	**Concentration** (mg tol. eq./kg)	Mass (u)	C_{mod} Fridge (mg/kg)	RCR Fridge	C_{mod} Freezer (mg/kg)	RCR Freezer
Butylated hydroxytoluene	93	220	1394246	0.00007	1500746	0.00006
Palmitic acid	78	257	1035752	0.00008	1114868	0.00007
Strearic acid	40	285	1206985	0.00003	1299181	0.00003
Butyl stearate	62	341	1609575	0.00004	1732523	0.00004
DEHP	81	391	681735	0.00012	733810	0.00011
Styrene dimer 1	46	208	38895	0.00118	41866	0.00110
Styrene dimer 2	331	209	39135	0.00845	42124	0.00785
Styrene trimer 1	611	312	69483	0.00880	74790	0.00817

Compound	Concentration (mg tol. eq./kg)	Mass (u)	C_{mod} Fridge (mg/kg)	RCR Fridge	C_{mod} Freezer (mg/kg)	RCR Freezer
Styrene trimer 2	900	311	69124	0.01302	74404	0.01210
Styrene trimer 3	1371	311	69124	0.01983	74404	0.01842
Styrene trimer 4	435	311	69124	0.00629	74404	0.00584
Styrene trimer 5	486	311	69124	0.00704	74404	0.00654
Styrene trimer 6	226	312	69483	0.00325	74791	0.00302
Styrene trimer 7	82	312	69483	0.00118	74791	0.00110

The results show that none of the (N)IAS would cause an unacceptable risk for human health or the environment if introduced in new fridges or freezers.

6.1 Sensitivity Analysis Styrene Oligomers

If it is assumed that all styrene oligomers have similar toxicological properties and would have an additive effect, then it would be appropriate to calculate a sum of the RCRs for the oligomers in the different scenarios. This would result in a sum-RCR for SO oof 0.069 for the fridge scenario and 0.064 for the freezer scenario. Indicating that even with such a rather conservative assumption, the presence of styrene oligomers in the material used in fridge and freezer lining would not cause an unacceptable risk to human health.

The results and underlying calculations can be reviewed in the accompanying excel file (worksheet: "RiskAssessment").

7 UNCERTAINTY ANALYSIS

There are several uncertainties that need to be discussed: the (N)IAS screening methodology, use of toluene equivalent concentrations, exposure scenario parameters, and diffusion coefficient estimation.

The (N)IAS Screening methodology was based on methodology normally used for the quantification of brominated flame retardants (BFRs) in PS materials. This means that solvent extraction was performed, and the extract analysed with GC-MS. The methodology thus was designed for compounds with rather high molecular weights (e.g. TBBPA 543.9 g/mol). Validation was performed with tetracosane (338.65 g/mol) and benzophenone (182.217 g/mol), a non-volatile non-polar and a non-volatile polar substance according to US FDA guidance [2]. The method was not validated for volatile polar (e.g. chloroform, chlorobenzene, 1,1,1-trichloroethane, diethyl ketone) and volatile non-polar (e.g. toluene) substances. A complementary analysis with (dynamic) headspace GC-MS would be a good complementary method to determine whether such substances can be present and to what extent.

That being said, if such volatiles would have been present when the material was first brought to market, they will surely have migrated out of the fridge plastics during the use phase of multiple decades. Furthermore, the classical scenario of misuse of PET bottles to store gasoline, motor oil, and similar fluids, which could give rise to such volatile substances in PET recyclate, does obviously not apply here. As such ingress of volatile substances would be limited to whatever can normally be released from food, which may be assumed to be of a less concerning nature than petrochemicals.

Another uncertainty is caused by the quantification of the (N)IAS as toluene equivalent values. It is well known in the field of Volatile Organic Compound chamber testing that when using total ion chromatograms from GC-MS measurements that the true concentration of a substance in the chamber air might deviate by a factor 2 – 3 from the toluene equivalent values. In an ideal world, one would purchase the right analytical standards for all (N)IAS and run standards over the same GC-MS system to perform true quantitation, which may reduce error margins to below 50%. While this may normally be possible for IAS such as BHT, as it should normally be possible to purchase analytical standards for intentionally produced substances[4]; it becomes impossible or an enormous effort when the quantification of NIAS is concerned.

