REG No: 93/29837/23
VAT No: 4200155465
Unit 4, No. 6 Santhagen Road
Devon Valley, STELLENBOSCH 7600
www.roedigeragencies.co.za

ANALYTICAL LABORATORY

PO Box 3202
MATIELAND 7602
Tel: +27 21 887 0010
Cell: 083 250 9281

19 April 2023

Wayne Dickson
Super Thene Films (Pty) Ltd.
PO Box 24581
7779 LANDSDOWNE

Dear Mr. Dickson

REF no.: 0703SUP1/1-2

Cling film samples were sent to the analytical laboratory of Roediger Agencies cc for analysis according to EU 10/2011. The samples were:

1	SFV 3812
2	Superthene 12 micron

Migration according to European Standard EU 10/2011 (Methods and references)

Testing programs for overall migration are devised in accordance with the BS EN ISO 1186 series of standards and Commission Regulation No. 10/2011 as amended.

The method is based on EN 1186 and the parts thereof. Global (overall) migration from packaging materials into aqueous food simulants and substitute fatty food simulants by total immersion, single side contact by cell technique, single side contact by pouch technique and by article filling technique.
Samples were exposed by total immersion to simulants as in the table below. The simulant, time of exposure, and temperature were determined according to EU 10/2011 and amendments up to and including EU 2020/1245 and EU 2022/2388.

Sample	Test number	Simulant	Conditions
SFV 3812	1a; 1b	10% Ethanol	10 days at 40 °C
	1c; 1d	3% Acetic Acid	
	1e; 1f	95% Ethanol	
	1g; 1h	Isooctane	2 days at 20 °C
Superthene 12 micron	2a; 2b	10% Ethanol	10 days at 40 °C
	2c; 2d	3% Acetic Acid	
	2e; 2f	95% Ethanol	
	2g; 2h	Isooctane	2 days at 20 °C

The simulant solutions were removed and evaporated to dryness. The extracts were weighed before reconstituting in 3 mL of solvent and injected into the HPLC and GC-MS as described below. The analyses were conducted in duplicate.

In addition the heavy metal content was analysed as described below.

Ash content

The ash content was determined by ashing each sample in a muffle oven up to 550 °C, then weighing each sample and the percentage residue is calculated by mass difference from the original mass.

Sample	Ash content (%)
SFV 3812	0.003
Superthene 12 micron	0.004

The ash was sent for elemental analysis.

EDAX

EDAX is the employment of x-rays to analyse the elements present on a surface of a sample. Only the higher atomic numbers can be detected, the cut off limit is oxygen, thus the relative abundance of an element will result in a higher output signal from the excitation of the x-rays.

Sample		**Elemental weight (%)**											
		C	**O**	**F**	**Na**	**Mg**	**Al**	**Si**	**P**	**S**	**K**	**Ca**	**Ti**
SFV 3812	1	31.68	30.64	21.07	1.13	2.78	2.16	2.39	0.99	0.65	0.80	5.40	0.32
	2	40.06	29.21	17.74	0.84	2.09	1.60	2.00	0.66	0.44	0.54	4.62	0.21
	3	44.90	29.44	14.08	0.63	1.58	1.44	1.61	0.73	0.37	0.55	4.36	0.31
	4	48.24	30.77	11.69	0.66	1.37	1.16	1.32	0.66	0.34	0.47	3.13	0.19
	5	52.14	30.62	9.06	0.62	1.27	1.09	1.16	0.65	0.27	0.36	2.53	0.23
Average	**%**	**43.40**	**30.13**	**14.73**	**0.78**	**1.82**	**1.49**	**1.70**	**0.74**	**0.41**	**0.54**	**4.01**	**0.25**
	ppm	**13**	**9**	**4**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**1**	**0**
Superthene 12 micron	1	38.51	33.47	14.86		3.16	1.98	2.48	1.21	0.15		4.20	
	2	39.28	34.89	11.54		1.85	1.34	6.98	1.04	0.00		3.09	
	3	54.58	32.09	7.76		1.16	0.86	0.84	0.71	0.17		1.82	
	4	50.27	32.48	10.14		1.73	1.24	1.20	0.58	0.33		2.03	
	5	50.54	33.24	7.94		2.07	1.36	1.10	0.77	0.23		2.75	
Average	**%**	**46.63**	**33.23**	**10.45**		**1.99**	**1.36**	**2.52**	**0.86**	**0.18**		**2.78**	
	ppm	**19**	**13**	**4**		**1**	**1**	**1**	**0**	**0**		**1**	

Overall migration

Overall migration limit (OML) – the maximum permitted amount of non-volatile substances released from a material or article into food simulants.

10% Ethanol			
Test number	**Extraction (mg/dm^2)**	**Allowable (mg/dm^2)**	**Pass/Fail**
1a	0.20	10	Pass
1b	0.15	10	Pass
2a	0.17	10	Pass
2b	0.15	10	Pass

3% Acetic Acid			
Test number	**Extraction (mg/dm^2)**	**Allowable (mg/dm^2)**	**Pass/Fail**
1c	0.20	10	Pass
1d	0.15	10	Pass
2c	0.20	10	Pass
2d	0.10	10	Pass

95% Ethanol			
Test number	**Extraction (mg/dm^2)**	**Allowable (mg/dm^2)**	**Pass/Fail**
1e	0.65	10	Pass
1f	0.68	10	Pass
2e	0.35	10	Pass
2f	0.30	10	Pass

Isooctane			
Test number	**Extraction (mg/dm^2)**	**Allowable (mg/dm^2)**	**Pass/Fail**
1g	1.25	10	Pass
1h	1.30	10	Pass
2g	0.75	10	Pass
2h	0.65	10	Pass

Specific migration limit

Specific migration limit (SML) – the maximum permitted amount of a given substance released from a material or article into food or food simulant.

Determination of antioxidant and processing stabilisers using High Performance Liquid Chromatography (HPLC)

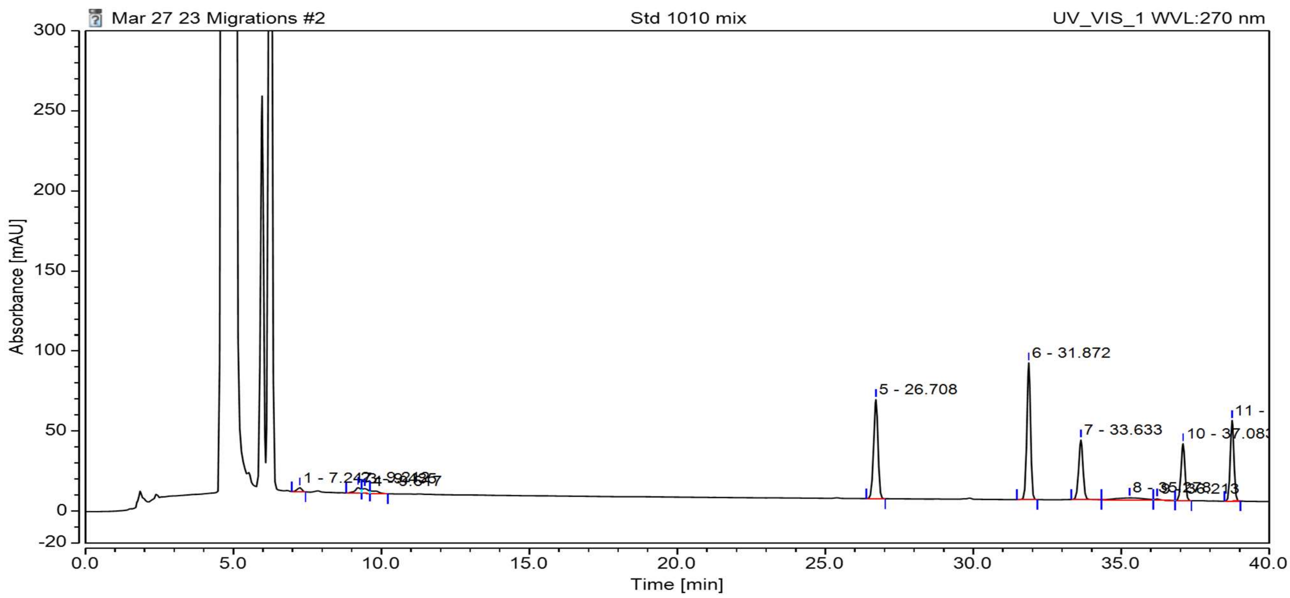
The reconstituted extract was introduced into the HPLC under the following conditions:

Instrument:	Gradient pumping system with UV detection
Column:	Zorbax ODS, 150 x 3.0 mm
Mobile Phase:	A = 75/25 methanol / water
	B = 50/50 ethyl acetate / acetonitrile

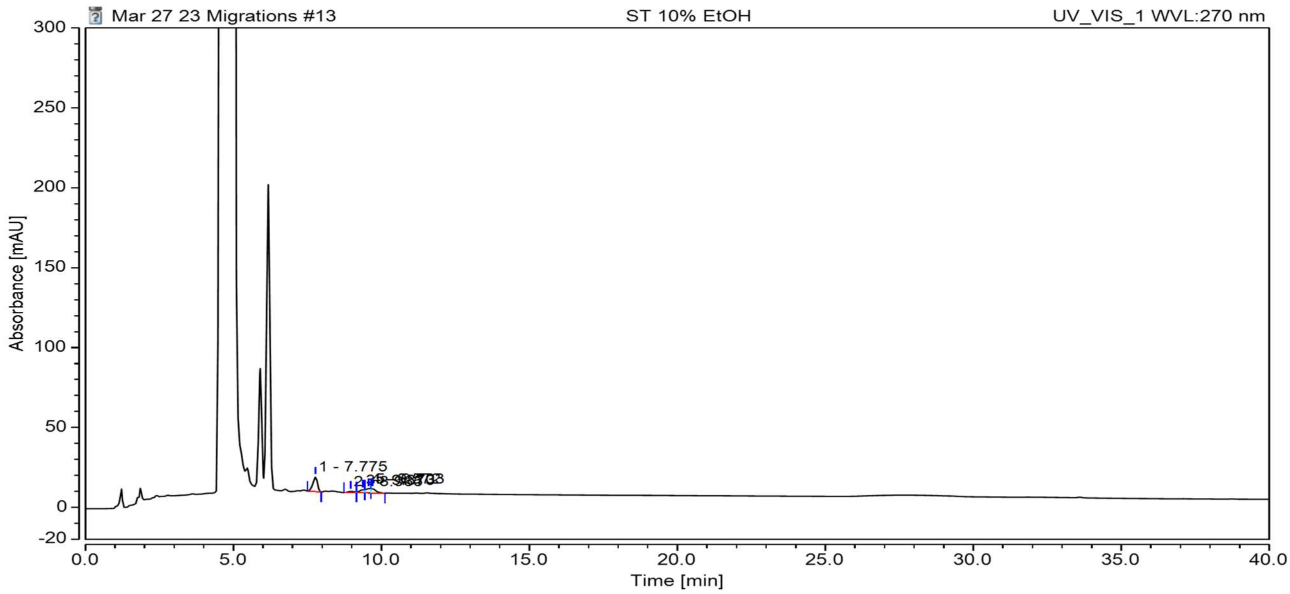
Gradient:

Time	%A	%B
Initial	90	10
35min	0	100

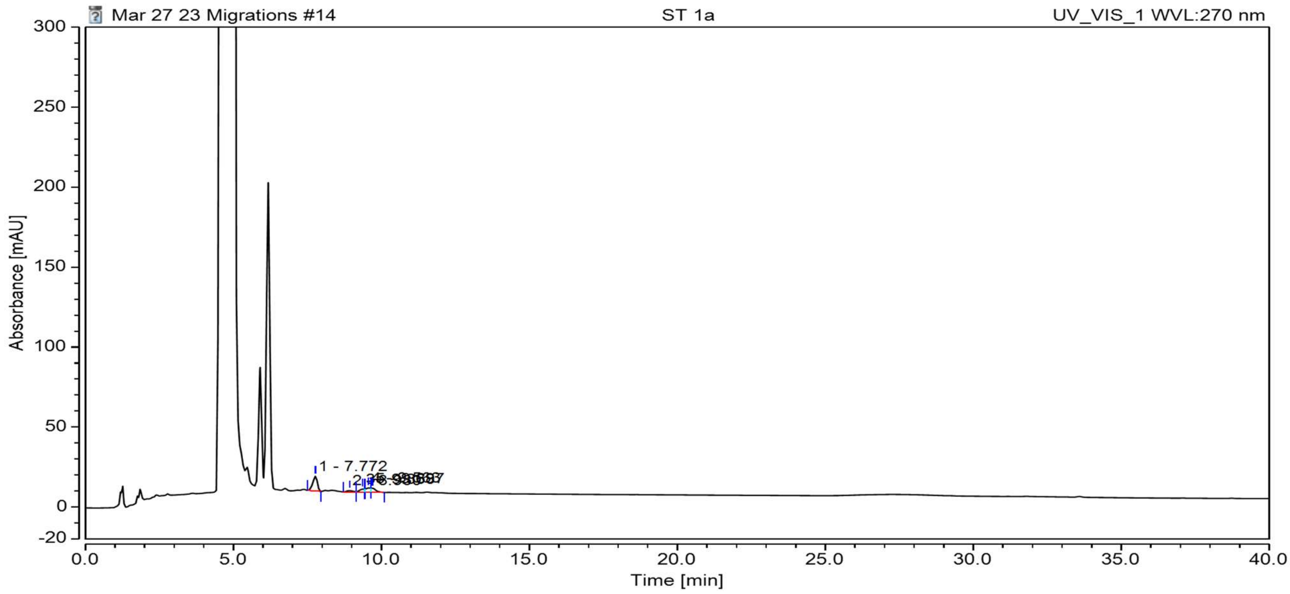
Flow rate:	1 ml/minute
Column temperature:	40 °C
Detection:	270 nm
Injection volume:	25 μl



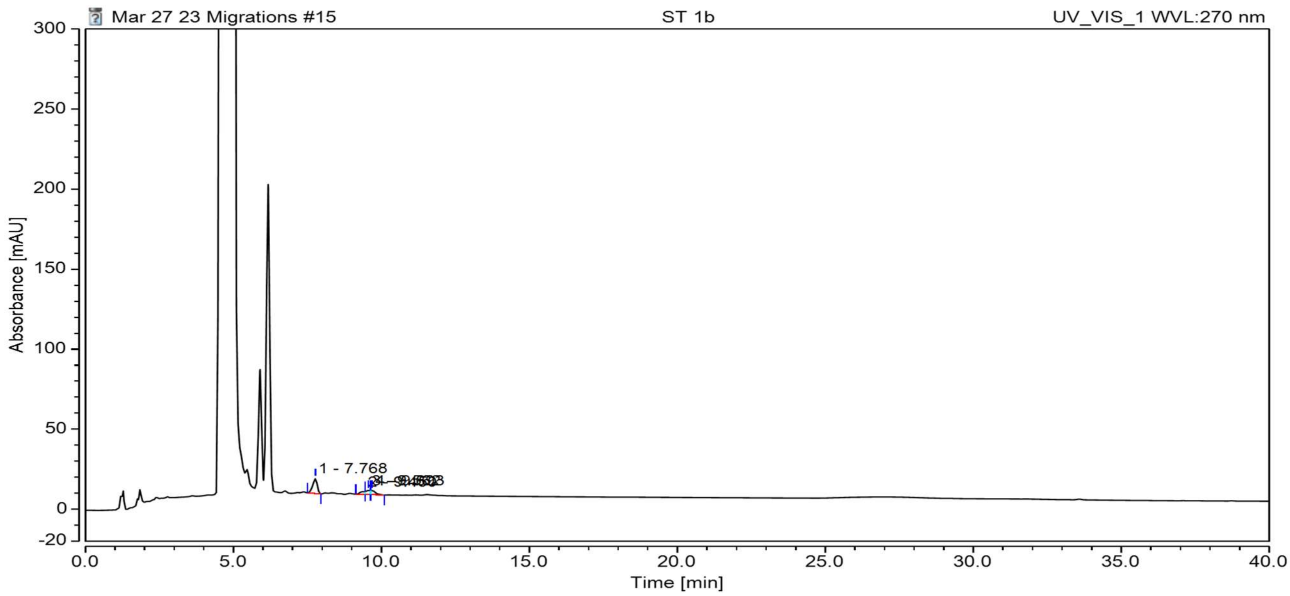
Standards of Irganox®1010, 1035 and 1076, Irgafos®168 and 168d



