Final Report SAM3516i

PHYSICOCHEMICAL CHARACTERIZATION OF FOUR PLASTIC MATERIALS OF ANDRO-PENIS

Study Program: SAM3516

Contract n.: E06/0160.0MI

Sponsor: ANDROMEDICAL S.L.
EDIFICIO AMÉRICA II
C/ PROCIÓN, 7
NUCLEO 4 OFICINAS I-J
28023 MADRID

Test substance: ANDRO-PENIS

Study Director..... Released on: .....
(Dr. P. Pescio)

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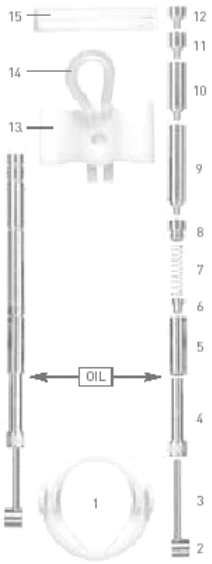
SUMMARY

A study was performed to characterise four different plastic components of ANDRO-PENIS.

The device is constituted of different materials:

1.	**Plastic base ring**	**Plastic**
2.	Rod (for the articulated screw)	Metal
3.	Articulated screw	Metal
4.	Adjustable bar screw	Metal
5.	Metal bar	Metal
6.	Screw	Metal
7.	Spring	Metal
8.	Screw to ground the spring	Metal
9.	Large 4 cm axis	Aluminium alloy
10.	Medium 2 cm axis	Aluminium alloy
11.	Small 0.5 cm axis	Aluminium alloy
12.	Minimum 0.3 cm axis	Aluminium alloy
13.	**Superior plastic support**	**Plastic**
14.	**Silicone band**	**Silicon**
15.	**Andro-Top**	**Foam**



The following analytical tests were carried out to analyse the materials 1, 13, 14 and 15.

- FT-IR analysis
- DSC analysis
- Determination of density
- Determination of hardness
- Determination of resistance to tensile stress

The detailed findings are reported in the section dedicated to “Results”.

INTRODUCTION

This study has been carried on behalf of the Sponsor ANDROMEDICAL S.L. to characterise four different plastic components of the device.

This study was performed in Biolab Española de Análisis e Investigación S. L. located in Barcelona, C/Baldiri Reixac 4-6 – Spain.

The analyses were performed in the laboratories of Barcelona Science Park with support of researchers of Scientific -Technical Services and in the Assay Centre Biolab S. p. A. of Vimodrone (MI) – via B. Buozzi, 2 (Italy).

The experimentation started on July 24th, 2006 and ended on August 31st, 2006.

RECORD FILING

The study program and all raw data are filed in Biolab SpA archives for ten years after the issuing of the final report.
No retained sample will be kept.
At the end of the conservation period, the sponsor may request an extension of the conservation of all or part of the substance for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the Biolab Procedures Manual.

TEST SUBSTANCE

The test substance is a device consisting of different parts made of plastic and metallic materials intended to human use in contact with the skin.

Name: ANDRO-PENIS

ANALYSED SAMPLES

Sample 1

Name: 1. PLASTIC BASE RING

Description: WHITE PLASTIC

Composition declared by the sponsor: POM

Acceptance number: 06.17772

Batch: 11/04

Receiving number: R03912.06

Receiving date: July 25th, 2006

Sample 2

Name: 13. SUPERIOR PLASTIC SUPPORT

Description: WHITE PLASTIC

Composition declared by the sponsor: POM

Identification name: 06.17773

Batch: 09/05

Receiving number: R03912.06

Receiving date: July 25th, 2006

Sample 3

Name:	14. SILICONE BAND
Description:	TRANSPARENT PLASTIC
Composition declared by the sponsor:	SILICONE
Identification name:	06.17774
Batch:	09/05
Receiving number:	R03912.06
Receiving date:	July 25th, 2006

Sample 4

Name:	15. ANDRO - TOP
Description:	WHITE FOAM
Composition declared by the sponsor:	FOAM
Identification name:	06.17775
Batch:	02/05
Receiving number:	R03912.06
Receiving date:	July 25th, 2006

The characterisation of the test substance is under Sponsor responsibility.

Experimental Report SAM3516i

PHYSICOCHEMICAL CHARACTERIZATION OF FOUR PLASTIC MATERIALS OF ANDRO - PENIS

Senior Researcher: Claudia Dei Negri

EXPERIMENTAL PROCEDURE

1 FT/IR ANALYSIS

A small particle of each sample test was extracted from the sample and transferred to a diamond cell. The particle was pressed with the other diamond cell to get a bigger surface and thinner thickness.

1.1 REAGENTS AND REFERENCE SUBSTANCE

All reagents were analytical reagent grade, unless otherwise stated.

1.2 EQUIPMENT

FT/IR Bomem MB120 with a coupled Spectra Tech Microscope
KBr Beam splitter
Glowbar source
MCT Detector

1.3 INSTRUMENTAL CONDITION

Spectra were collected in transmission mode, and were recorded between 4000 and 720 cm^{-1} using a resolution of a 4 cm^{-1}.

2 DSC ANALYSIS

Each sample was put in an aluminium melting pot and put in the sampler of the equipment for the analysis.

2.1 REAGENTS AND REFERENCE SUBSTANCE

All reagents were analytical reagent grade, unless otherwise stated.

2.2 EQUIPMENT

DSC-30 Mettler Toledo
Aluminium melting pot

2.3 INSTRUMENTAL CONDITION

Nitrogen gas 50ml/min
Method: heating from -100 ºC to 400 ºC (10ºC/min)

3 DETERMINATION OF DENSITY

The samples were weighed and placed in a graduated cylinder containing water. The increase of level of water is the volume of the sample added. Using the following formula the density is:

$$\delta = m/v \ [kg/m^3]$$

where:
δ is density
m is the mass of the sample (weigh [g] / 9,8ms^{-2})
v is the volume of the sample.

For Androtop the volume was calculated directly measuring the dimension of the cylinder.

3.1 EQUIPMENT

Scale	METTLER AM100
Graduated Cylinder	
Micrometer	RUPAC

4 DETERMINATION OF HARDNESS

Five samples were analysed in order to determinate the hardness of the surface. The hardness is expressed in Shore A.
The silicone band was cut and spread on a flat surface.

4.1 EQUIPMENT

Durometer Rupac RR-15

5 DETERMINATION OF RESISTANCE TO TENSILE STRESS

The samples were inserted into the clamps and pre-stressed in order to allow a correct alignment and thus a correct reading of the parallel length. Then, a 300 mm/min constant rate tensile stress was applied until the sample broke apart.
Load and elongation values before breakage were logged, the test was repeated on five samples.

5.1 EQUIPMENT

Macchina universale di prova Galdabini SUN 1000 (10 kN), 10 kN load cell with SIT certification, software Graphwork 3 for data recordings

RESULTS

SAMPLE 1 – PLASTIC BASE RING

FT/IR ANALYSIS

Two different particles of the same sample were analysed and identical spectra was obtained. According to the KnowItAll Biorad database the bands of the spectrum match the bands of a polyether. This polyether is the Polyoxymethylene copolymer (POM) as declared by the Sponsor.

DSC ANALYSIS

Differential Scanning Calorimetry analysis shows an endothermic reaction at 157ºC with an associating heat of 138.7 J/g.

The full DSC characterization profile is attached to this report.