A way to reduce uncertainty with toluene equivalent values, employed in this study, is to use GC-FID for the quantification instead of the total ion spectrum of GC-MS as this normally results in a lower discrepancy between toluene equivalent values and true values. When doing so it should be understood that Flame Ionisation Detection (FID) detects ions formed during combustion of **organic compounds**. Compounds containing heteroatoms can exhibit notably different FID response compared to toluene, which is a pure hydrocarbon. For example, cyclic siloxanes (e.g. D4, D5, D6) contain silicon atoms and can be expected to produce a different signal intensity than an equivalent amount of toluene. In this case, all identified (N)IAS were mainly organic in nature and should not cause too great deviation. Furthermore, even if total ion chromatograms from GC-MS were used for quantification, the margin between the safe concentration and the measured concentration was such that an error margin of 2 – 3 times would not change the conclusion on the safety of the material.

Exposure scenario parameters for the estimation of the tolerable concentration in the polymer were based on the basket of goods used by the United Kingdom to keep track of consumer price inflation. To the best of our knowledge this is the first time such a basket of goods is used to estimate the proportion of foods that can be brought in contact with a particular food contact material. Since it can be assumed that keeping track of consumer prices is an endeavour that is seen as a high national priority in developed countries, it is not unreasonable to assume that great care is taken to ensure that the selected basket of goods is reflective of- or at least a good approximation of- what an average citizen purchases. However, a more exact, albeit more time-consuming approach would be to hold a consumer survey across the European Union, to determine the foods in contact direct contact with the fridge and freezer plastics. Such a resource intensive action would allow for a refinement of this model. Whether or not it would result in substantial changes and potentially even largely different conclusions, is however doubtful.

A key uncertainty in the analysis is on the validity of the migration model. The same model is used in EFSA Guidance on the preparation of applications for the safety

[4] There are exceptions to this rule. For example, UVCB substances would present a difficulty in purification and quantification. For example, the Palmitic acid and Stearic acid that were found are normally components of a single UVCB substance produced in the oleochemical industry.

assessment of post-consumer mechanical PET recycling processes [17][5]. One key aspect in this model is the diffusion coefficient and the estimation thereof. To estimate the polymer diffusion coefficient conservative conductance values (Ap) are used based on work by Begley and colleagues [20], which calculated average Ap values and 95% confidence interval upper bound conductance values (Ap*) values. As the authors put it: "*The use of these parameters in migration modelling leads to 'worst-case' estimations that ensure, in at least of 95% of cases*". As such the used Ap* parameters are likely resulting in overestimation of hazard. As such the model is conservative and causes overestimation, which the EFSA argues is a factor 2, 5, or 10 dependent on the polymer and migrant's molecular weight [17, 21]. Such a factor is not incorporated quantitatively in the model used in this paper but should be understood as covering the aforementioned uncertainties on the use of toluene equivalent values and exposure scenario parameters.

[5] The EFSA guidance relies on exposure modelling software, which produces the same results as the formula used in the current work (when populated with PET, scenario, and migrant specific values).

8 CONCLUSION AND DISCUSSION

8.1 Summary of achievements

This report establishes methodology for the risk evaluation of post-consumer Fridge HIPS recyclate in new fridge and freezer food contact materials. The (N)IAS identified and quantified in the Fridge HIPS recyclate do not cause any concern for human health, indicating that the material can be safely used in new fridge and freezer FCM applications.

8.2 Relation to continued developments

It was envisaged that COR would submit an application to EFSA for the evaluation of whether its material would be fit for use in new fridges and freezers. However, in the meantime the regime for the approval of recycling processes was fundamentally revised with Commission Regulation (EU) 2022/1616 on recycled plastic materials. This allowed COR to apply through a so-called Novel Technology application prior to the completion of this model. This model is still expected to be of utility in refining the safety assessment that needs to be submitted under this Novel Technology path.