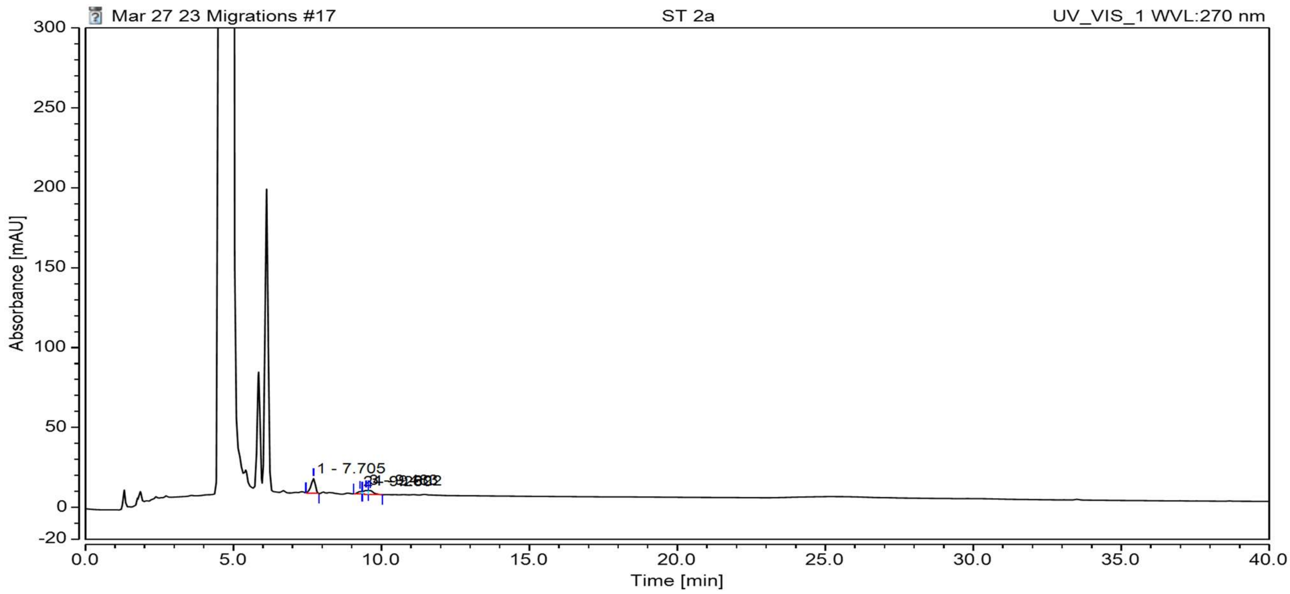
Control sample – 10% Ethanol



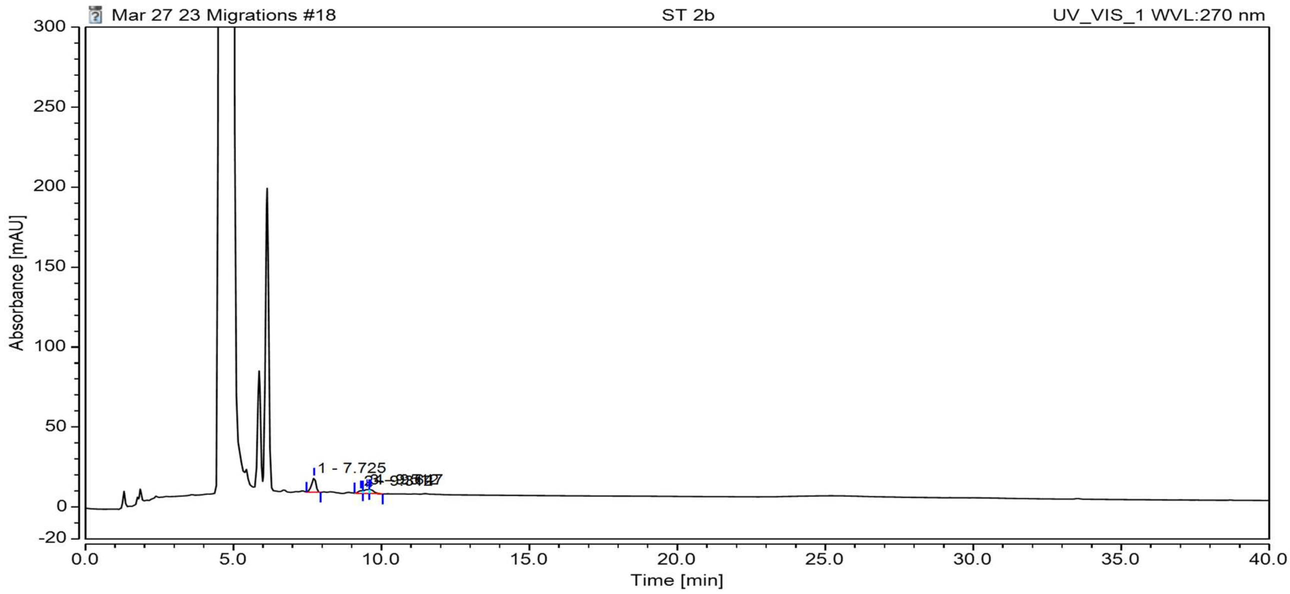
1a



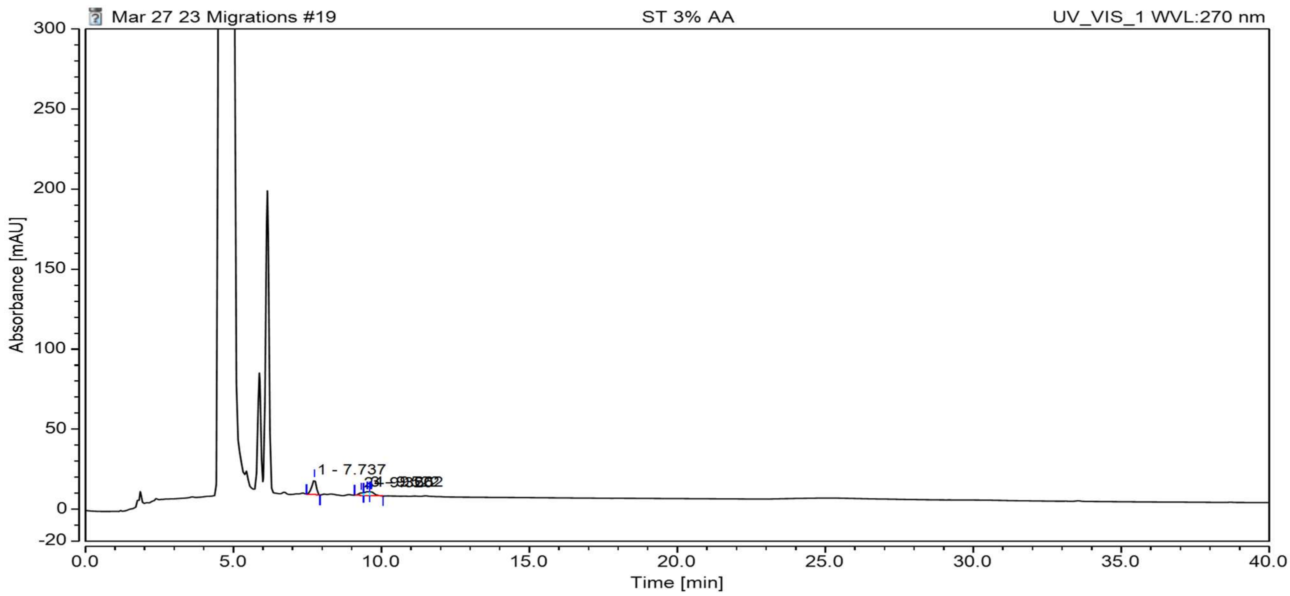
1b



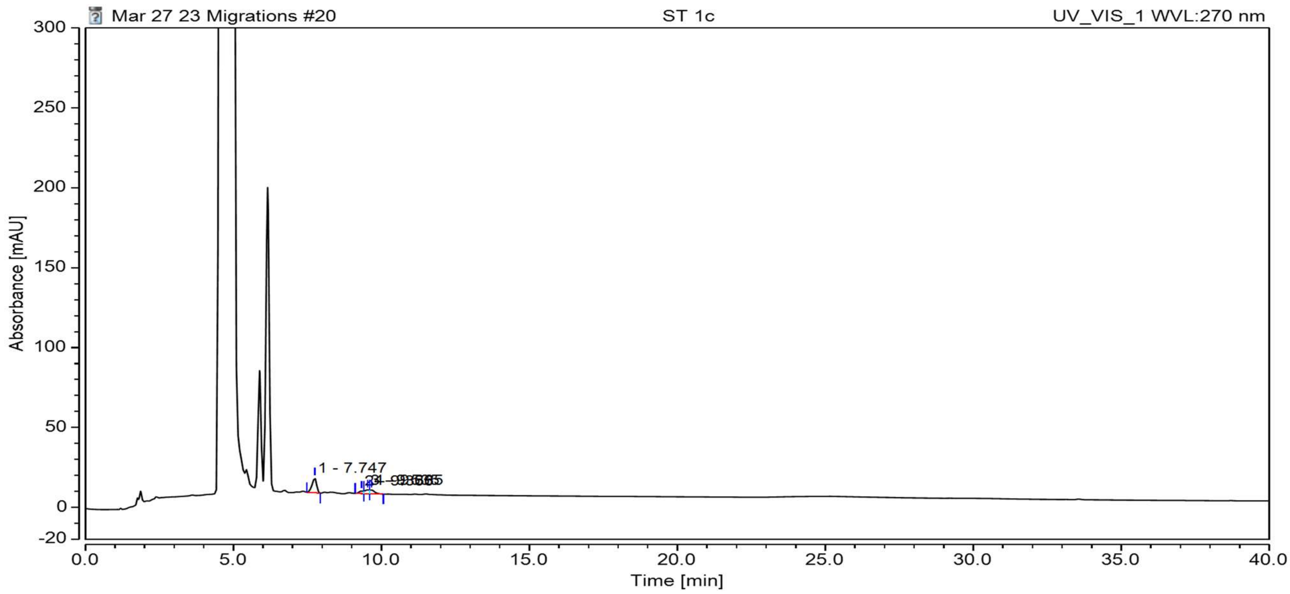
2a



2b



Control sample – 3% Acetic Acid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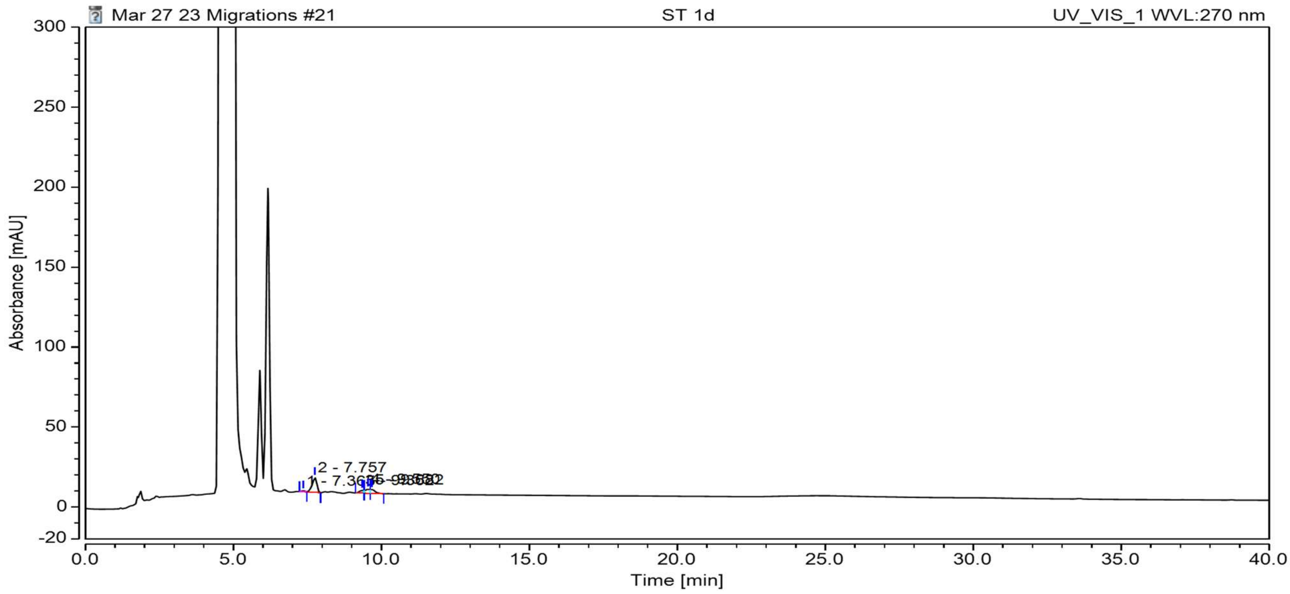
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
1 - 7.747

1c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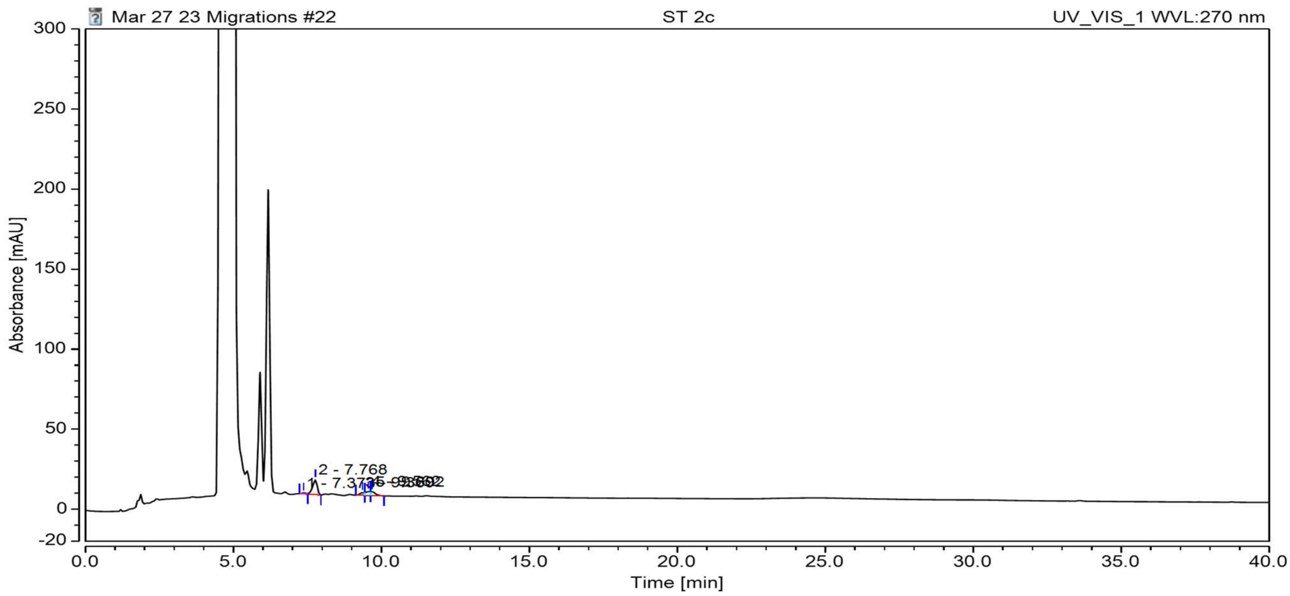
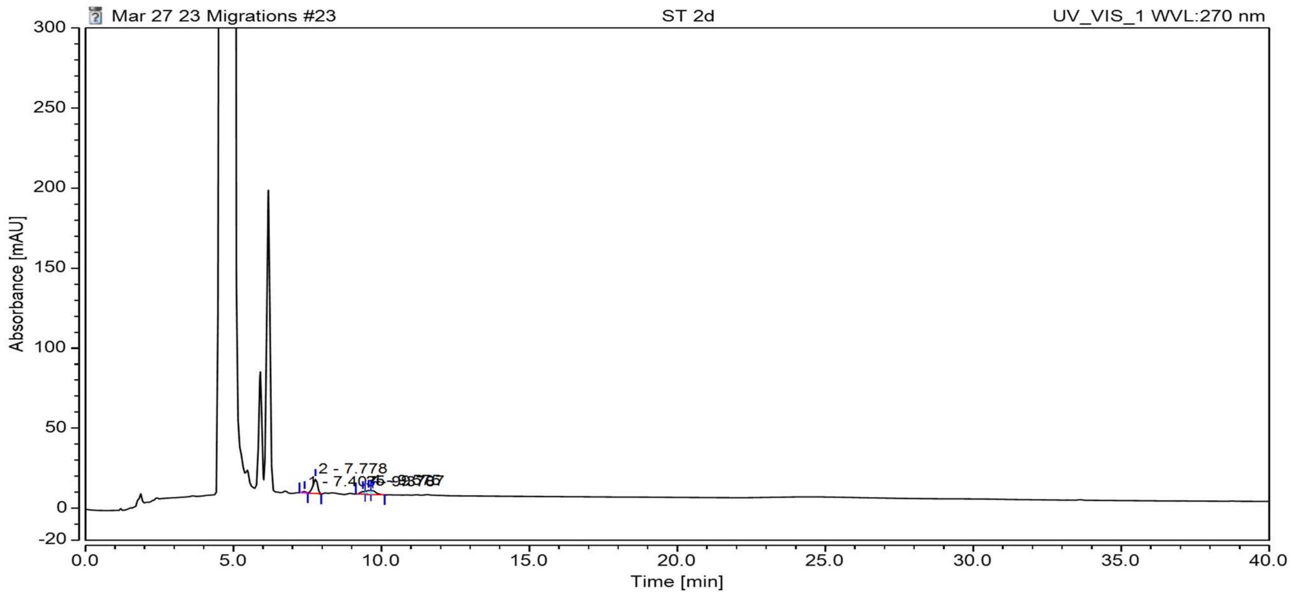
ST 1d
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.757