DETERMINATION OF DENSITY

In the following table are reported the density of each sample:

Sample	*Weigh [g]*	*Volume [ml]*	*Density [kg/m^3]*
1	22,6300	21	1,0996
2	22,9093	23	1,0164
3	23,02150	23	1,0214
Mean			***1,0458***

DETERMINATION OF HARDNESS

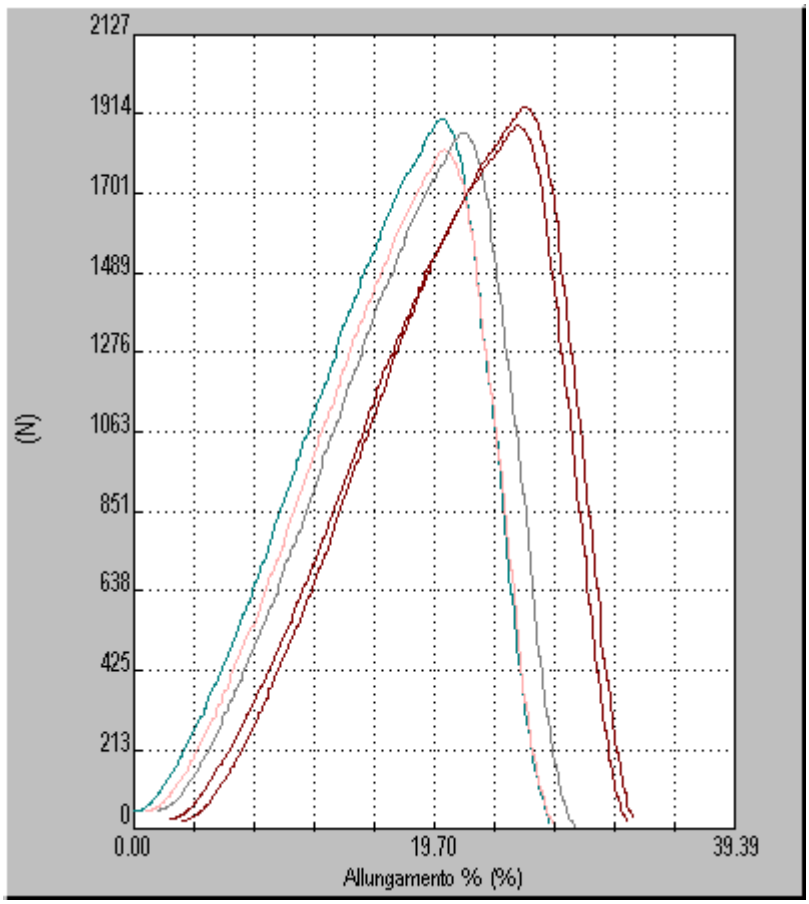
In the following table are reported the hardness of each sample:

Sample	*Hardness Shore A*
1	92
2	98
3	89
4	94
5	95
Mean	***94***

DETERMINATION OF RESISTANCE TO TENSILE STRESS

In the following table are reported the maximum load and the elongation at break of each sample:

Sample	*Maximum Load [N]*	*Elongation at break [%]*
1	1933,25	22,45
2	1881,75	22,68
3	1862,85	19,97
4	1816,55	19,58
5	1897,40	20,10
Mean	***1878,36***	***20,96***



SAMPLE 2 – SUPERIOR PLASTIC SUPPORT

FT/IR ANALYSIS

Two different particles of the same sample were analysed and identical spectra was obtained. These spectra match the spectra obtained for the sample 1: plastic base ring. According to the KnowItAll Biorad database the bands of the spectrum match the bands of a polyether. This polyether is the Polyoxymethylene copolymer (POM) as declared by the Sponsor.

DSC ANALYSIS

Differential Scanning Calorimetry analysis shows an endothermic reaction at 157ºC with an associating heat of 130.2 J/g.

The full DSC characterization profile is attached to this report.

DETERMINATION OF DENSITY

In the following table are reported the density of each sample:

Sample	*Weigh [g]*	*Volume [ml]*	*Density [kg/m^3]*
1	9,8500	9	1,1168
2	9,8410	10	1,0042
3	9,8625	10	1,0064
Mean			***1,0424***

DETERMINATION OF HARDNESS

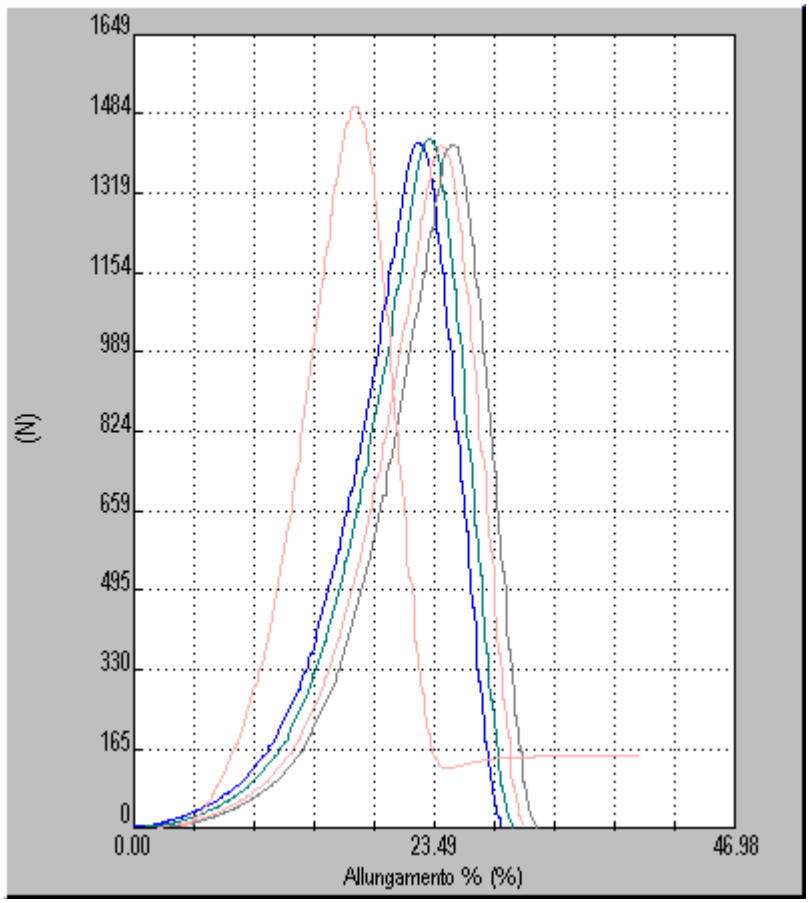
In the following table are reported the hardness of each sample:

Sample	*Hardness Shore A*
1	90
2	90
3	88
4	89
5	91
Mean	***90***

DETERMINATION OF RESISTANCE TO TENSILE STRESS

In the following table are reported the maximum load and the elongation at break of each sample:

Sample	*Maximum Load [N]*	*Elongation at break [%]*
1	1498,80	13,59
2	1419,90	21,94
3	1417,25	22,10
4	1430,25	22,49
5	1422,65	22,35
Mean	***1337,77***	***20,49***



SAMPLE 3 – SILICONE BAND

FT/IR ANALYSIS

Two different particles of the same sample were analysed and identical spectra was obtained. According to the KnowItAll Biorad database the bands of the spectrum match the bands of silicone as declared by the Sponsor.

DSC ANALYSIS

Differential Scanning Calorimetry analysis shows an endothermic reaction at -59ºC with an associating heat of 17.2 J/g.