This work supports the work performed under WP3 and WP4 on demonstrating refrigerators to refrigerators recycling.

It is currently being considered to publish this work in a scientific journal.

8.3 Deviations to the plan

It was foreseen that should the (N)IAS quantification and risk assessment thereof demonstrate an unacceptable risk for human health, that VTT would then create new samples with different processing conditions. Since the model demonstrates a substantial margin of safety, this was not necessary.

Next to this, as already outlined earlier the major deviation is that this work was not used to create a petition to EFSA with the aim of getting approval to use the use of the Fridge HIPS recyclate in new refrigerators. Instead, the new Novel Technology route was employed by COR to achieve the same aim. This report and model will however be of use for the reports that need to be submitted on the contamination found in the Fridge HIPS recyclate.

9 REFERENCES

[1] M. Shao, J. Jiang, M. Li, L. Wu, and M. Hu, "Recent developments in the analysis of polybrominated diphenyl ethers and polybrominated biphenyls in plastic," vol. 35, no. 3, pp. 133-143, 2016, doi: doi:10.1515/revac-2016-0012.

[2] FDA, "Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations)," 2021. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

[3] A. Mortensen *et al.*, "Re-evaluation of fatty acids (E 570) as a food additive," *EFSA Journal,* vol. 15, no. 5, p. e04785, 2017/05/01 2017, doi: https://doi.org/10.2903/j.efsa.2017.4785.

[4] A. European Food Safety, "Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to the 14th list of substances for food contact materials," *EFSA Journal,* vol. 5, no. 2, p. 452, 2007/02/01 2007, doi: https://doi.org/10.2903/j.efsa.2007.452.

[5] BfR, "Gemessene Gehalte an Styrol-Oligomeren in Lebensmittelsimulanzien: Gesundheitliche Risiken sind unwahrscheinlich [Levels of styrene oligomers measured in food simulants show that health risks are unlikely.]," Bundesi, 2016.

[6] H.-P. Gelbke *et al.*, "Risk assessment for migration of styrene oligomers into food from polystyrene food containers," *Food and Chemical Toxicology,* vol. 124, pp. 151-167, 2019/02/01/ 2019, doi: https://doi.org/10.1016/j.fct.2018.11.017.

[7] H.-P. Gelbke *et al.*, "Oligomers of styrene are not endocrine disruptors," *Critical Reviews in Toxicology,* vol. 48, no. 6, pp. 471-499, 2018/07/03 2018, doi: 10.1080/10408444.2018.1447547.

[8] E. Beneventi, C. Goldbeck, S. Zellmer, S. Merkel, A. Luch, and T. Tietz, "Migration of styrene oligomers from food contact materials: in silico prediction of possible genotoxicity," *Archives of Toxicology,* vol. 96, no. 11, pp. 3013-3032, 2022/11/01 2022, doi: 10.1007/s00204-022-03350-x.

[9] F. Aguilar *et al.*, "Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials," *EFSA Journal,* vol. 6, no. 7, p. 21r, 2008/07/01 2008, doi: https://doi.org/10.2903/j.efsa.2008.21r.

[10] E. S. Committee, "Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)," *EFSA Journal,* vol. 10, no. 7, p. 2750, 2012/07/01 2012, doi: https://doi.org/10.2903/j.efsa.2012.2750.

[11] UK. "Consumer price inflation basket of goods and services." Office for National Statistics. https://www.ons.gov.uk/economy/inflationandpriceindices/datasets/consumerpriceinflationbasketofgoodsandservices (accessed 14 February, 2025).

[12] EC. "Fruit and vegetables intake in European countries." European Commission. https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/fruit-vegetables-5_en (accessed 14 February, 2025).