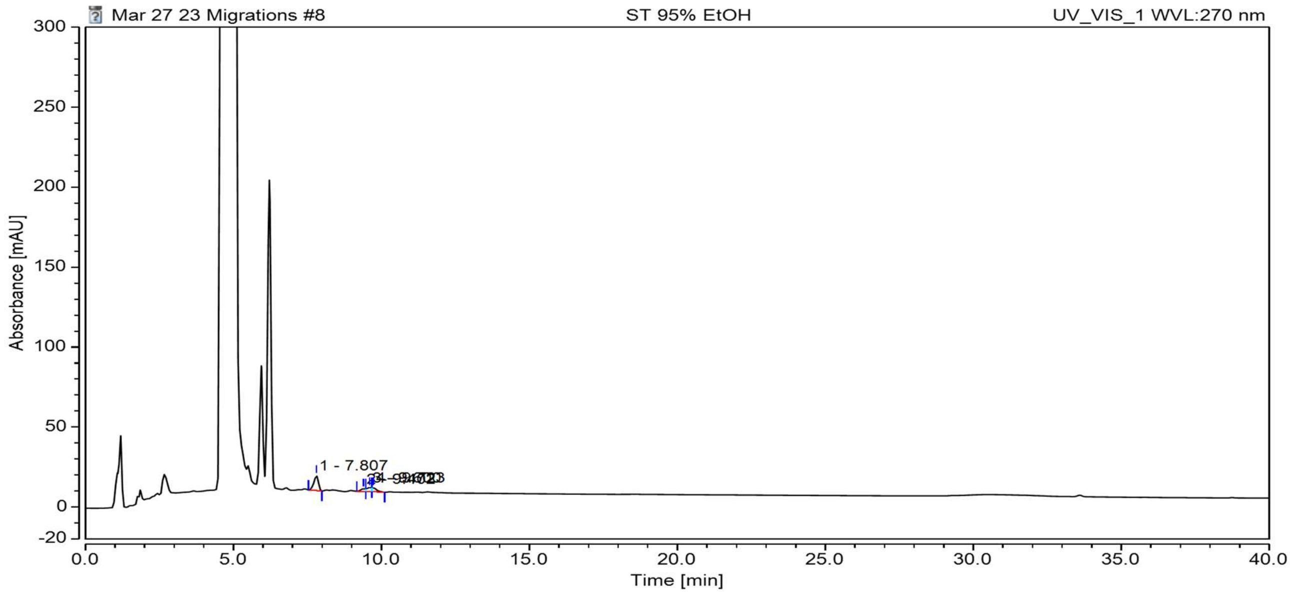
1d


Mar 27 23 Migrations #22
ST 2c
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.768

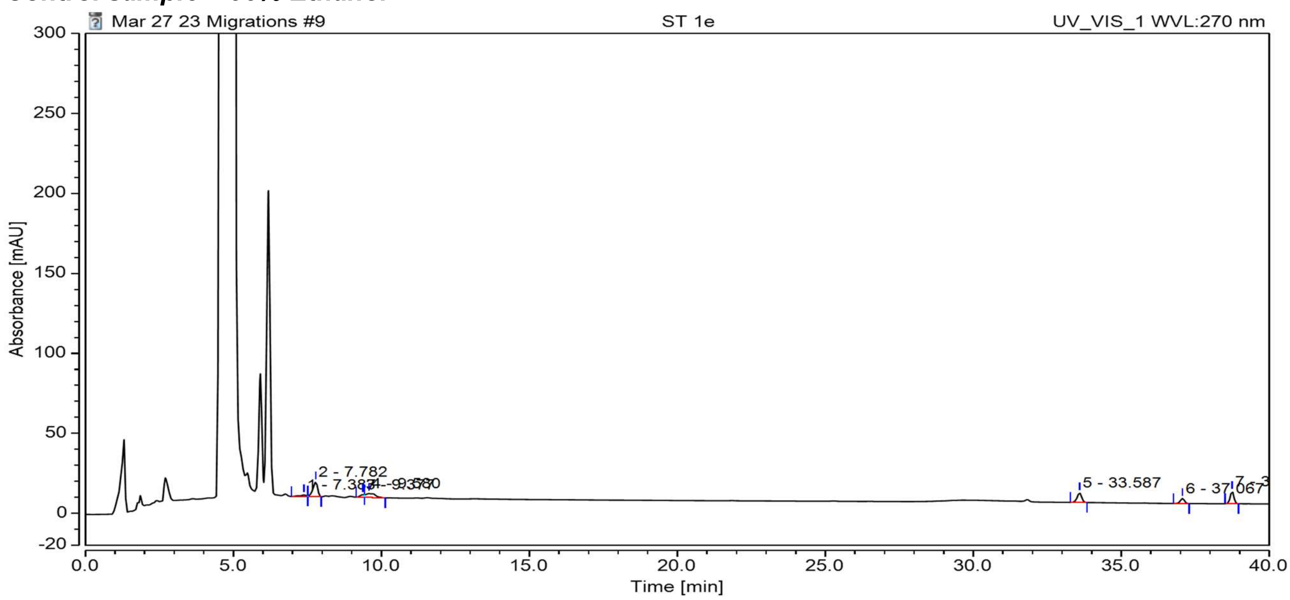
2c



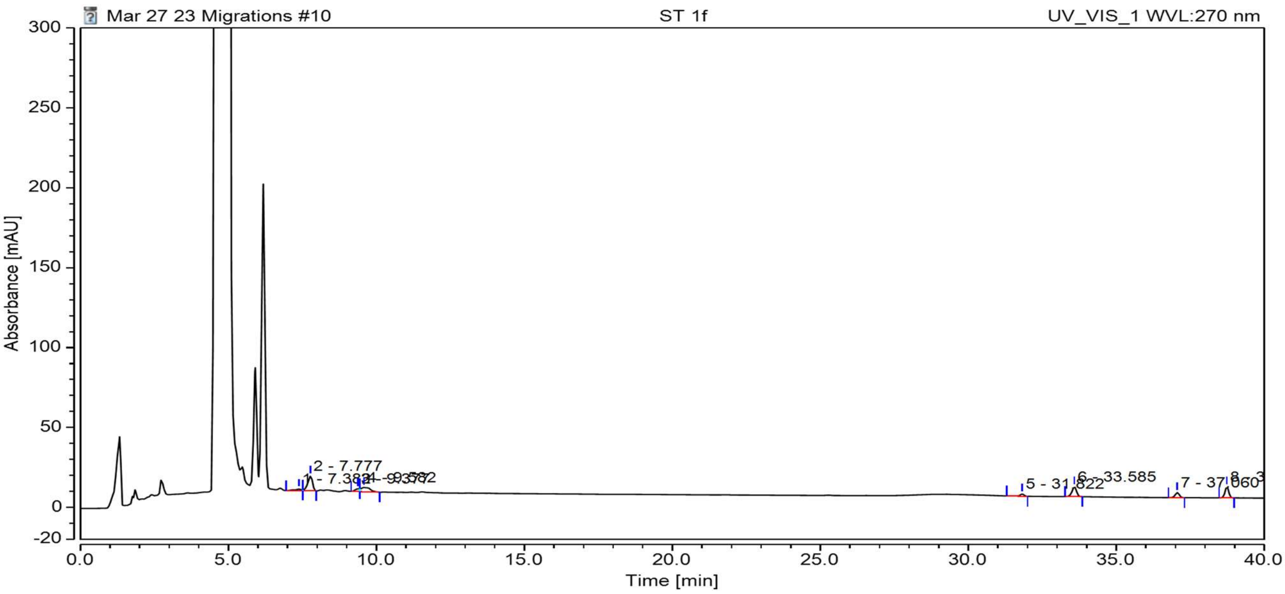
2d



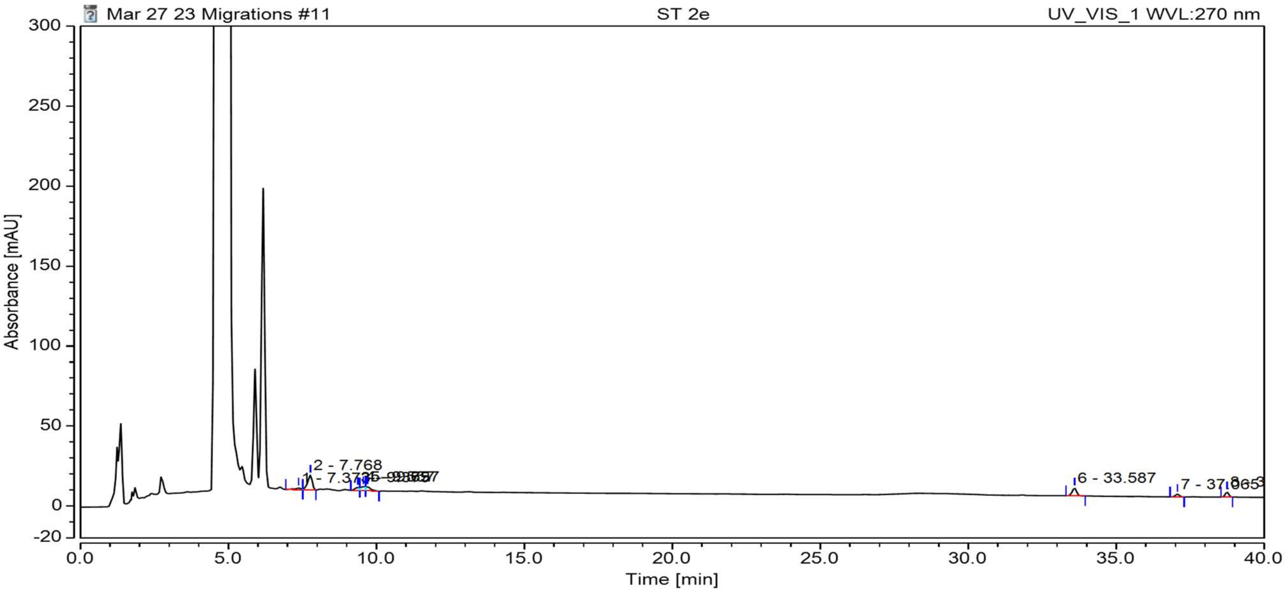
Control sample – 95% Ethanol



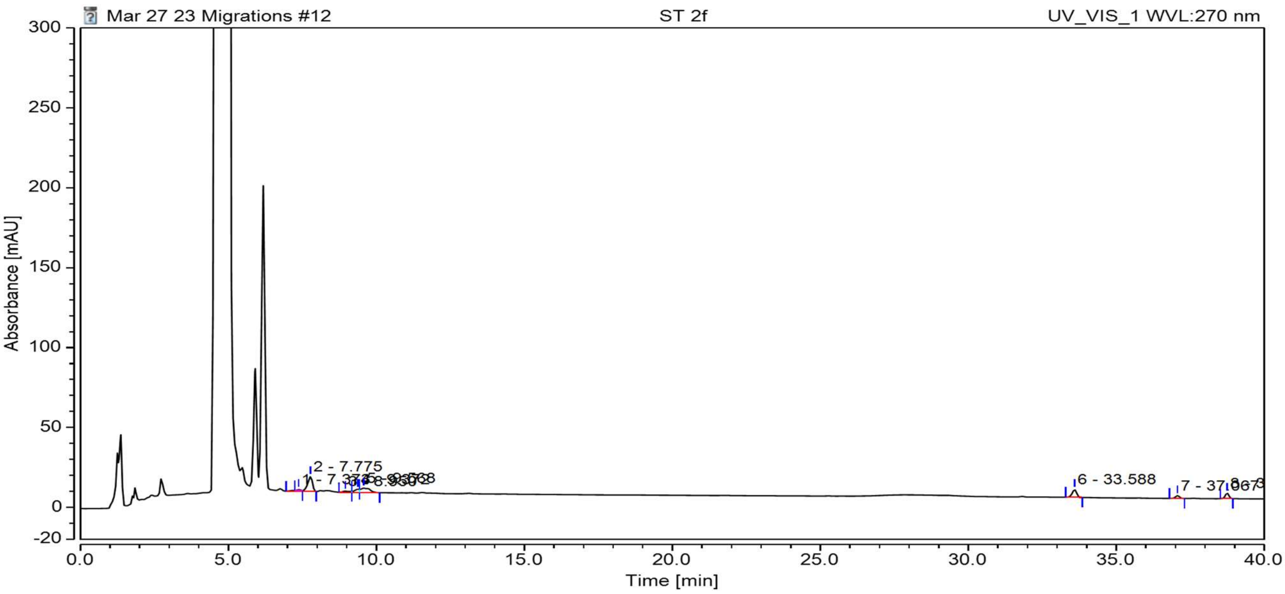
1e


Mar 27 23 Migrations #10
ST 1f
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.777
6 - 33.585

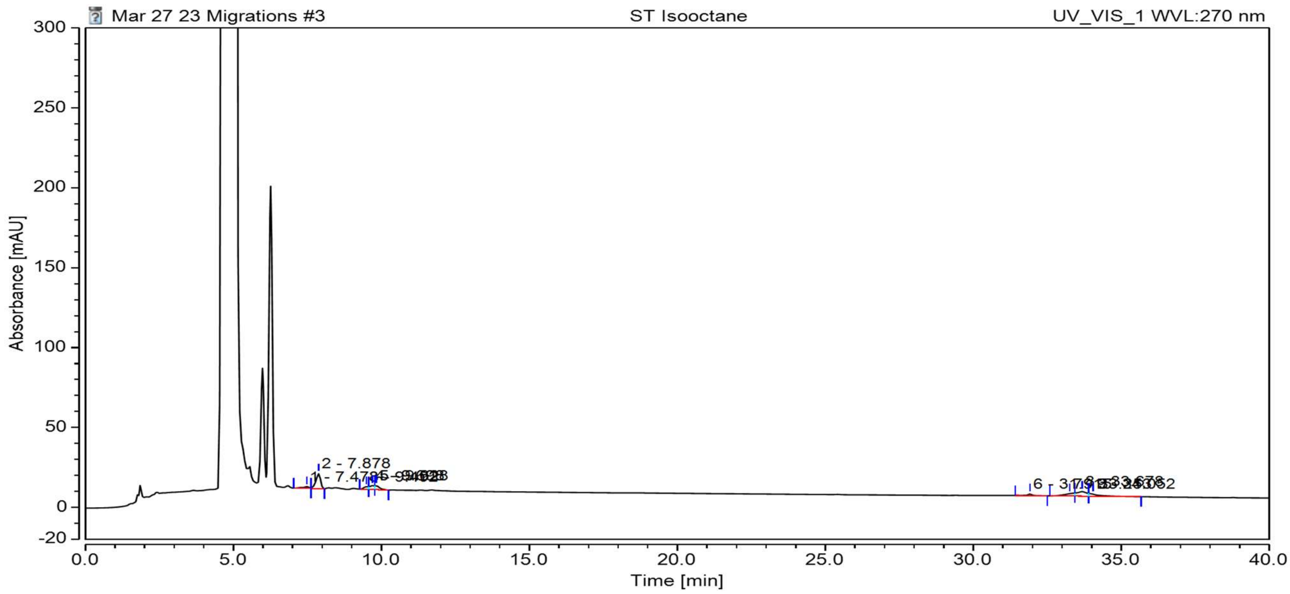
1f


Mar 27 23 Migrations #11
ST 2e
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.768
6 - 33.587

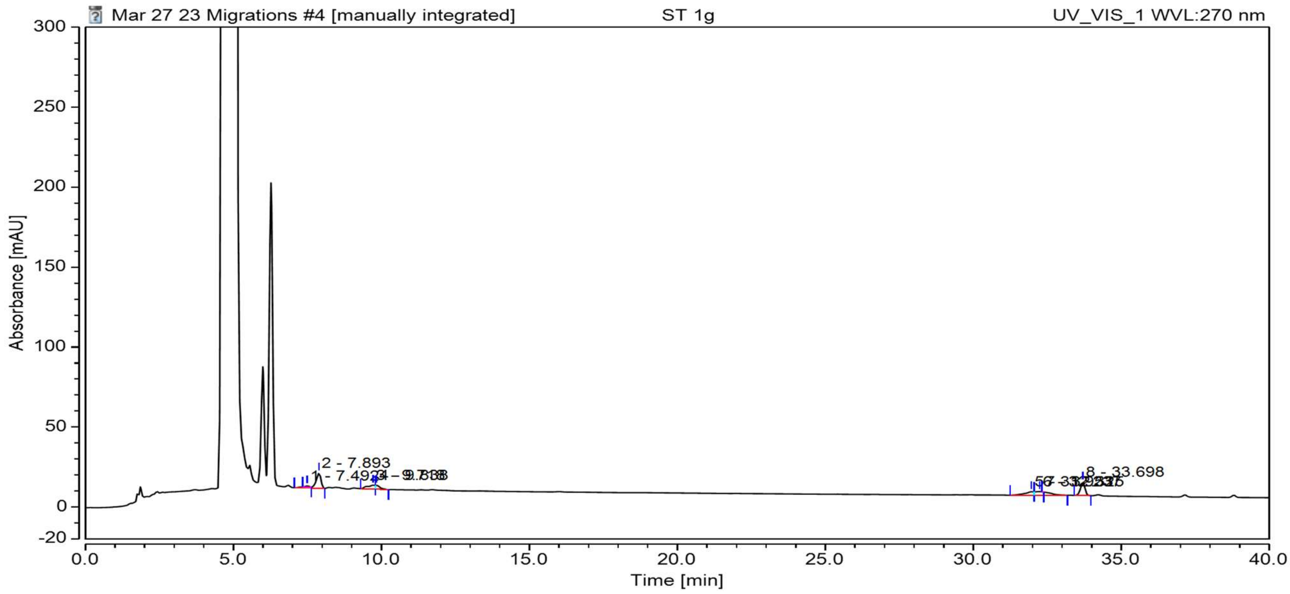
2e


Mar 27 23 Migrations #12
ST 2f
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.775
6 - 33.588