The full DSC characterization profile is attached to this report.

DETERMINATION OF DENSITY

In the following table are reported the density of each sample:

Sample	***Weigh [g]***	***Volume [ml]***	***Density [kg/m^3]***
1	10,2840	5	2,0988
2	10,3697	5	2,1163
3	10,3868	5	2,1198
Mean			***2,1116***

DETERMINATION OF HARDNESS

In the following table are reported the hardness of each sample:

Sample	***Hardness Shore A***
1	37
2	42
3	39
4	38
5	42
Mean	***40***

SAMPLE 4 – ANDRO - TOP

FT/IR ANALYSIS

Two different particles of the same sample have been analysed and identical spectra have been obtained. According to the KnowltAll Biorad database the bands of the spectrum match the bands of polyurethane.

DSC ANALYSIS

Differential Scanning Calorimetry analysis shows an endothermic reaction at 254 ºC with an associating heat of 350.3 J/g.

The full DSC characterization profile is attached to this report.

DETERMINATION OF DENSITY

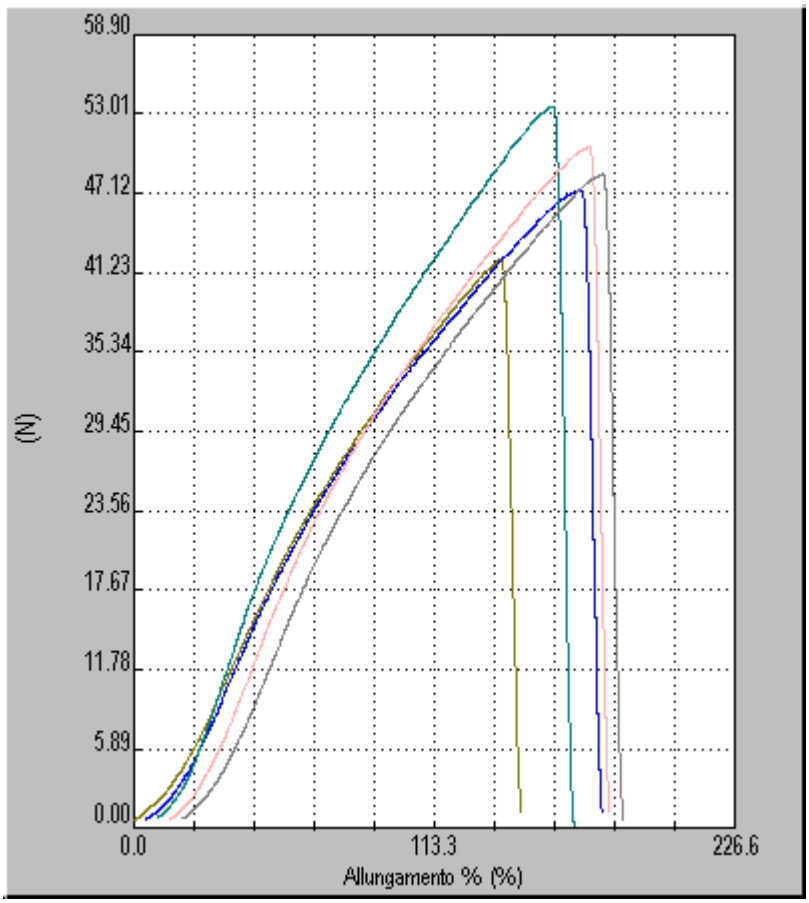
In the following table are reported the density of each sample:

Sample	*Weigh [g]*	*Volume [m^3]*	*Density [kg/m^3]*
1	1,0859	0,000039	2,8242
2	1,0537	0,000040	2,6892
3	1,0563	0,000040	2,7213
Mean			***2,7449***

DETERMINATION OF RESISTANCE TO TENSILE STRESS

In the following table are reported the maximum load and the elongation at break of each sample:

Sample	*Maximum Load [N]*	*Elongation at break [%]*
1	48,55	158,55
2	50,55	157,81
3	53,55	148,03
4	47,30	162,57
5	42,15	137,68
Mean	***48,42***	***152,93***


58.90
53.01
47.12
41.23
35.34
29.45
23.56
17.67
11.78
5.89
0.00
(N)
0.0
113.3
226.6
Allungamento % (%)

CONCLUSIONS

On the basis of the results, the test material PLASTIC (1 and 13) was identified as Polyoxymethylene (POM) as declared by the Sponsor.

On the basis of the results, the test material FOAM (15) was identified as polyurethane as declared by the Sponsor.

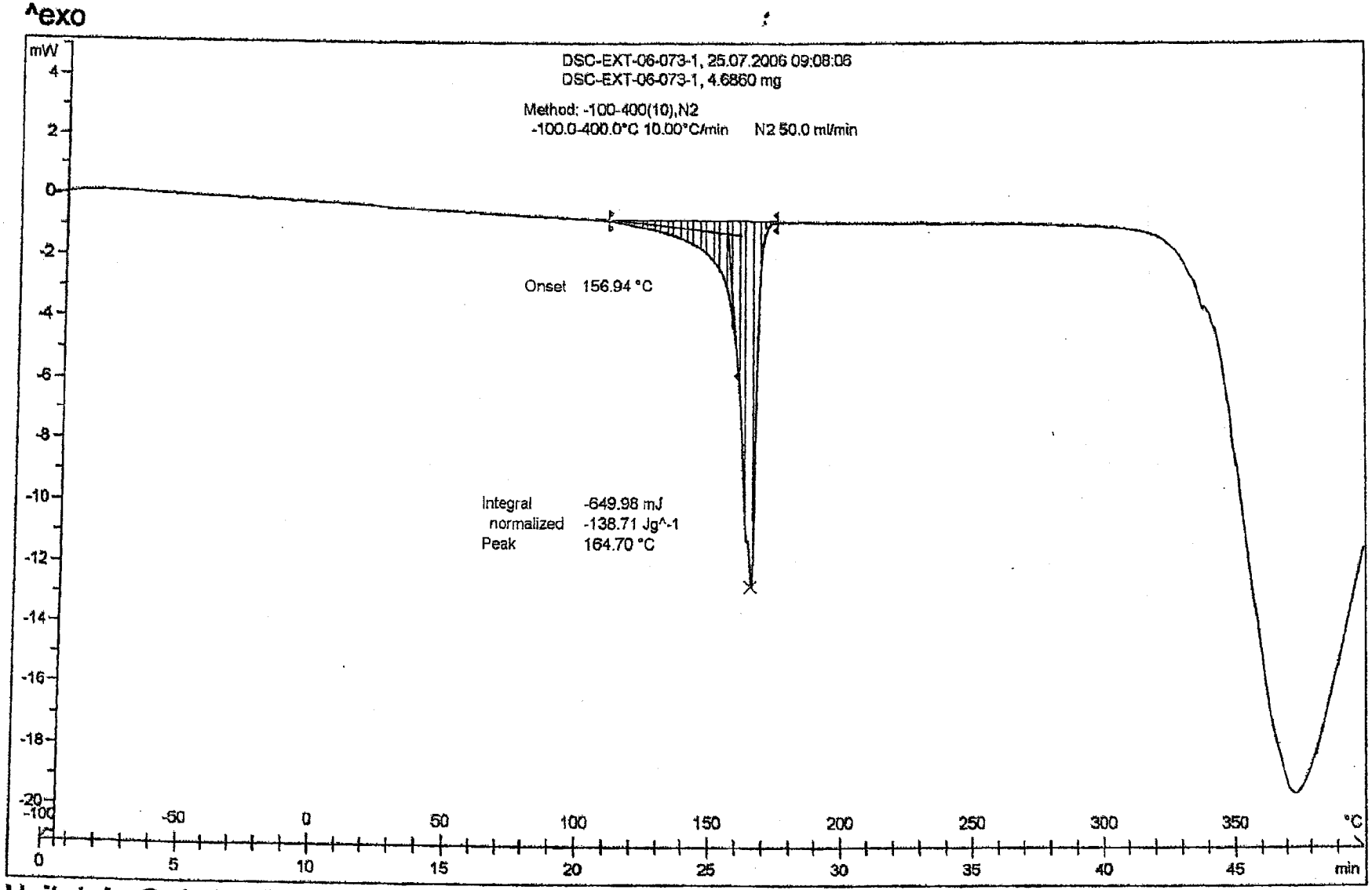
On the basis of the results, the test material SILICON (14) was identified as silicon as declared by the Sponsor.