[13] Flycatcher, "Koelkasttemperatuur," 2021. [Online]. Available: https://www.voedingscentrum.nl/Assets/Uploads/voedingscentrum/Documents/Consumenten/Nieuws/Voedingscentrum%20-%20Rapportage%20Koelkasttemperatuur.pdf

[14] W. van der Vossen and C. van Dooren, "Storage of Food: Fact Sheet," 2016. [Online]. Available: https://mobiel.voedingscentrum.nl/Assets/Uploads/voedingscentrum/Documents/Professionals/Pers/Factsheets/VC_FSheet%20Bewaren%20ENG_def%20LR-2.pdf
[15] R. Brandsch *et al.*, "Practical guidelines on the application of migration modelling for the estimation of specific migration," Luxembourg (Luxembourg), 2015. [Online]. Available: https://publications.jrc.ec.europa.eu/repository/handle/JRC98028
[16] J. Crank, *The Mathematics of Diffusion*. Oxford: Clarendon Press, 1975.
[17] C. Lambré *et al.*, "Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food," *EFSA Journal,* vol. 22, no. 7, p. e8879, 2024/07/01 2024, doi: https://doi.org/10.2903/j.efsa.2024.8879.
[18] BPF. "Polystyrene (High Impact) HIPS." https://www.bpf.co.uk/plastipedia/polymers/HIPS.aspx (accessed 14 February, 2025).
[19] O. Piringer and A. L. Baner, "Plastic Packaging: Interactions with Food and Pharmaceuticals, 2nd, Completely Revised Edition," ed, 2008.
[20] T. Begley *et al.*, "Evaluation of migration models that might be used in support of regulations for food-contact plastics," (in eng), *Food Addit Contam,* vol. 22, no. 1, pp. 73-90, Jan 2005, doi: 10.1080/02652030400028035.
[21] EFSA, "Scientific Opinion on the safety assessment of the processes 'Biffa Polymers' and 'CLRrHDPE' used to recycle high-density polyethylene bottles for use as food contact material," *EFSA Journal,* vol. 13, no. 2, p. 4016, 2015/02/01 2015, doi: https://doi.org/10.2903/j.efsa.2015.4016.

ANNEX I (N)IAS RESULTS RAW DATA

Table 7 NIAS Screening Results. * Identification reliability levels: Level 1: Confirmed Identification. The accurate mass, isotopic pattern, and fragmentation pattern and retention time match those of an authentic standard analysed under the same conditions. Level 2: Probable Identification. The identification is based on accurate mass, isotopic pattern and retention index matching with a reference database, but without confirmation by an authentic standard. Level 3: Tentative Identification. The identification is based on accurate mass alone. Level 4: Unknowns. Compounds detected but not identified.