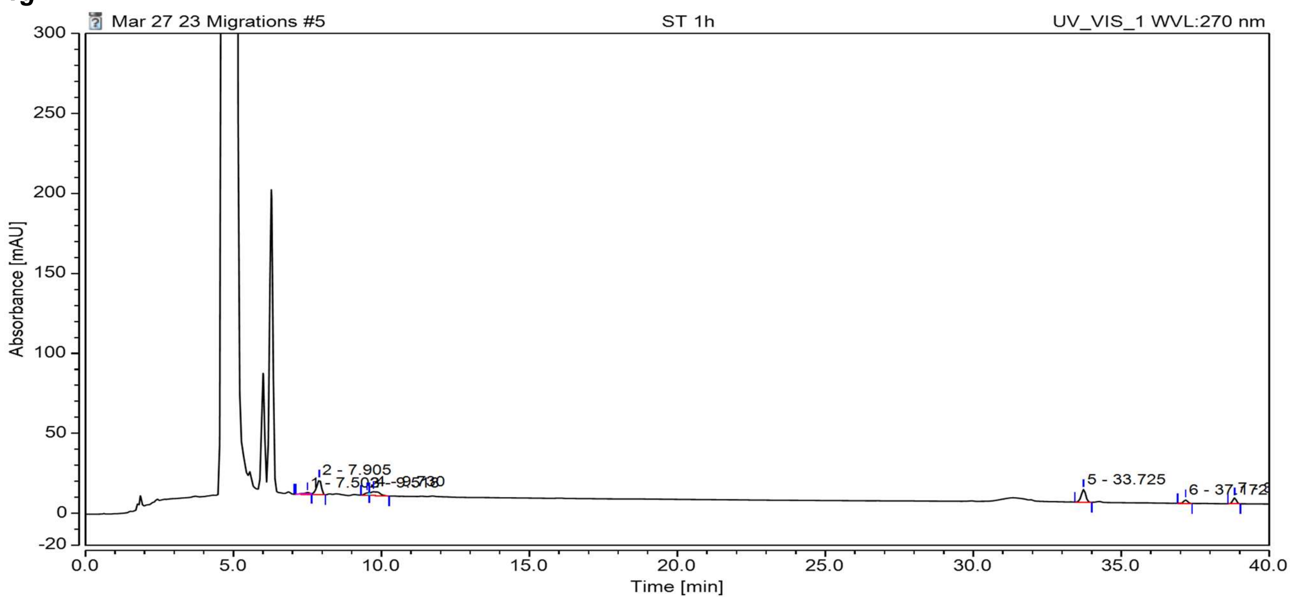
2f



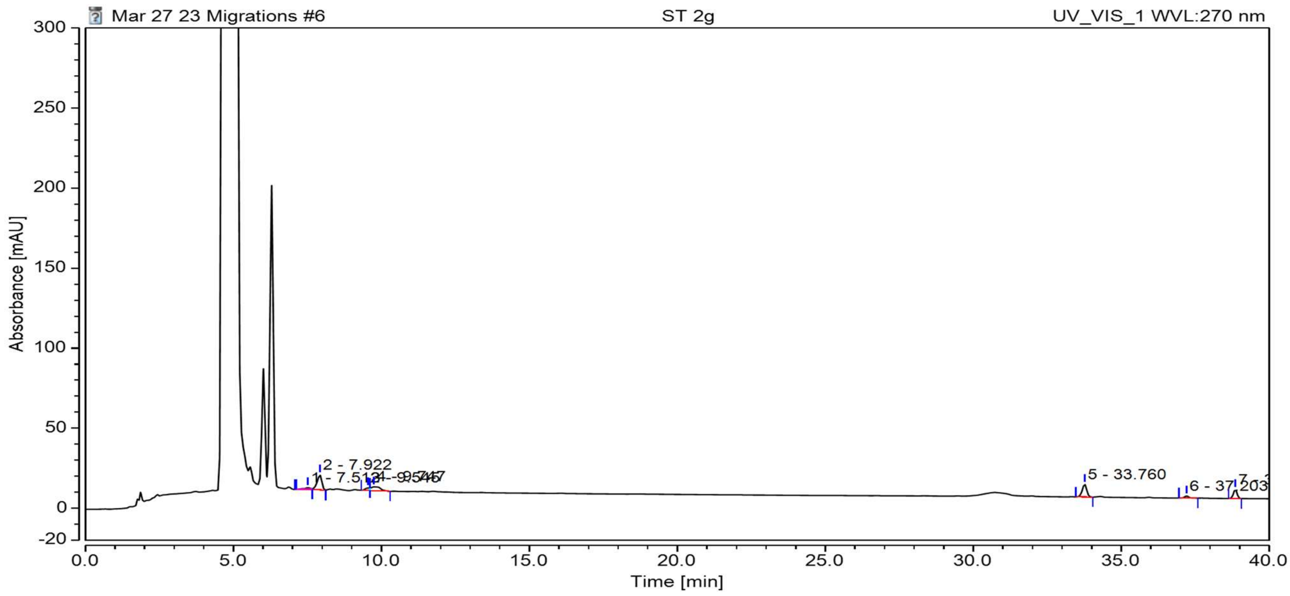
Control sample – Isooctane



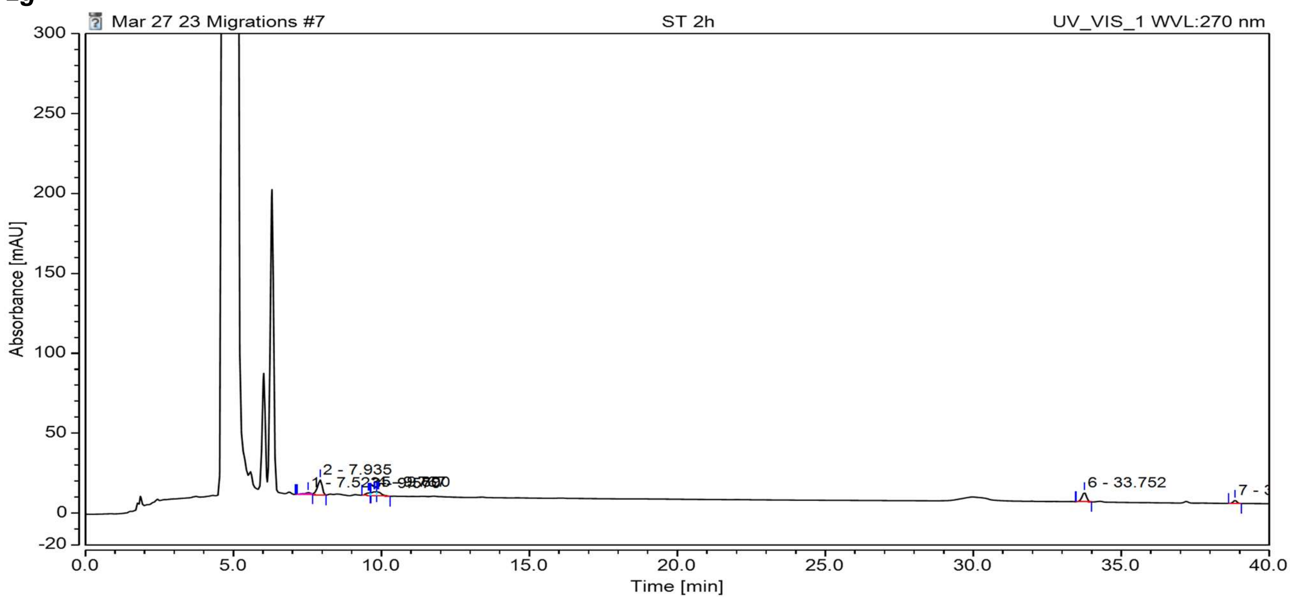
1g



1h


Mar 27 23 Migrations #6
ST 2g
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.922
5 - 33.760

2g


Mar 27 23 Migrations #7
ST 2h
UV_VIS_1 WVL:270 nm
Absorbance [mAU]
Time [min]
2 - 7.935
6 - 33.752

2h

Test number	Measurement	CAS no. 6683-19-8 (Antioxidants) Irganox®1010 / generic SML 496	CAS no. 9506-11-9 (Processing stabiliser-degraded) Irgafos®168d / generic SML 671	CAS no. 31570-04-4 (Processing stabiliser) Irgafos®168 / generic SML 671	CAS no. 2082-79-3 (Antioxidants) Irganox®1076 / generic SML 433
1a	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
1b	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
2a	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
2b	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
1c	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
1d	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
2c	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
2d	Migration (mg/dm^2)	0	0	0	0
	Migration (mg/kg food)*	0	0	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6

*The setting of migration limits takes into account that 1 kg of food is packaged in a cubic container of 6 dm^2 surface area releasing the substance.

For substances for which no SML or other restrictions are provided in Annex 1, a generic SML of 60 mg/kg shall apply.

Test number	Measurement	CAS no. 6683-19-8 (Antioxidants) Irganox®1010 / generic SML 496	CAS no. 9506-11-9 (Processing stabiliser-degraded) Irgafos®168d / generic SML 671	CAS no. 31570-04-4 (Processing stabiliser) Irgafos®168 / generic SML 671	CAS no. 2082-79-3 (Antioxidants) Irganox®1076 / generic SML 433
1e	Migration (mg/dm^2)	0	0.02332	0.02779	0.01534
	Migration (mg/kg food)*	0	0.13991	0.16671	0.09206
	SML allowable (mg/kg food)	None given	None given	None given	6
1f	Migration (mg/dm^2)	0	0.02404	0.02526	0.01534
	Migration (mg/kg food)*	0	0.14424	0.15154	0.09206
	SML allowable (mg/kg food)	None given	None given	None given	6
2e	Migration (mg/dm^2)	0	0.01834	0.01087	0.00797
	Migration (mg/kg food)*	0	0.11002	0.06524	0.04780
	SML allowable (mg/kg food)	None given	None given	None given	6
2f	Migration (mg/dm^2)	0	0.01882	0.01220	0.00859
	Migration (mg/kg food)*	0	0.11290	0.07319	0.05152
	SML allowable (mg/kg food)	None given	None given	None given	6
1g	Migration (mg/dm^2)	0	0.03232	0	0
	Migration (mg/kg food)*	0	0.19394	0	0
	SML allowable (mg/kg food)	None given	None given	None given	6
1h	Migration (mg/dm^2)	0	0.03055	0.01311	0.01000
	Migration (mg/kg food)*	0	0.18332	0.07864	0.06002
	SML allowable (mg/kg food)	None given	None given	None given	6
2g	Migration (mg/dm^2)	0	0.03082	0.02013	0.00655
	Migration (mg/kg food)*	0	0.18489	0.12076	0.03930
	SML allowable (mg/kg food)	None given	None given	None given	6
2h	Migration (mg/dm^2)	0	0.02244	0.00687	0
	Migration (mg/kg food)*	0	0.13467	0.04124	0
	SML allowable (mg/kg food)	None given	None given	None given	6

*The setting of migration limits takes into account that 1 kg of food is packaged in a cubic container of 6 dm^2 surface area releasing the substance.

For substances for which no SML or other restrictions are provided in Annex 1, a generic SML of 60 mg/kg shall apply.

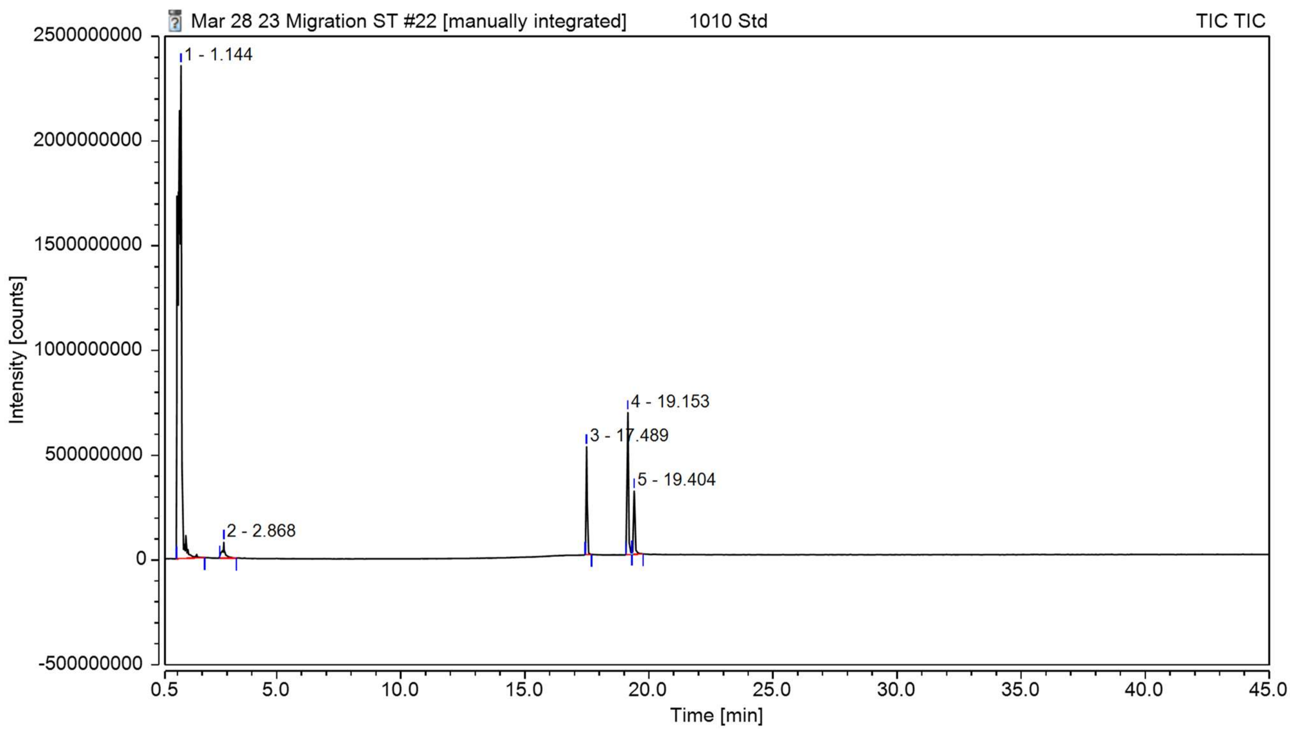
Determination of SML substances by GC-MS

The reconstituted extract was introduced into the GC-MS under the following conditions:

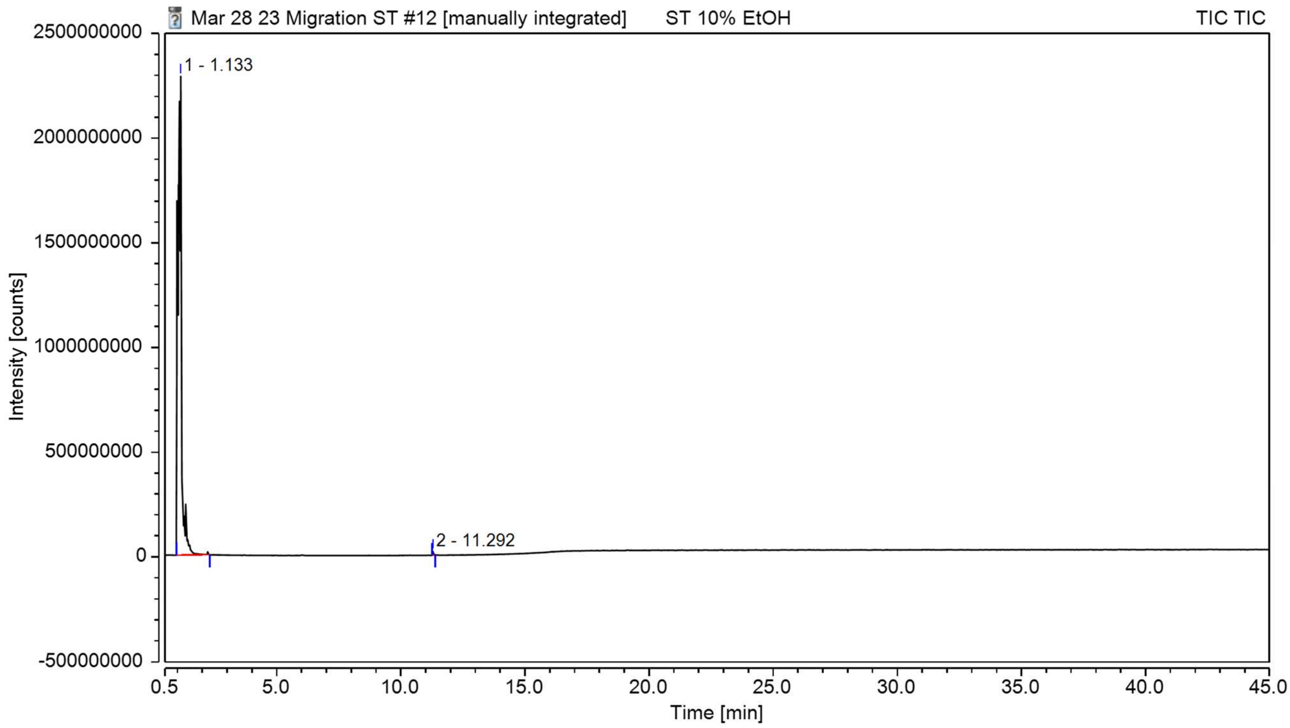
Column type:	Capillary
Column coating:	BP-5MS
Column dimensions:	30 m, 0.25 mm ID, 0.25 micron
Injector temperature:	200 °C
Split Injection:	1:20
Line Velocity:	75.9 cm s^{-1}
Carrier gas:	Helium
Initial oven temperature:	150 °C
Initial time:	0 min
Ramp at:	10 °C/min.
Final oven temperature:	310 °C
Time @ final temperature:	29 min.