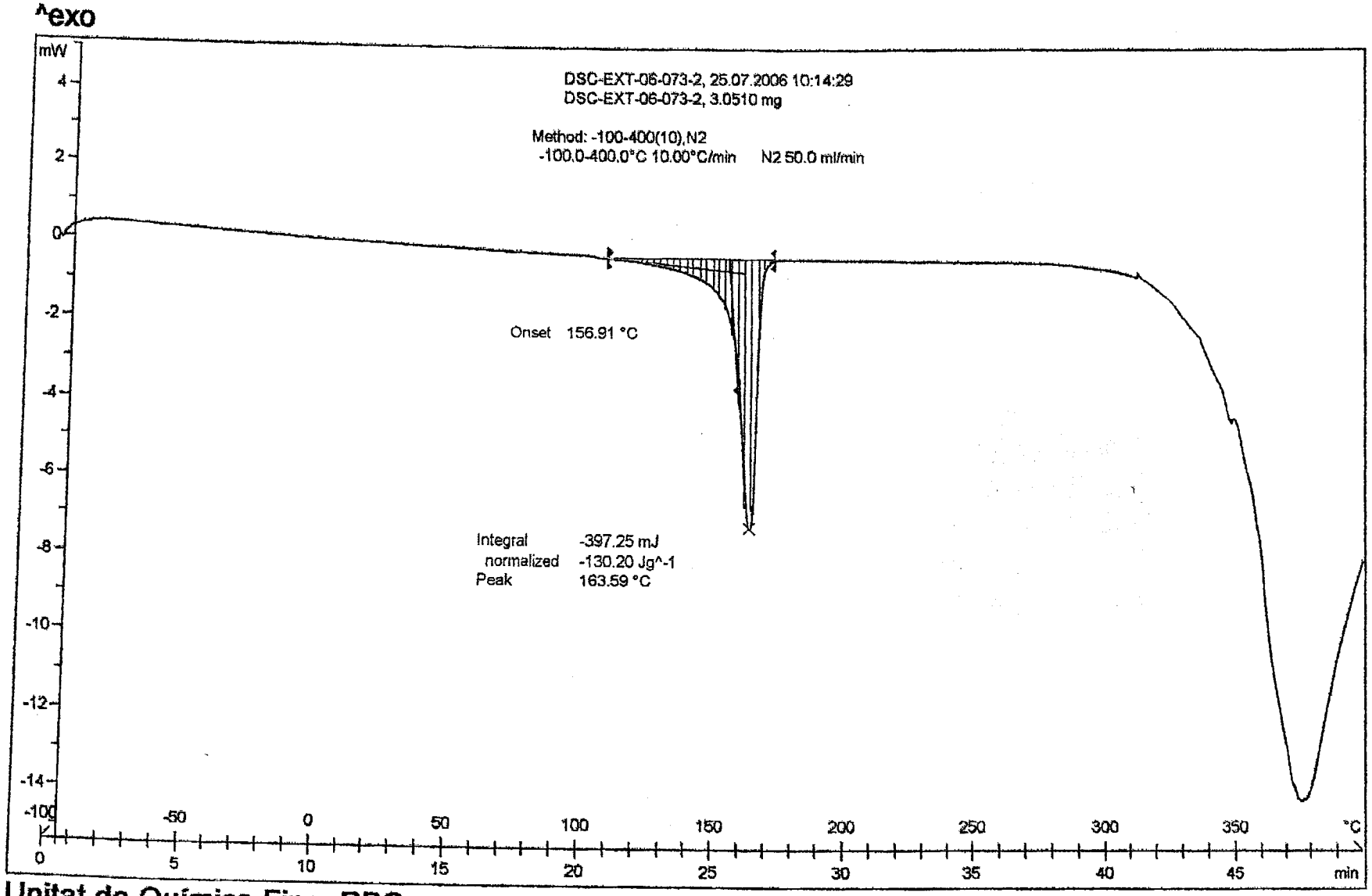
DSC profile, density, hardness and resistance to tensile stress were determined in order to characterise each plastic component.