Chromatographic data (FID)					**Kovats retention index**				MS data				
#	RT (min)	Area	I	S/N	TR_z	$TR_{(z+1)}$	z	Kovats index	m/z	Ion formula	Molecular formula	Compound	Reliability*
12	4.74	83178.2	27961	640.1	0.000	5.590	0		93.0697	$C_7H_9^+$	C_7H_8	Toluene (internal standard)	1
13	22.34	3115.7	2409	58	22.270	23.190	15	1508	220.1821	$C_{15}H_{24}O^+$	$C_{15}H_{24}O$	Butulated hydroxytoluene	2
14	24.3	1518	1176	27.1	24.020	24.790	17	1736	208.124	$C_{16}H_{16}^+$	$C_{16}H_{16}$	Styrene dimer 1	3
15	24.54	11172	9354	221.2	24.020	24.790	17	1768	209.1323	$C_{16}H_{17}^+$	$C_{16}H_{16}$	Styrene dimer 2	3
16	25.9	3262.8	2379	55.8	25.510	26.190	19	1957	257.2475	$C_{16}H_{33}O_2^+$	$C_{16}H_{32}O_2$	Palmitic acid	2
17	27.21	2245	1237	27.4	26.830	27.450	21	2161	285.2789	$C_{18}H_{37}O_2^+$	$C_{18}H_{36}O_2$	Strearic acid	2
18	28.53	2073.2	1391	30.5	28.040	28.610	23	2386	341.341	$C_{22}H_{45}O_2^+$	$C_{22}H_{44}O_2$	Butyl stearate	2
19	29.02	20402.1	15878	373.9	28.610	29.160	24	2475	312.187	$C_{24}H_{23}^+$	$C_{24}H_{24}$	Styrene trimer 1	3
20	29.37	2557.6	2208	46.9	29.160	29.680	25	2540	391.2841	$C_{24}H_{39}O_4^+$	$C_{24}H_{38}O_4$	Phthalate (DEHP)	2
21	29.56	30174.3	24716	580.9	29.160	29.680	25	2577	311.1795	$C_{24}H_{23}^+$	$C_{24}H_{24}$	Styrene trimer 2	3
22	29.63	45951.6	35114	828.4	29.160	29.680	25	2590	311.1794	$C_{24}H_{23}^+$	$C_{24}H_{24}$	Styrene trimer 3	3
23	29.67	14596.1	12017	279.3	29.160	29.680	25	2598	311.1794	$C_{24}H_{23}^+$	$C_{24}H_{24}$	Styrene trimer 4	3
24	29.72	16308.3	12340	287.1	29.680	30.230	26	2607	311.1795	$C_{24}H_{23}^+$	$C_{24}H_{24}$	Styrene trimer 5	3
25	30.24	7424	5133	114	30.230	30.820	27	2702	312.1873	$C_{24}H_{24}^+$	$C_{24}H_{24}$	Styrene trimer 6	3
26	30.37	2619.9	1826	34.7	30.230	30.820	27	2724	312.1873	$C_{24}H_{24}^+$	$C_{24}H_{24}$	Styrene trimer 7	3

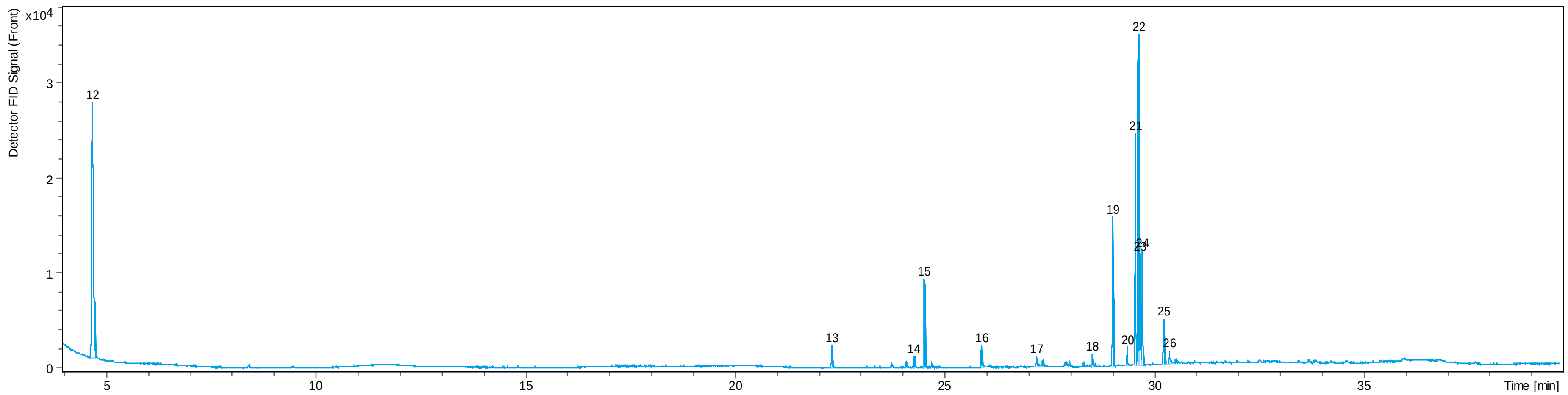


Figure 1 Exemplary FID chromatogram