MS conditions

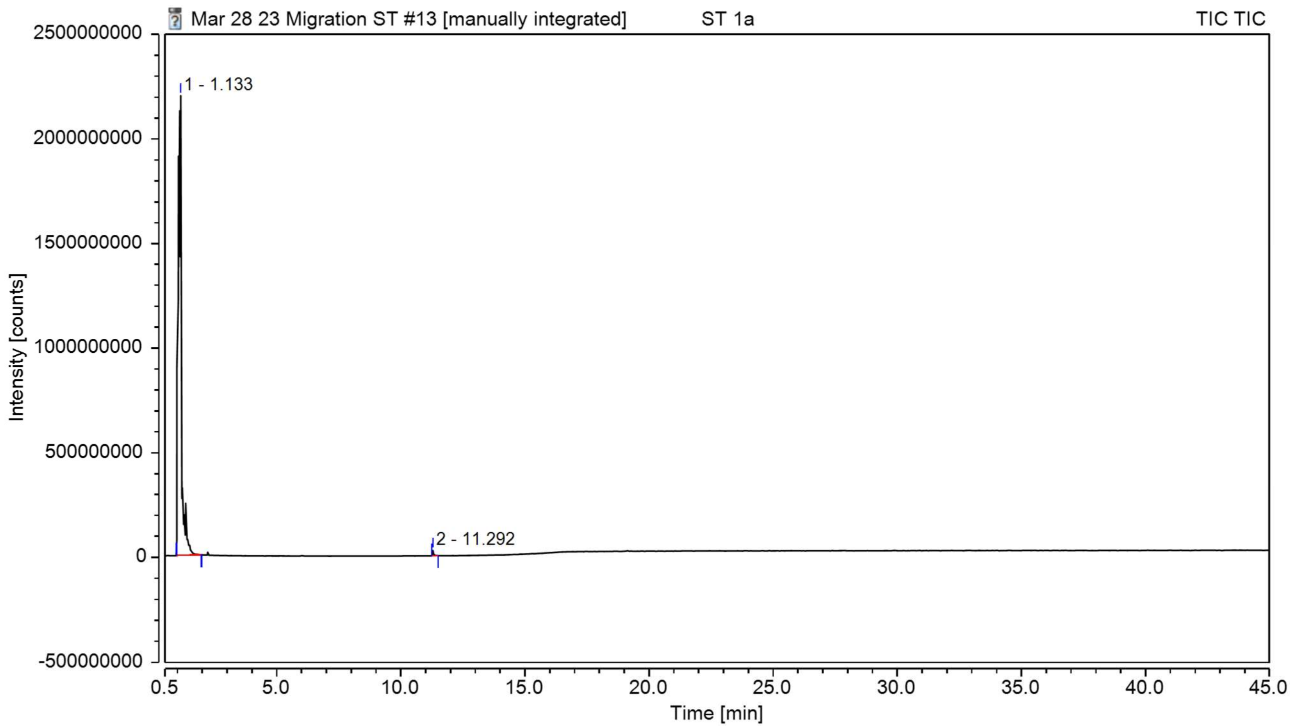
Transfer line:	280 °C
Ion source:	280 °C
Ionisation mode:	EI
Scan range:	35 – 1000 amu



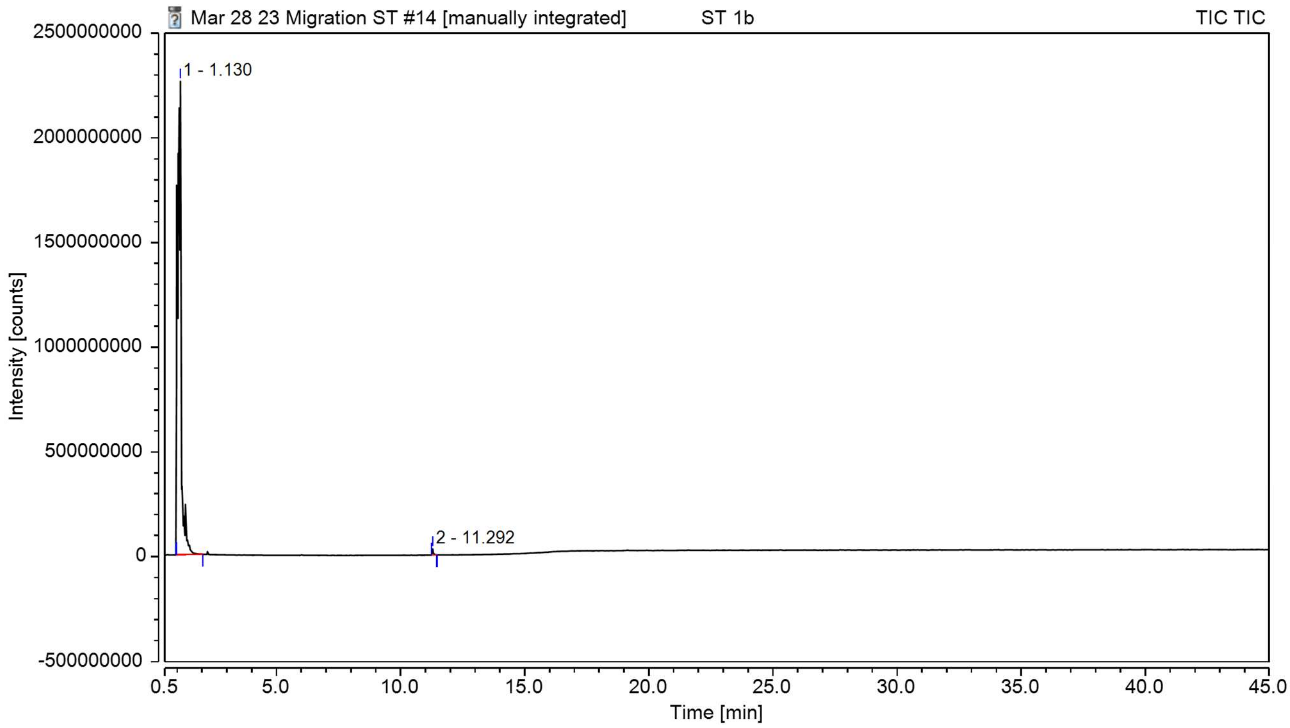
GC-MS of Standards of Irganox®1010, 1035 and 1076, Irgafos®168 and 168d