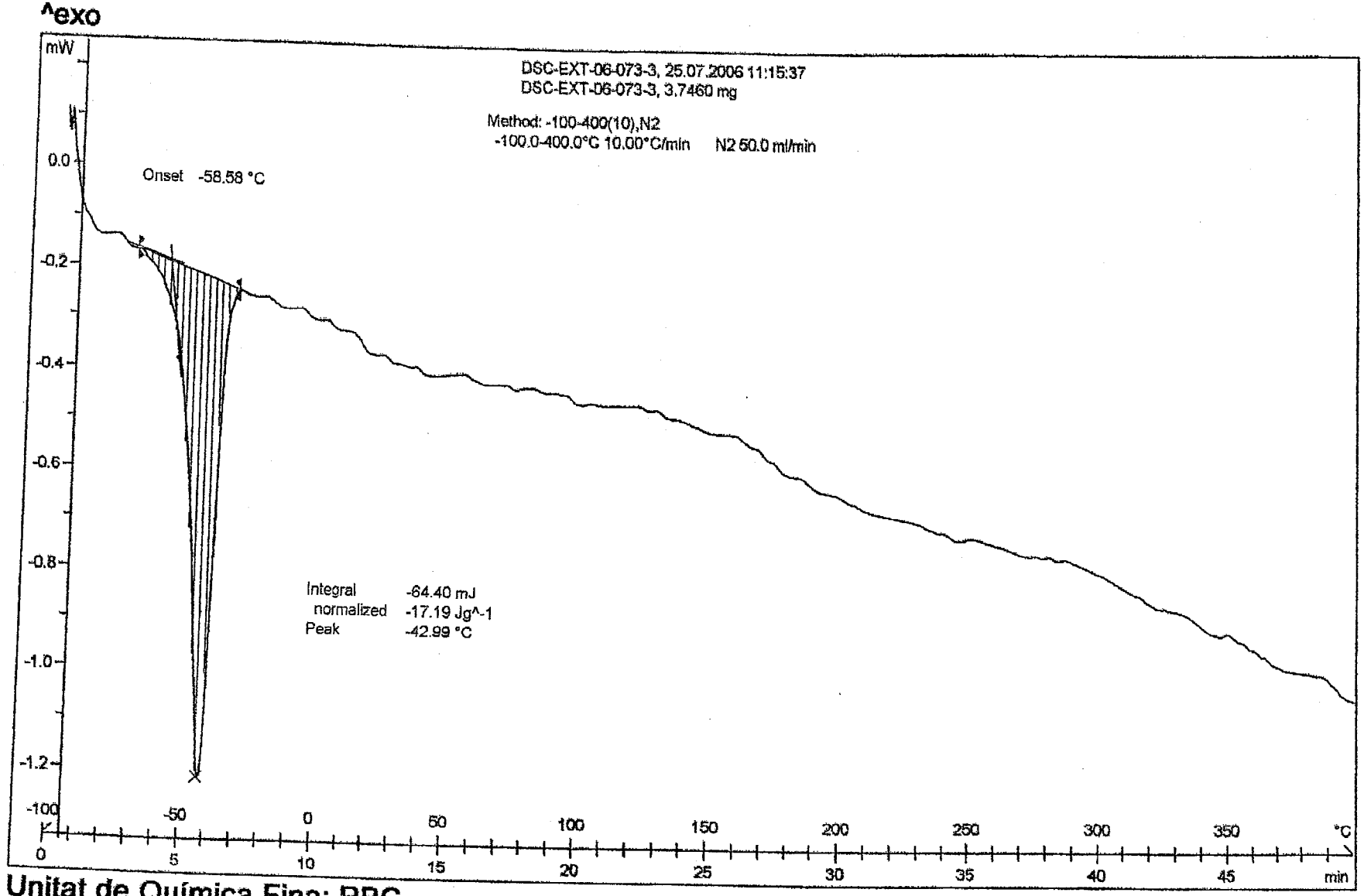
PHYSICOCHEMICAL CHARACTERIZATION OF FOUR PLASTIC MATERIALS OF ANDRO - PENIS

ATTACHMENT

FT/IR SPECTRA – 7 PAGES
DSC THERMOGRAMS – 4 PAGES

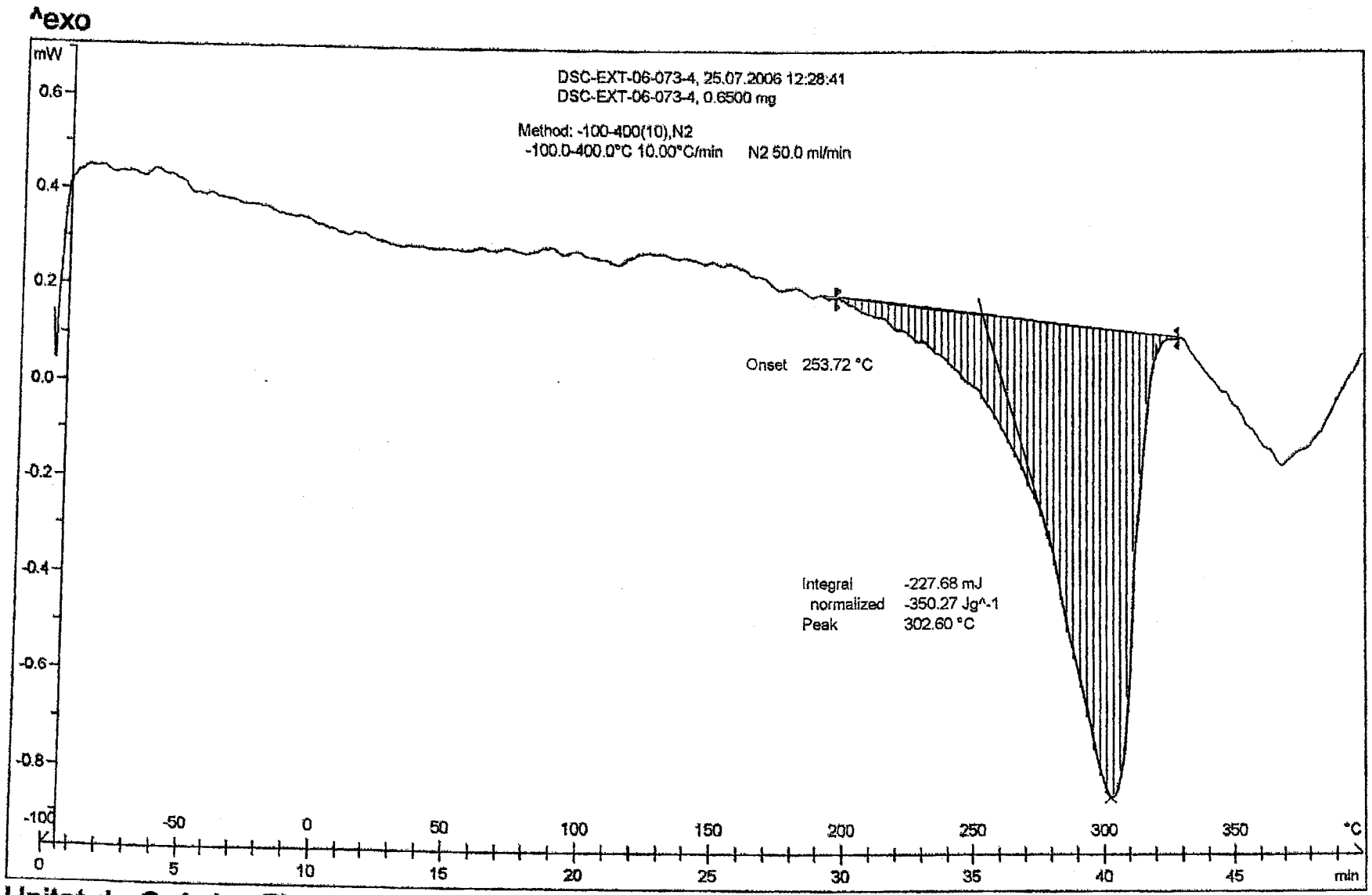






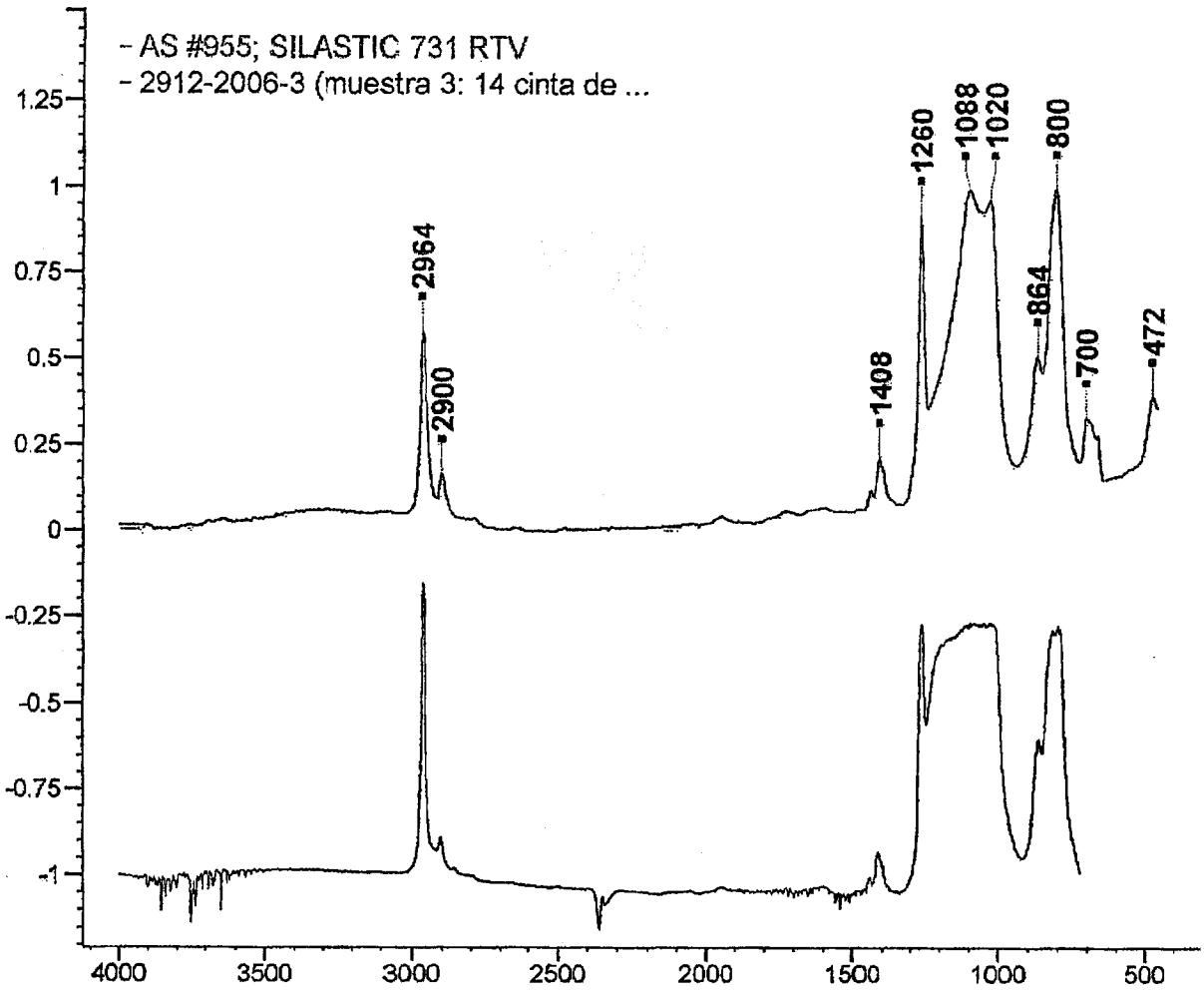
Unitat de Química Fina: RBC

STAR^{e} SW 8.10



Unitat de Química Fina: RBC

STAR^{e} SW 8.10



Name	Value	Unit
Name	SILASTIC 731 RTV	
Source of Sample	DOW CORNING CORPORATION	
Technique	FILM	
Comments	WHITE PASTEChemical Description= ONE-PART SILICONE RUBBER	
Classification	Adhesives and Sealants= SEALANT	
Density	1.070 G/CC	
Hardness	A25 (SHORE)	
Elongation	450%	

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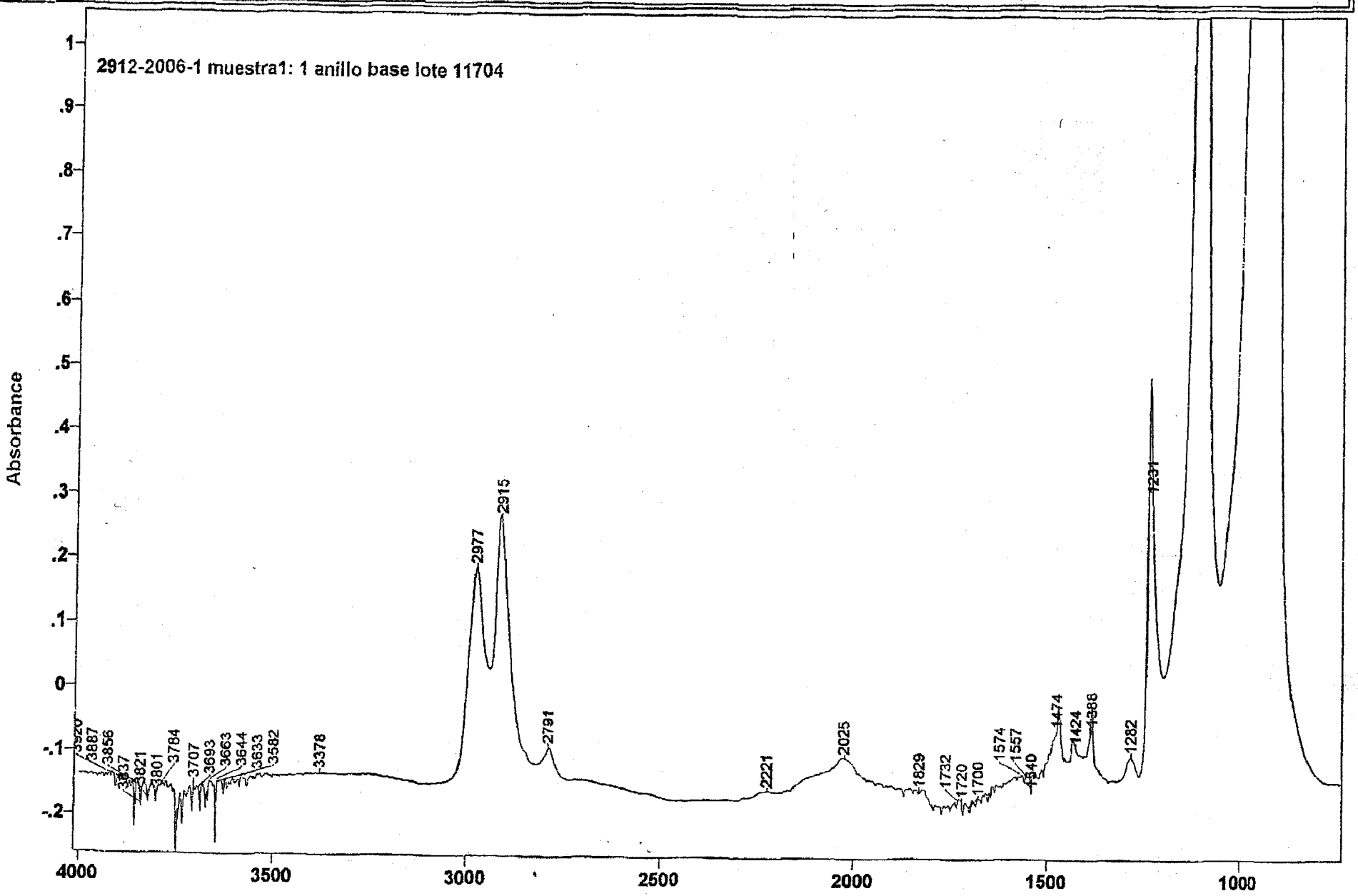