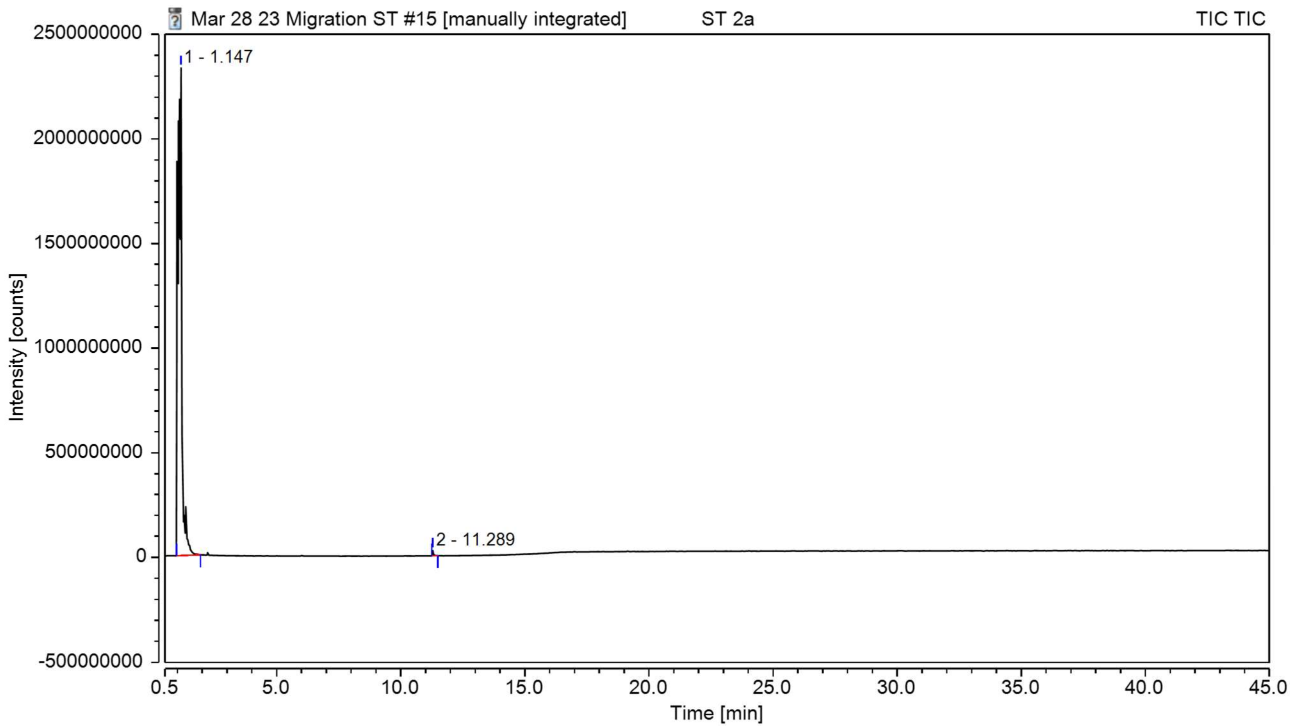
GC-MS of Control – 10% Ethanol



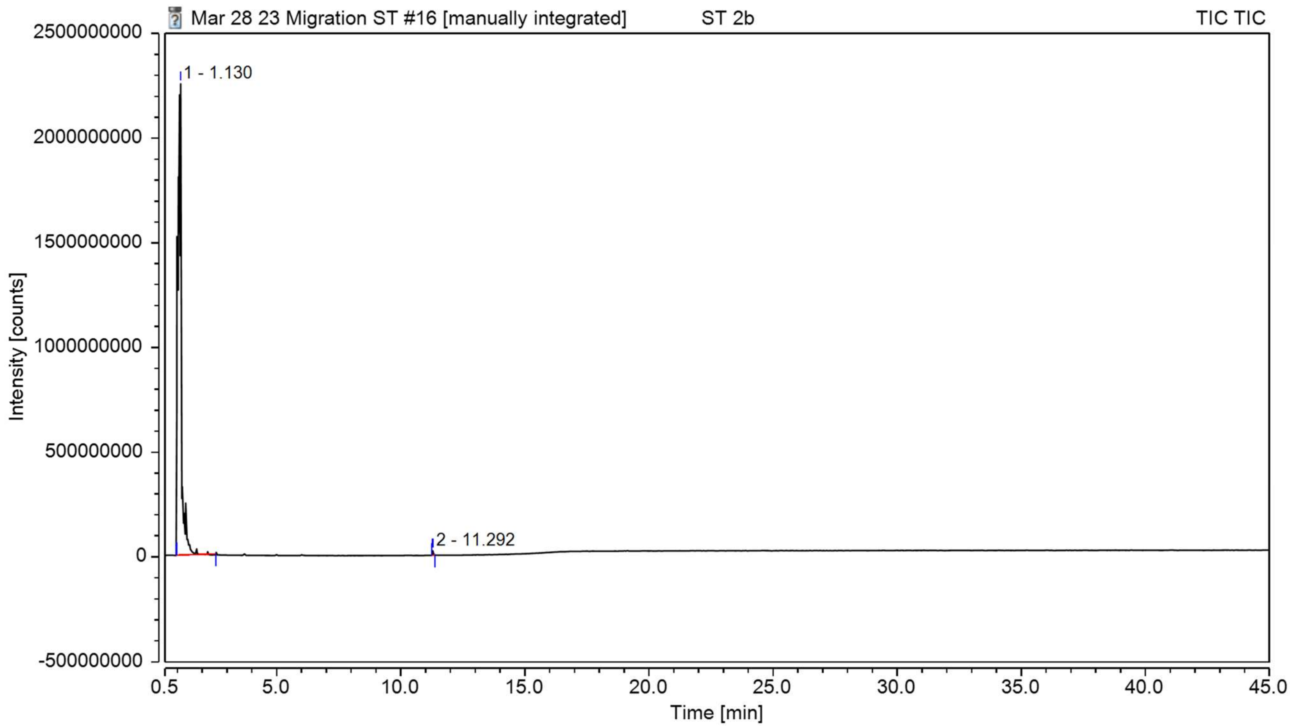
GC-MS of Test number 1a



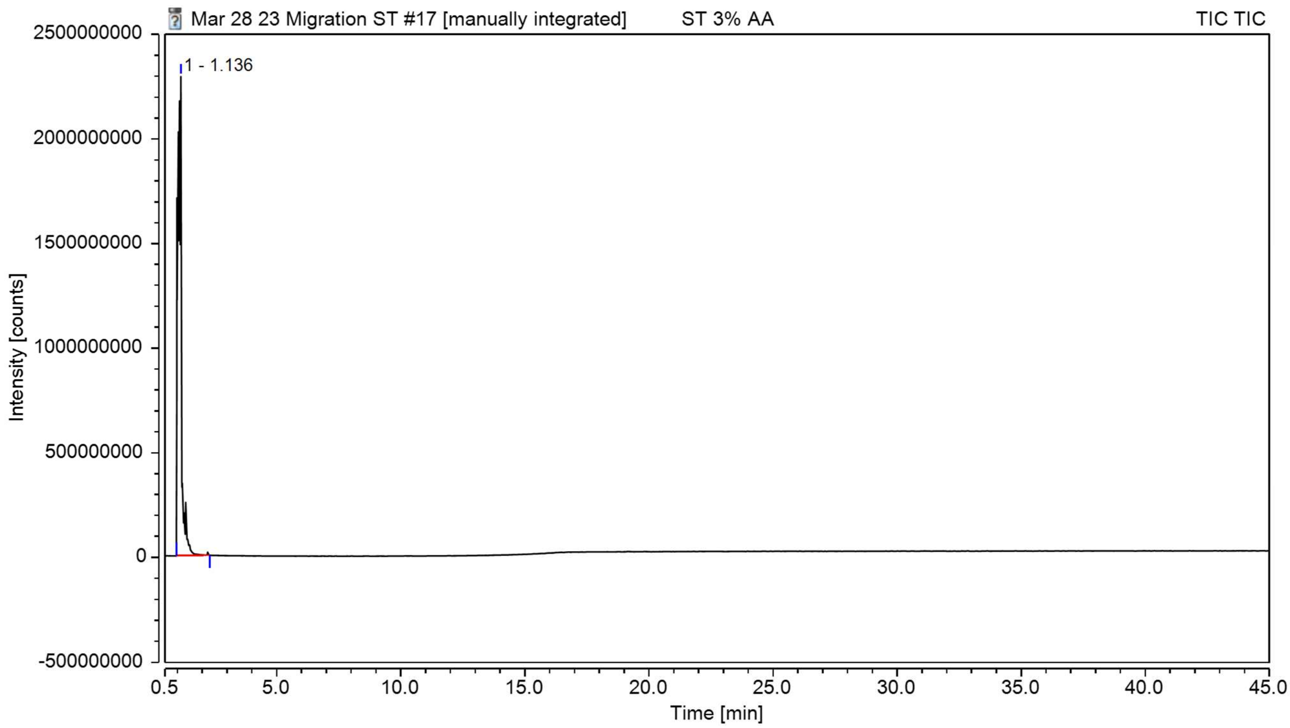
GC-MS of Test number 1b



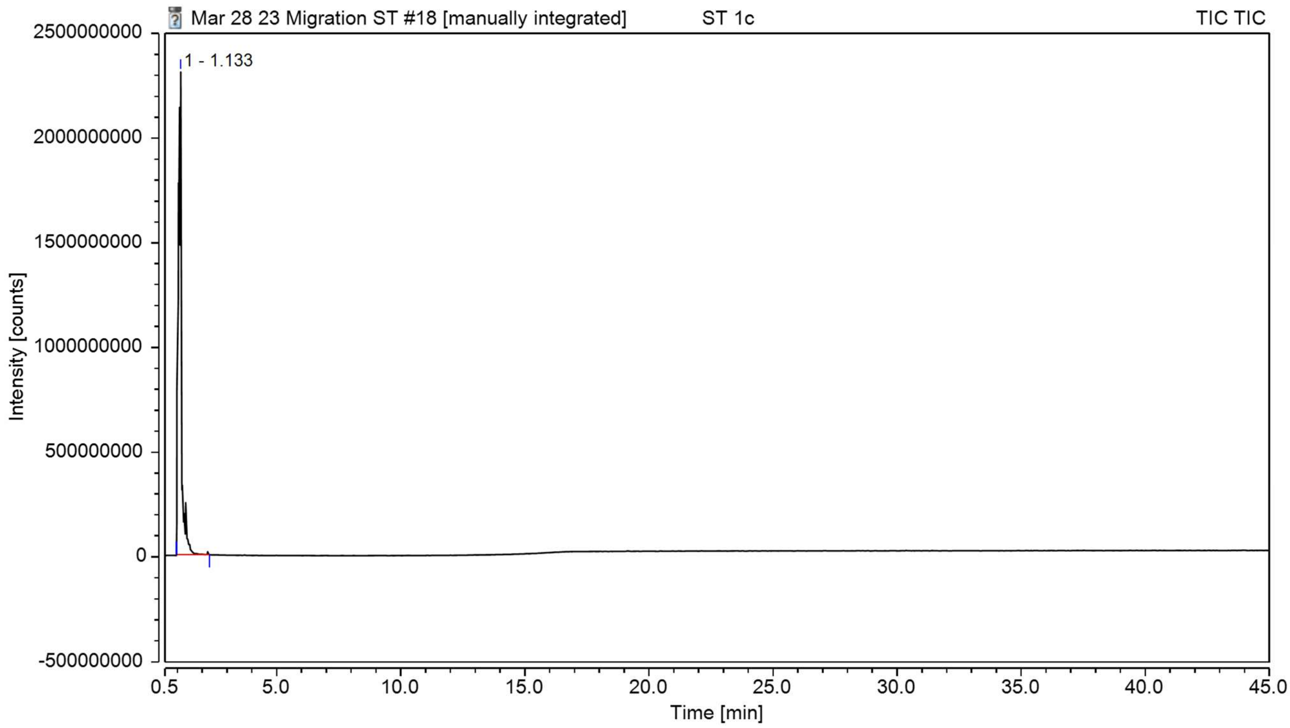
GC-MS of Test number 2a



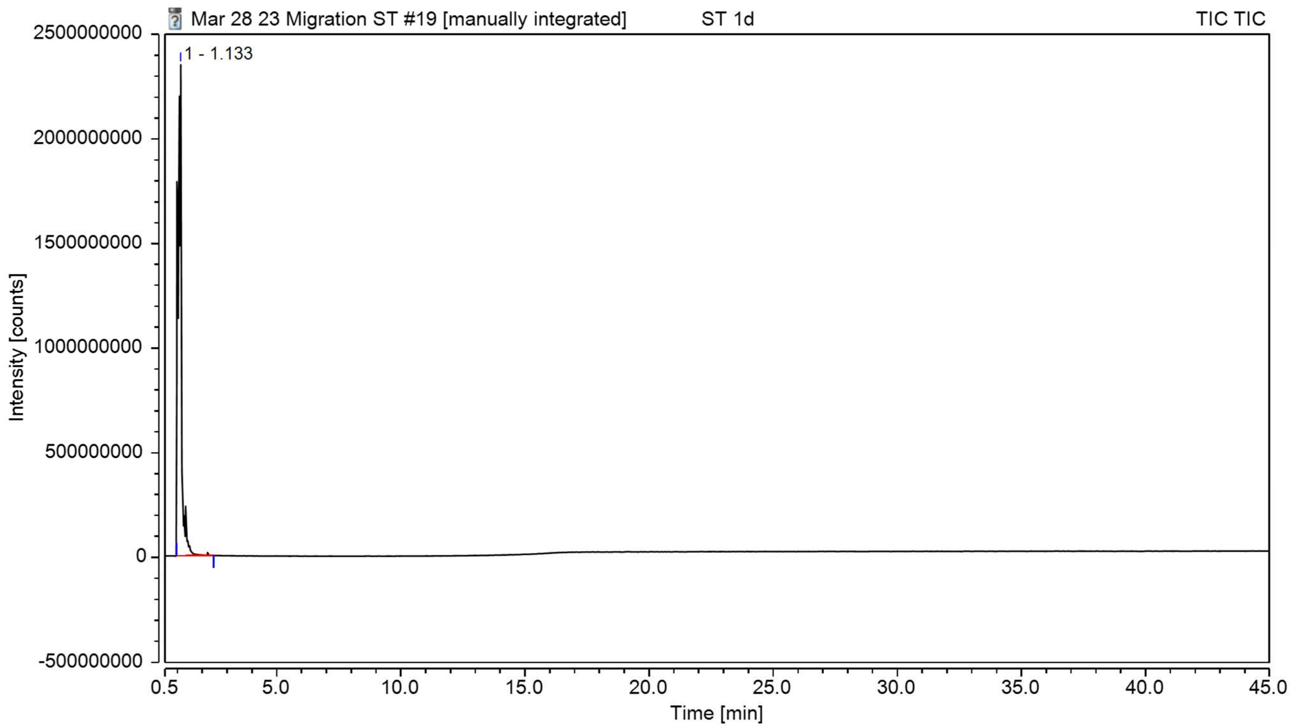
GC-MS of Test number 2b



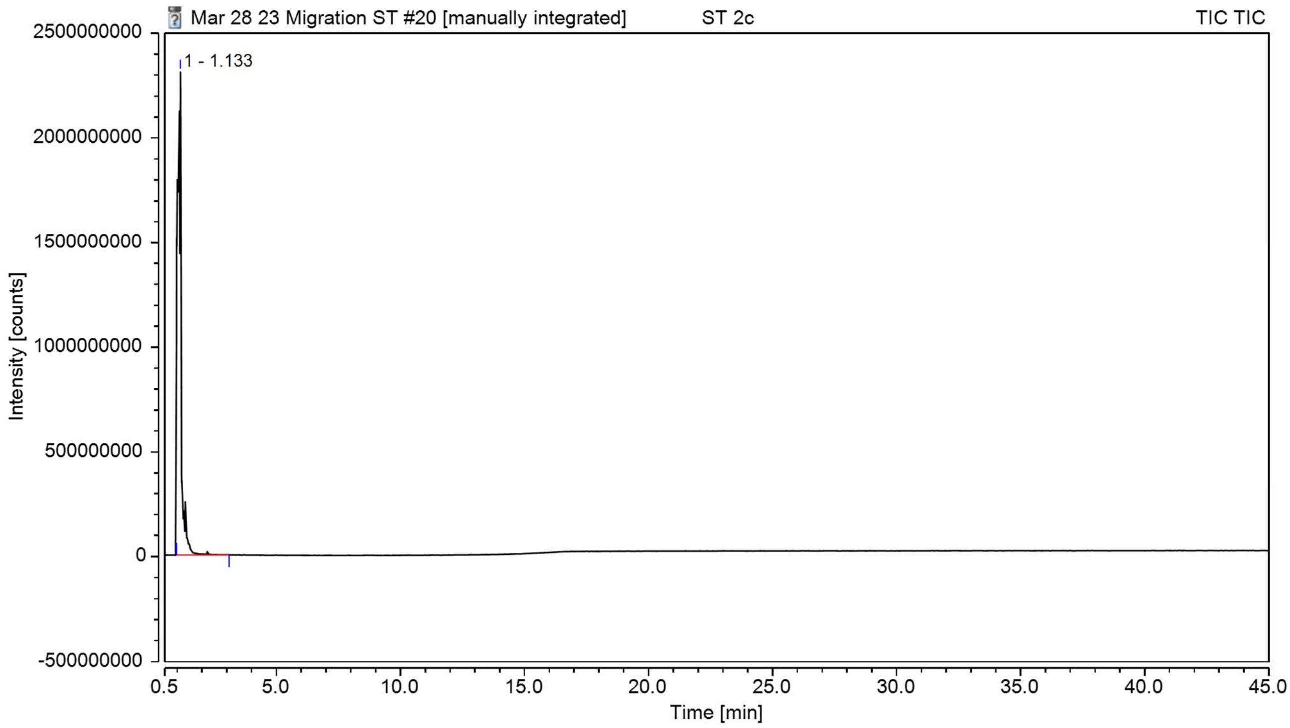
GC-MS of Control – 3% Acetic Acid



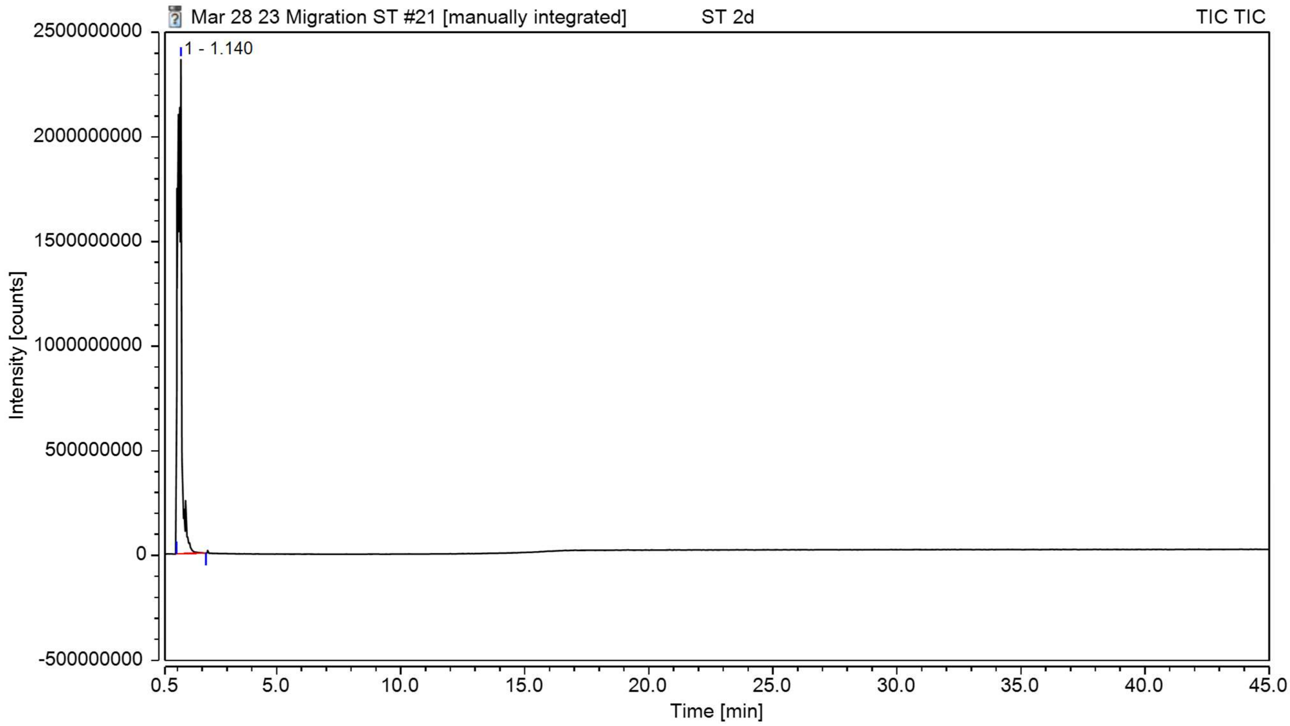
GC-MS of Test number 1c



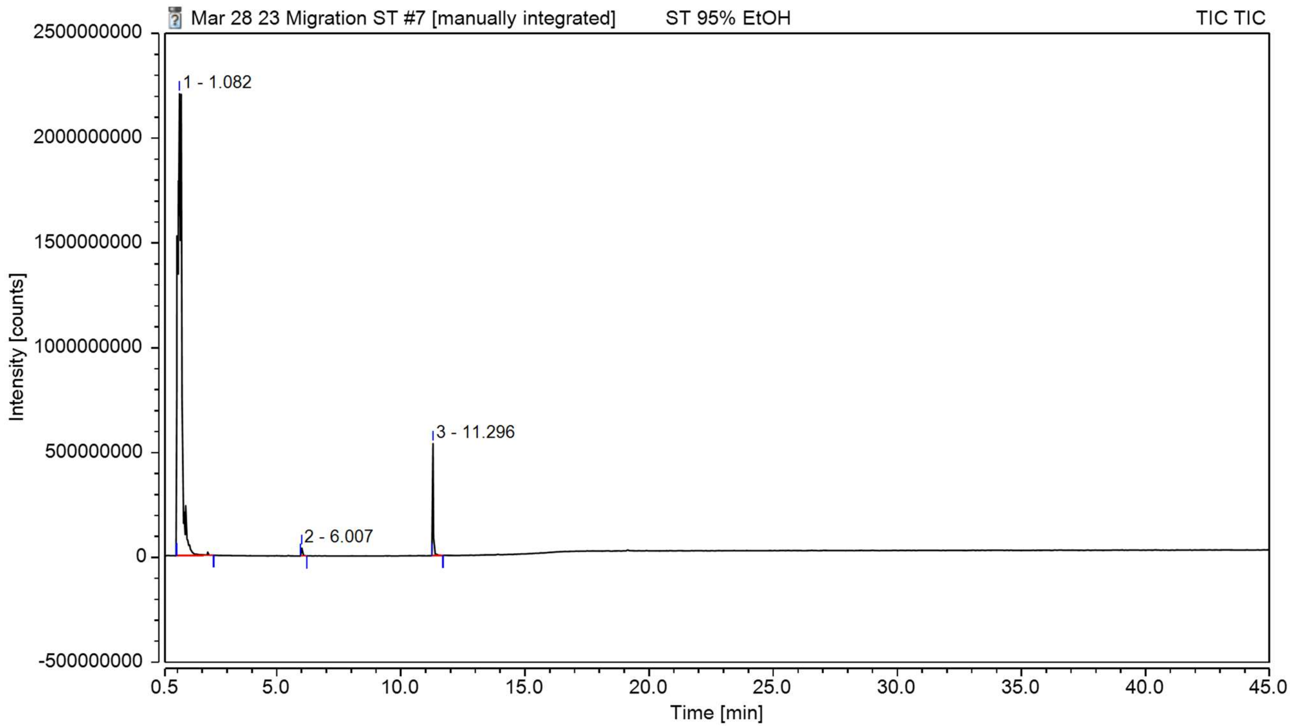