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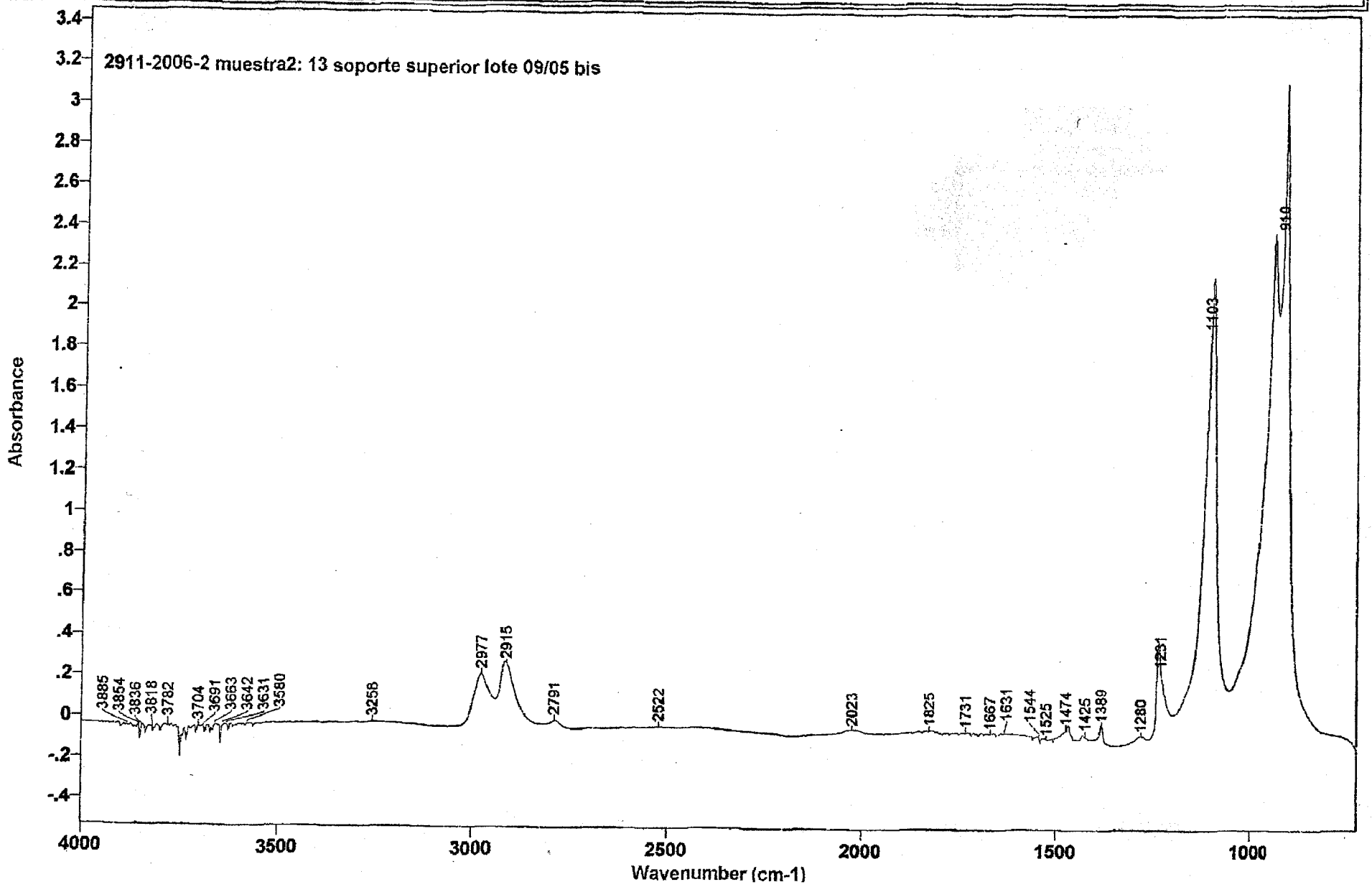

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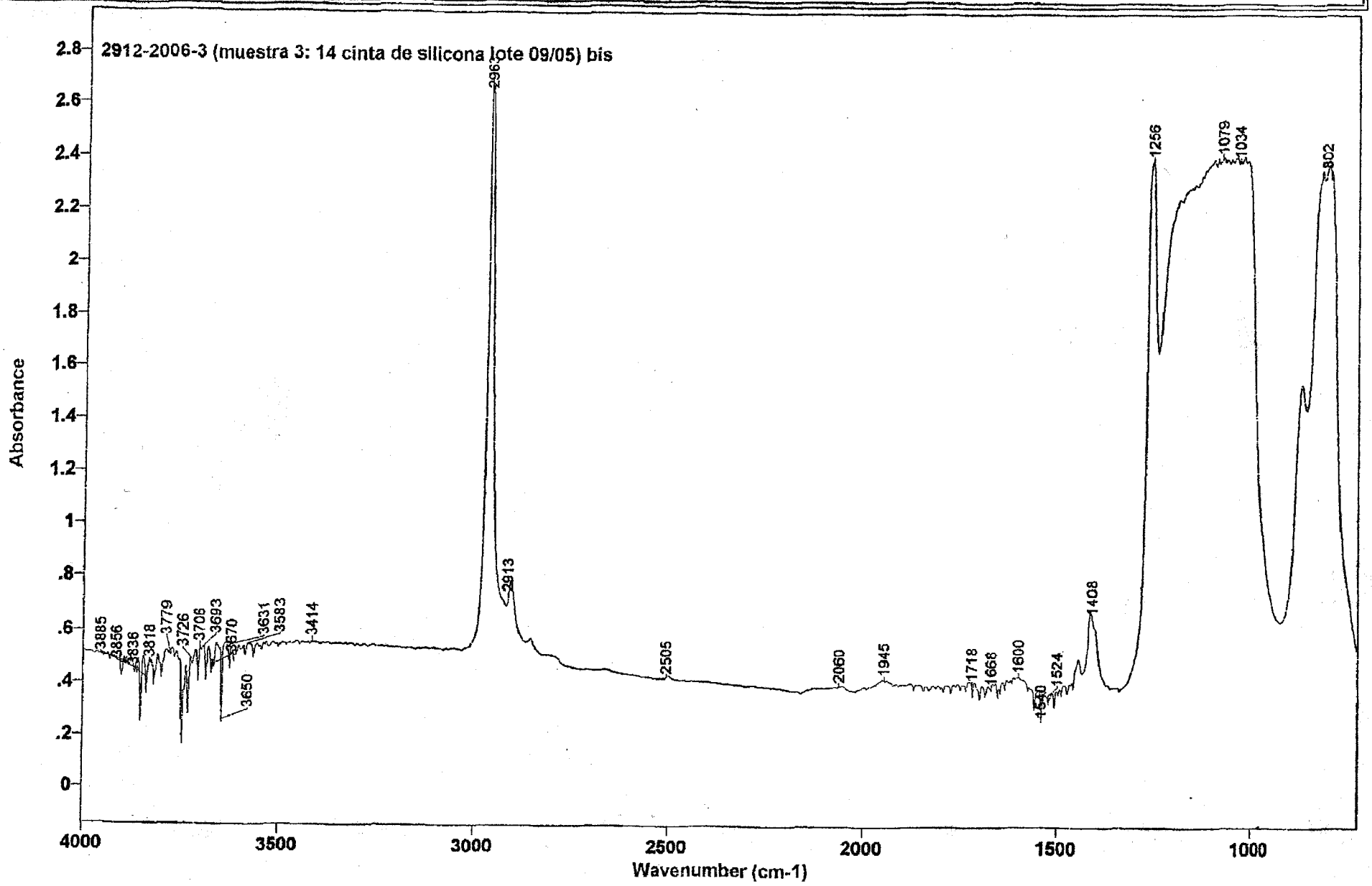