GC-MS of Test number 1d



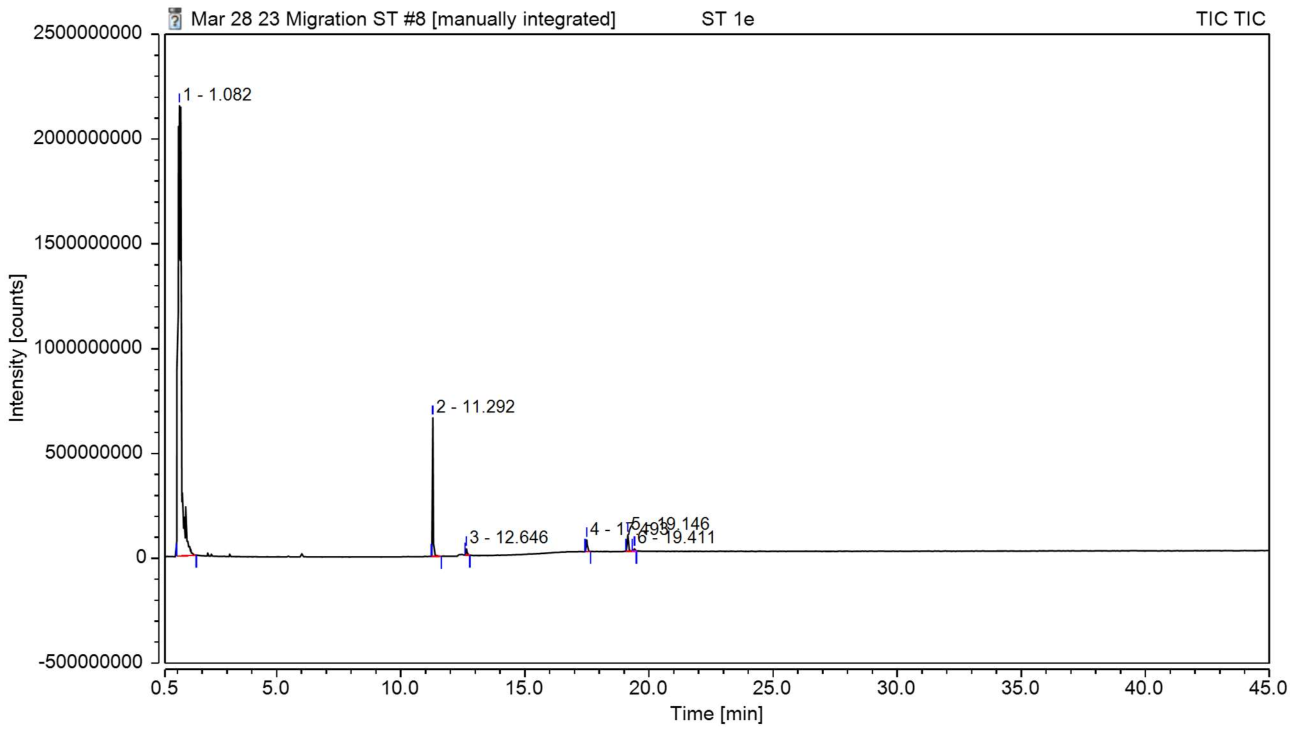
GC-MS of Test number 2c



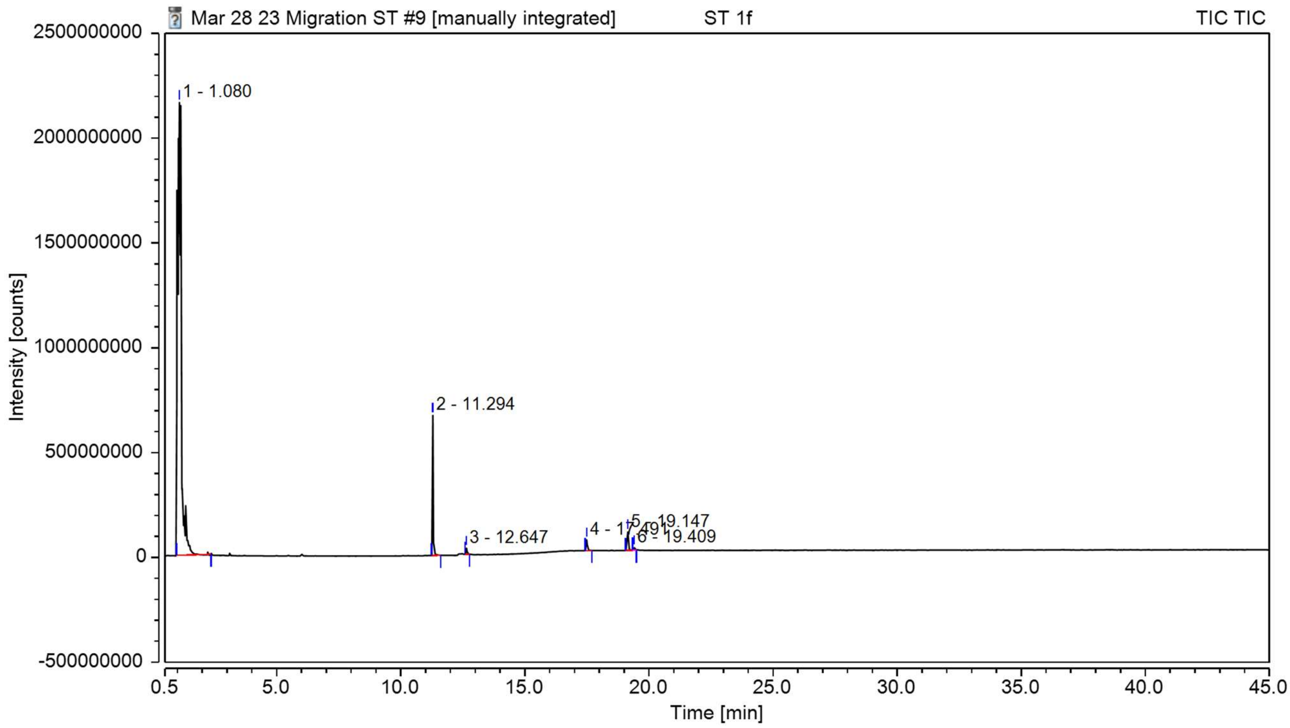
GC-MS of Test number 2d



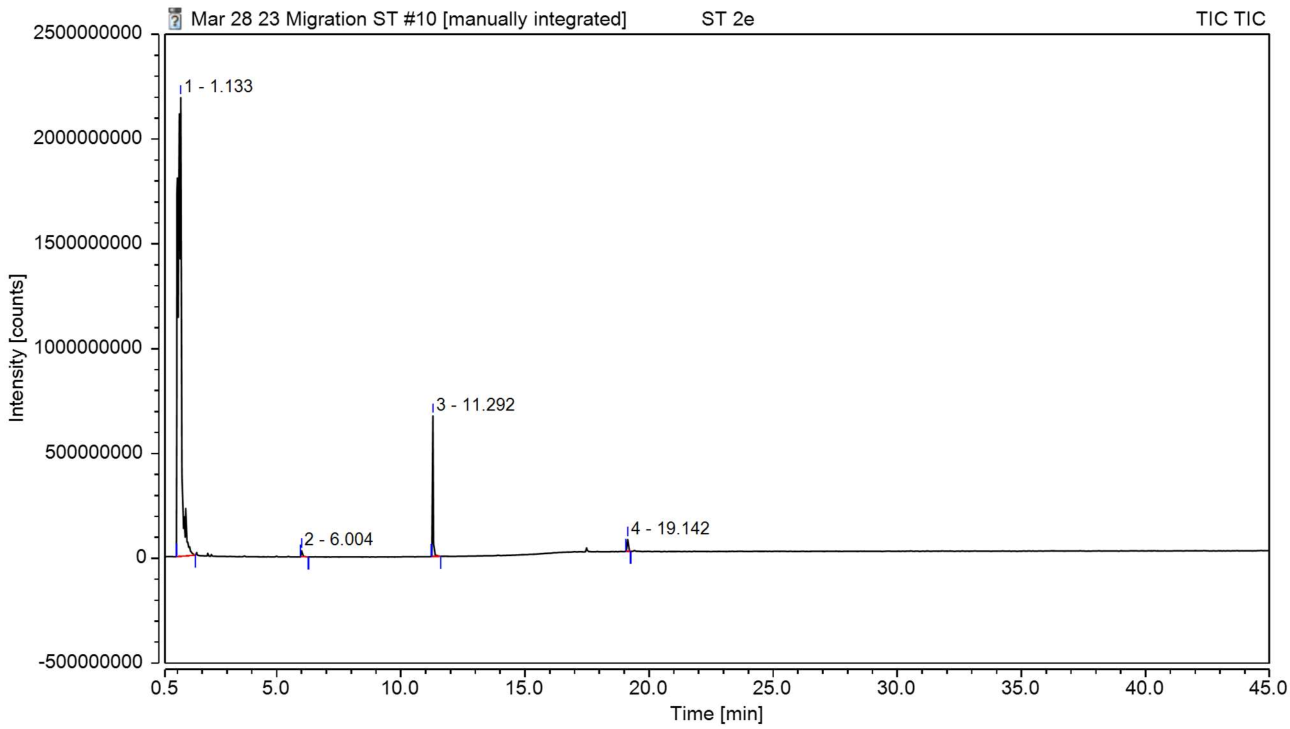
GC-MS of Control – 95% Ethanol



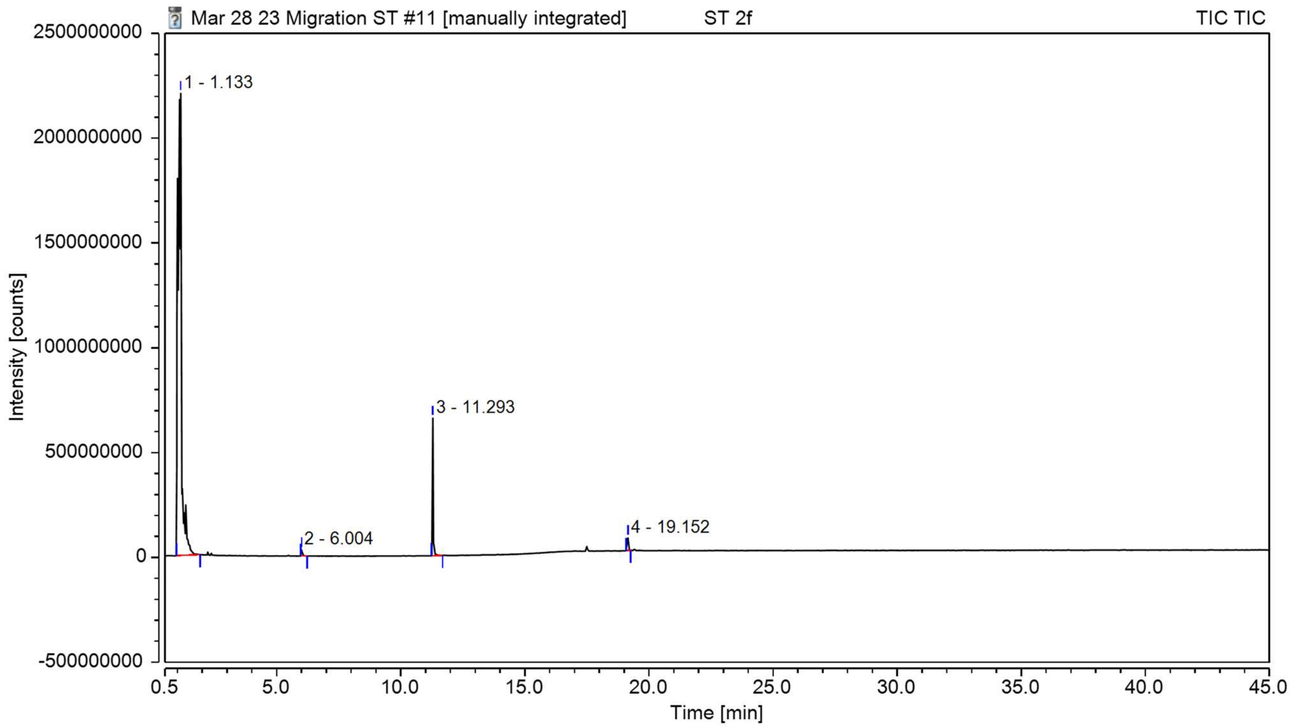
GC-MS of Test number 1e



GC-MS of Test number 1f



GC-MS of Test number 2e



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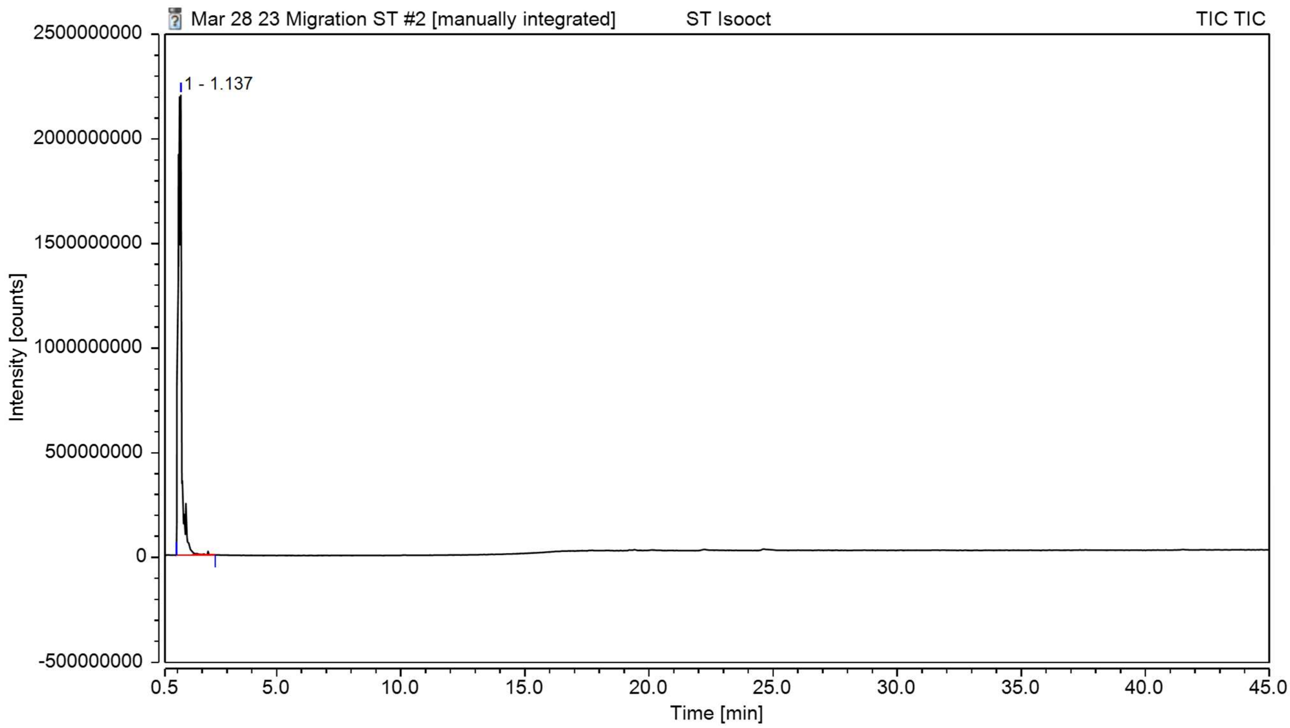
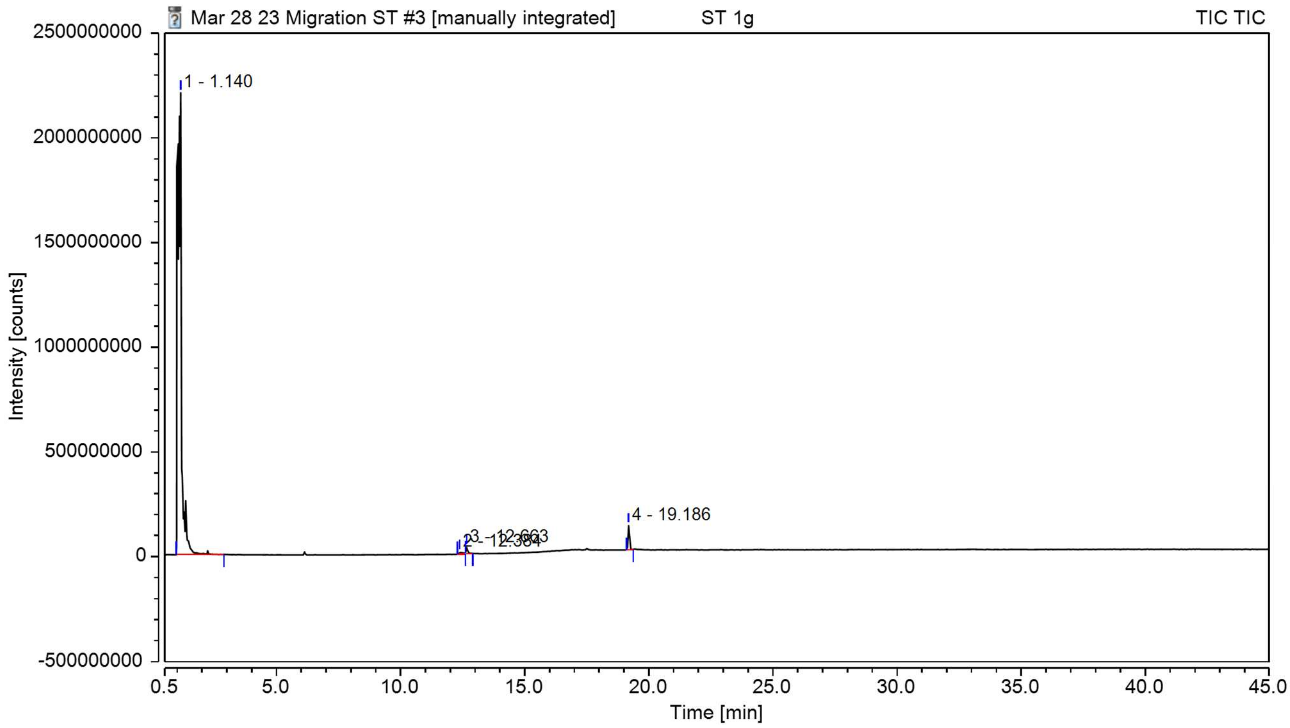
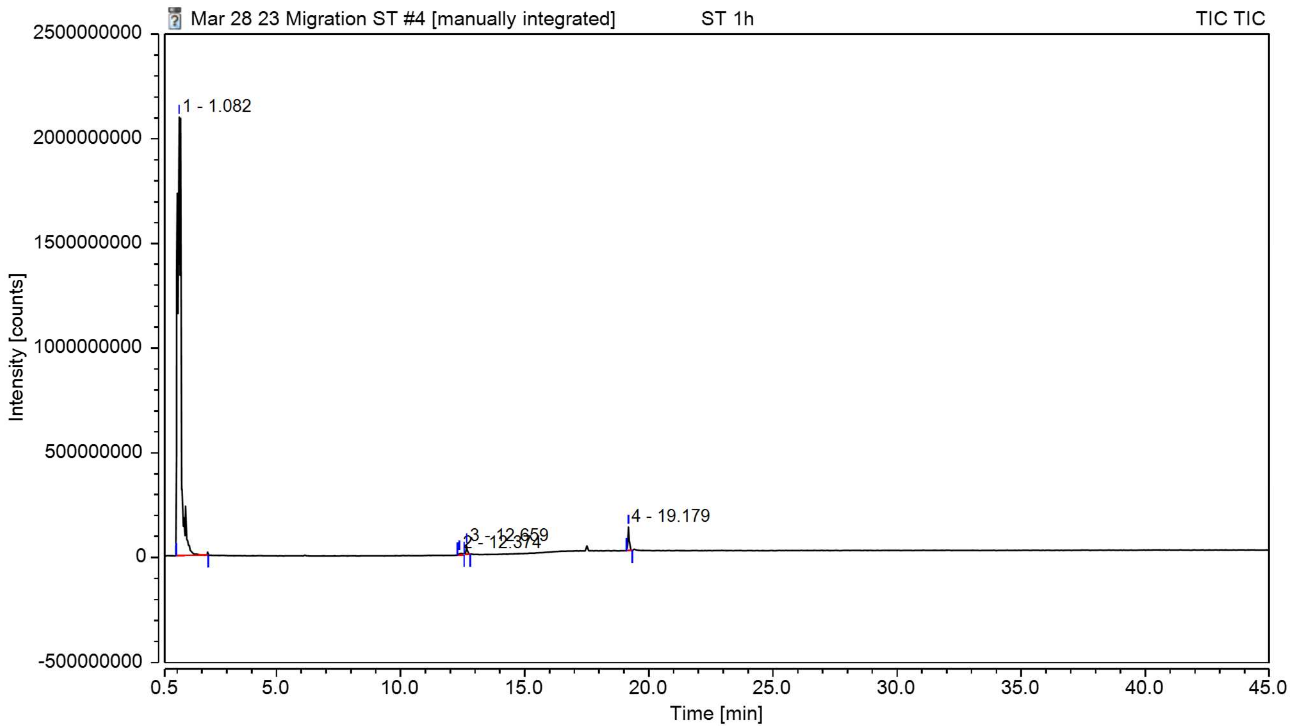


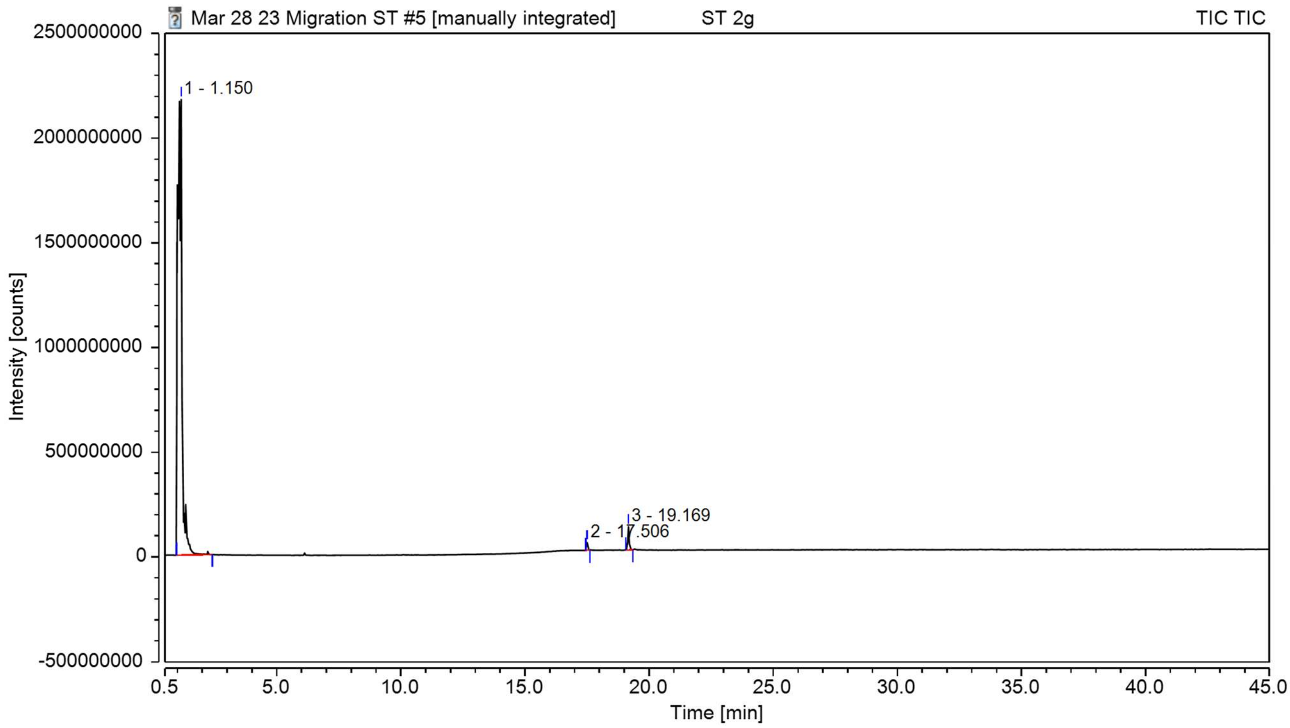
GC-MS of Control – Isooctane



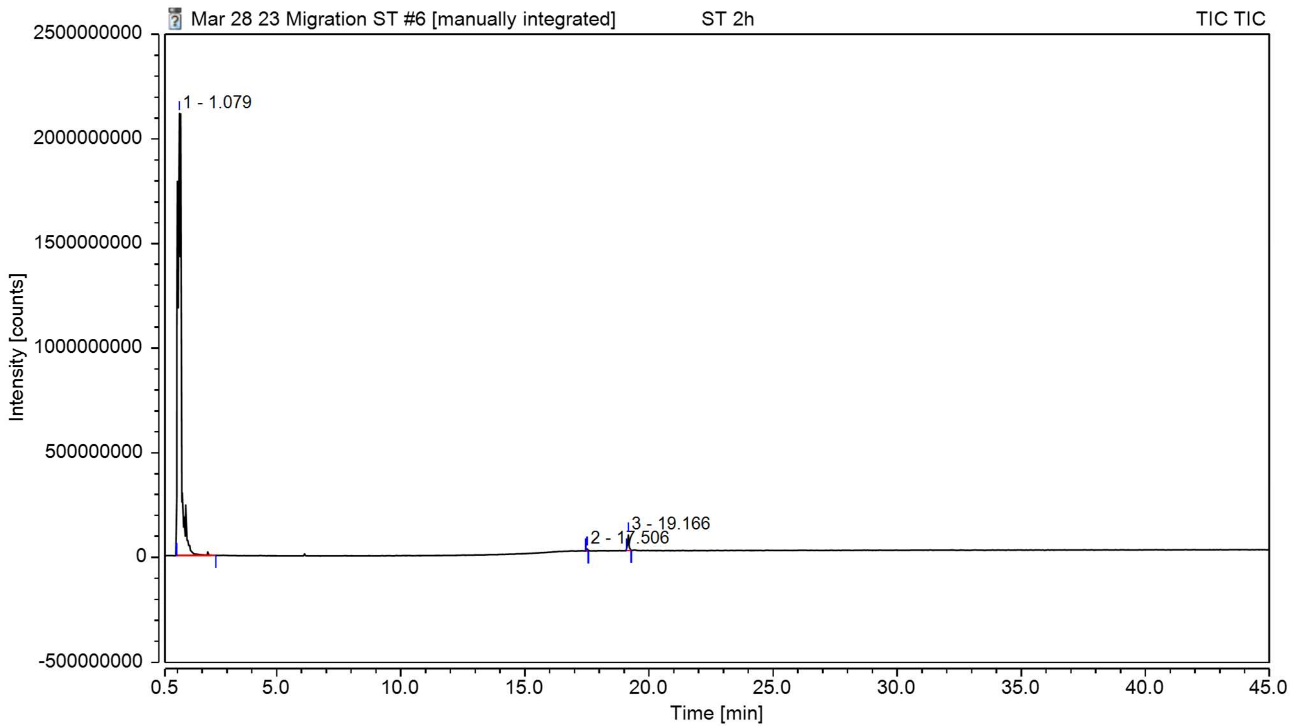
GC-MS of Test number 1g



GC-MS of Test number 1h



GC-MS of Test number 2g



GC-MS of Test number 2h

Retention times (minutes) and chemical compounds found.

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
1a & 1b	11.29	Benzyldiethyl-(2,6-xylylcarbamoylmethyl)-ammonium benzoate	Present in blank		None given
2a & 2b	11.29	Benzyldiethyl-(2,6-xylylcarbamoylmethyl)-ammonium benzoate	Present in blank		None given

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
1c & 1d	None detected				None given
2c & 2d	None detected				None given

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
1e & 1f	11.29	Benzyldiethyl-(2,6-xylylcarbamoylmethyl)-ammonium benzoate	Present in blank		None given
	12.65	9-Octadecenoic acid (Z)-, 2,3-dihydroxypropyl ester	0.056	0.335	None given
	17.49	Irgafos 168	Refer to HPLC results		None given
	19.15	Irgafos 168d			None given
	19.41	Irganox 1076			6

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
2e & 2f	6.00	Lidocaine	Present in blank		None given
	11.29	Benzyldiethyl-(2,6-xylylcarbamoylmethyl)-ammonium benzoate			None given
	19.14	Irganox 1076	Refer to HPLC results		6

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
1g & 1h	12.38	Glycine, N-[(3a,5ß)-24-oxo-3-[(trimethylsilyl)oxy]cholan-24-yl]-, methyl ester	0.065	0.390	None given
	12.66	9-Octadecenoic acid (Z)-, 2,3-dihydroxypropyl ester	0.085	0.508	None given
	19.19	Irganox 1076	Refer to HPLC results		6

Test number	Retention time (min)	Compound	Measurement		EU 10/2011
			Migration (mg/dm^2)	Migration (mg/kg food)*	SML allowable (mg/kg food)
2g & 2h	17.51	Irgafos 168	Refer to HPLC results		None given
	19.17	Irganox 1076			6

*The setting of migration limits takes into account that 1 kg of food is packaged in a cubic container of 6 dm^2 surface area releasing the substance.

For substances for which no SML or other restrictions are provided in Annex 1, a generic SML of 60 mg/kg shall apply.

Determination of volatile substances by GC-MS Headspace

According to EU 10/2011, no rules have yet been set out at EU level for the risk assessment and use of solvents in the manufacture of plastics. Therefore, their use should remain subject to national law. Solvents used in the manufacture of plastics to create a suitable reaction environment are expected to be removed in the manufacturing process as they are usually volatile.

The FSAP (Food Safety Alliance for Packaging) guidelines make reference to the Swiss Confederation Annex 10 of the Ordinance of the FDHA on materials and articles intended to come into contact with foodstuffs, that states the following: "For substances for which no specific migration limit or other restrictions are indicated, a generic specific migration limit of 60 mg/kg shall apply." This is also the limits set out in EU 10/2011. This Annex is used along with EU 10/2011 to check if residual solvents detected are within acceptable safety limits.

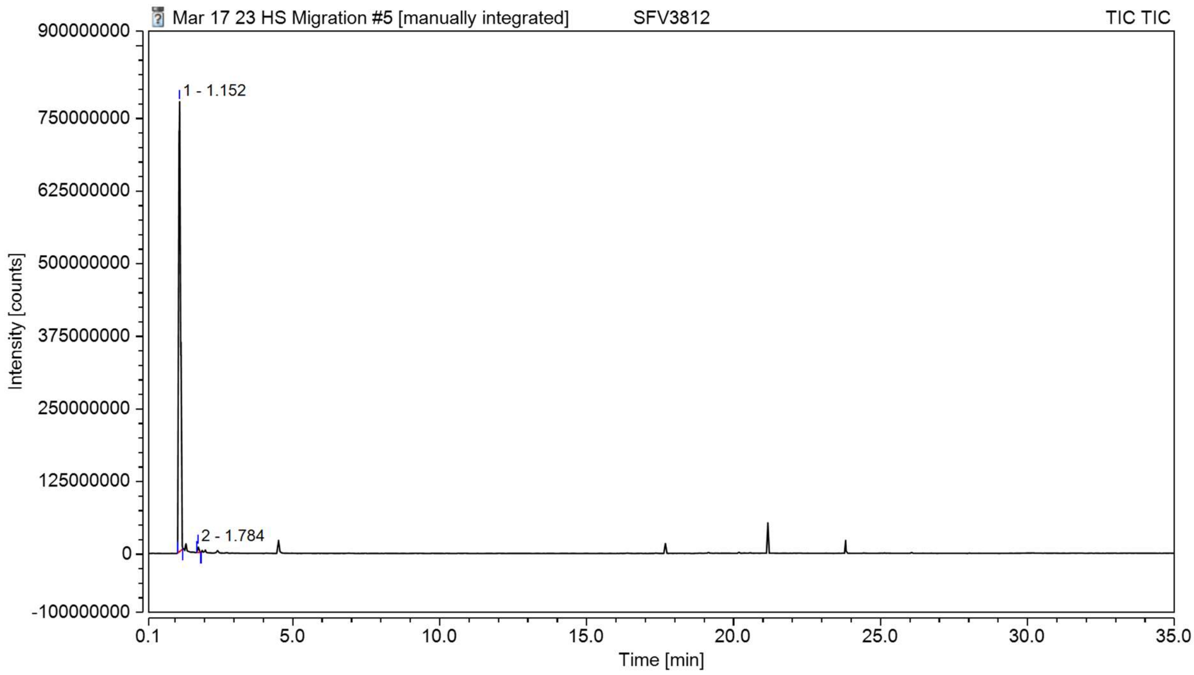
GC-MS – headspace solvents

The sample was sealed in a 22 mL vial equipped with as septum. The vial was heated at 150 °C for a period of 5 minutes while agitating every 10 seconds out of 20 seconds. 1 mL of headspace was injected into a gas chromatograph equipped with a mass spectrometer as described below.

Column type:	Capillary
Column coating:	BP-5MS
Column dimensions:	30 m, 0.25 mm ID, 0.25 micron
Injector temperature:	250 °C
Split Injection:	1:20
Front Inlet Flow:	2 mL/min.
Carrier gas:	Helium
Initial oven temperature:	30 °C
Initial time:	2 min
Ramp at:	1 °C/min.
Final oven temperature:	40 °C
Time at final temperature:	2 min
Ramp at:	10 °C/min.
Final oven temperature:	200 °C
Time @ final temperature:	5 min.

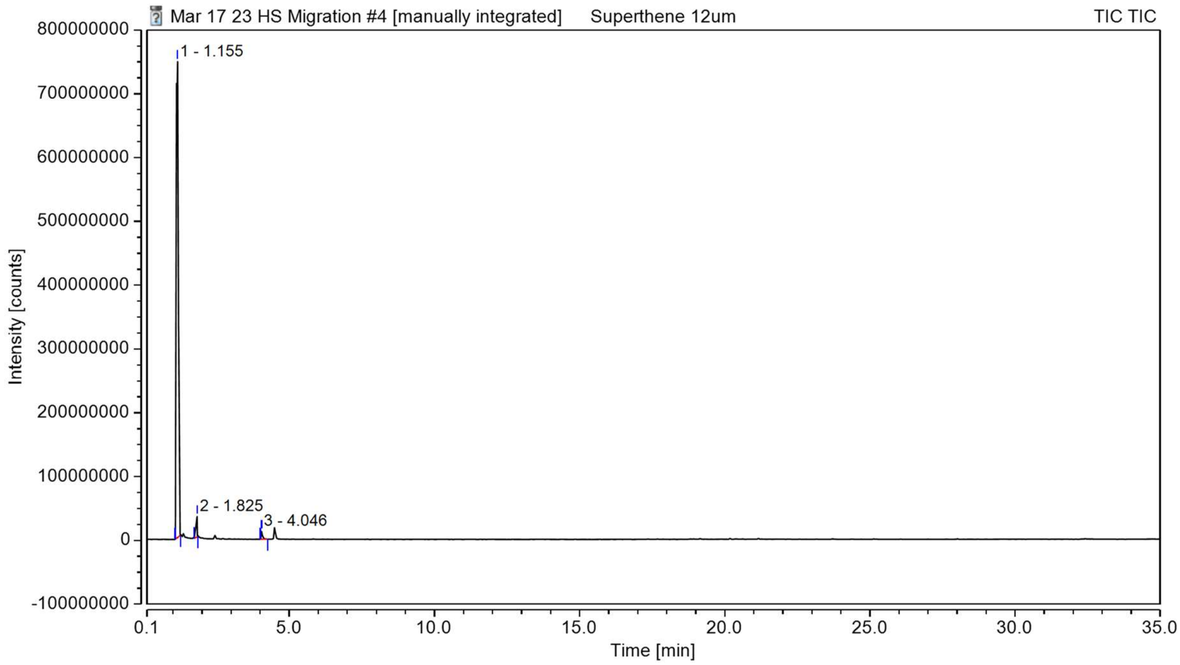
MS conditions

Transfer line:	280 °C
Ion source:	280 °C
Ionisation mode:	EI
Scan range:	25 – 1000 amu



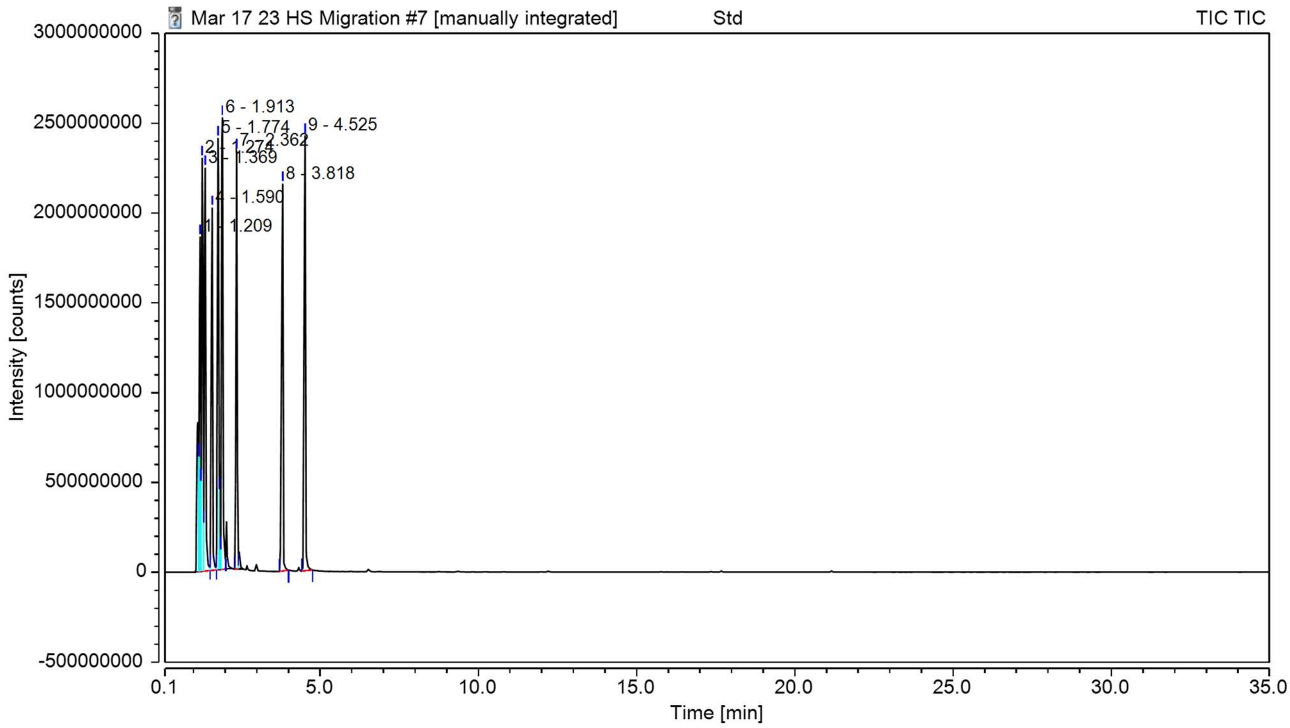
SFV 3812

SFV 3812				
Retention time (min)	**1st Hit**	**Library compound**	**Composition (%)**	**mg/m²**
1.15	794	Oxygen	N/A	
1.78	784	Acetic acid	0.59	0.09
			Total residual solvents (mg/m²)	**0.09**



Superthene 12 micron

Superthene 12 micron				
Retention time (min)	**1st Hit**	**Library compound**	**Composition (%)**	**mg/m²**
1.15	801	Oxygen	N/A	
1.82	897	Acetic acid	2.66	0.40
4.05	827	2-Propanol, 1-ethoxy-	0.92	0.14
			Total residual solvents (mg/m²)	**0.54**



GC-MS of Standard solvent mix

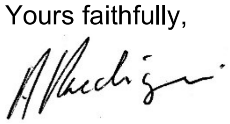
Summary

- No heavy metals were found to be present.
- No phthalates were detected.
- Samples do not contain residual solvents in a quantity exceeding 20 mg/m^2 total amount as stated in the FSAP guideline Food packaging product stewardship considerations.
- Samples do not contain residual solvents in a quantity exceeding 7 mg/m^2 total combined ketones and acetates as stated in the FSAP guideline Food packaging product stewardship considerations.
- Acetic acid is listed in EU 10/2011 with a generic SML of 60mg/kg which equates to 1000 mg/m^2. Thus the sample is well within its limits.
- 2-Propanol, 1-ethoxy is listed in Swiss Annex 10 with a group SML of 5mg/kg which equates to 83.33 mg/m^2. Thus the sample is well withing its limits.
- All SML's found in terms of European Union EU 10/2011 were within acceptable safety limits.

Conclusion

- Samples comply with EU10/2011 with regards to OML & SML migration for the tested simulants under the test conditions.

Yours faithfully,



Dr. AHA Roediger.

Please take note that samples will be retained for a six-month period and discarded thereafter. Food stuffs will only be kept for two weeks.