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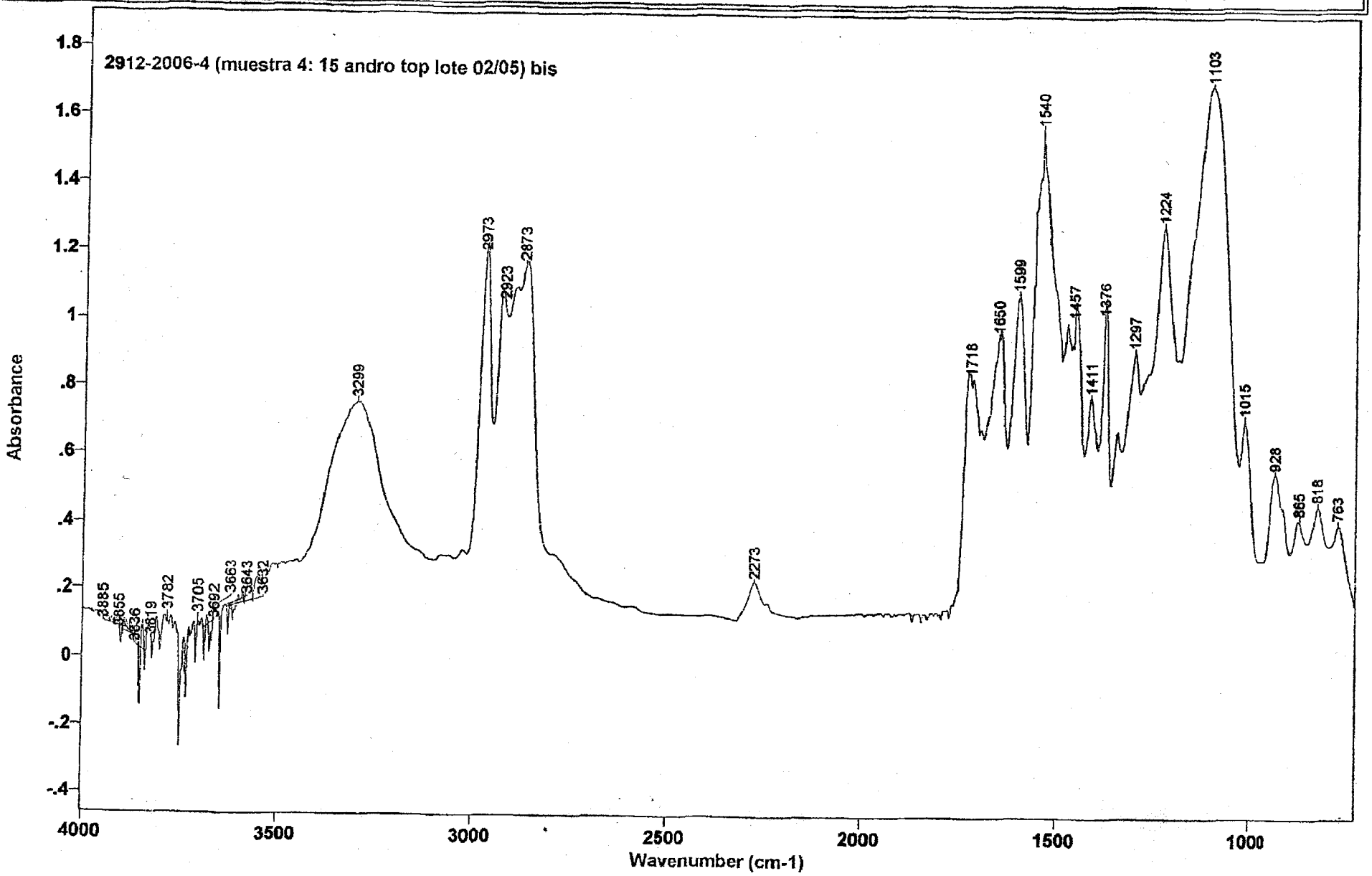
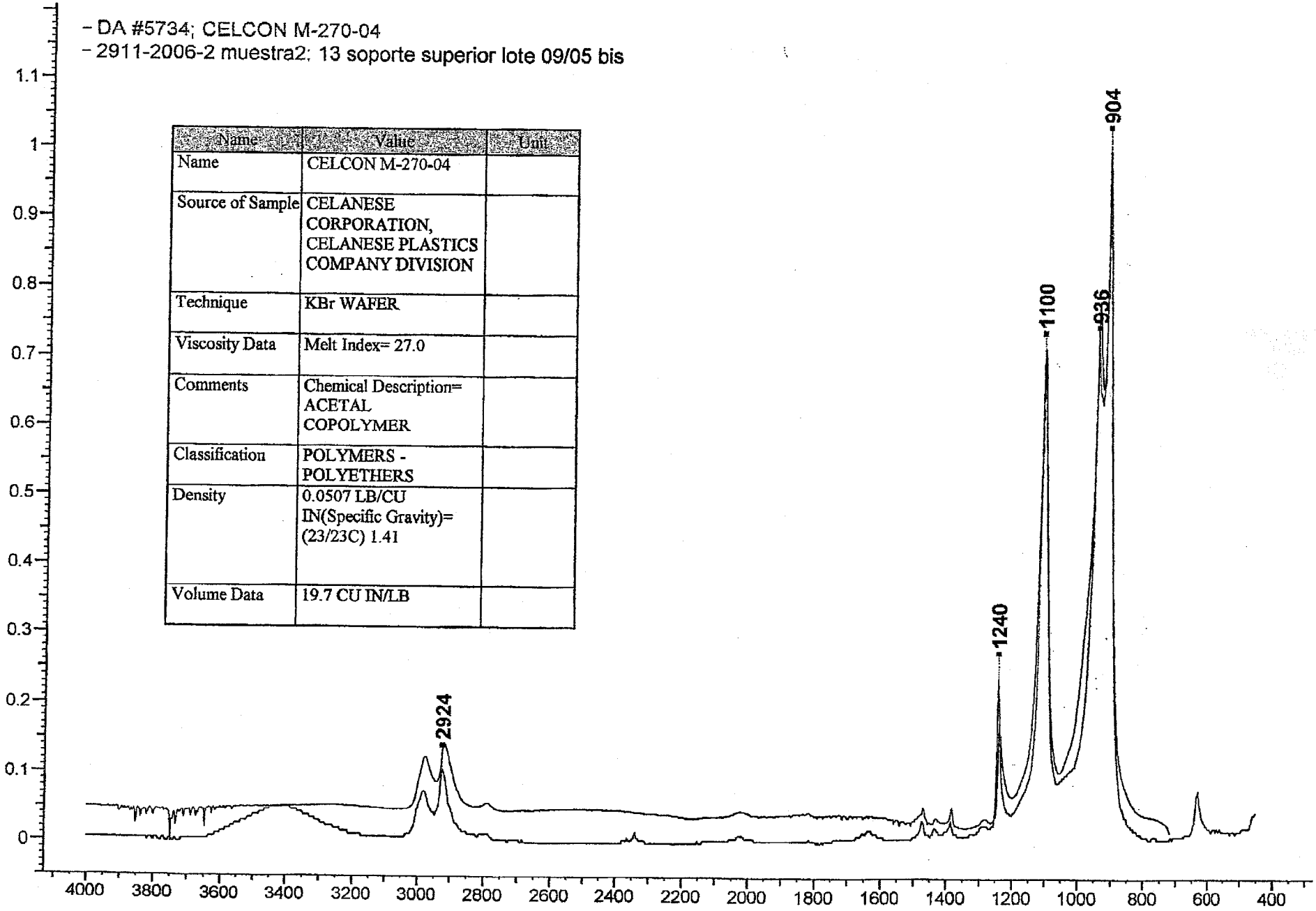


- DA #5734; CELCON M-270-04
- 2911-2006-2 muestra2; 13 soporte superior lote 09/05 bis

Name	Value	Unit
Name	CELCON M-270-04	
Source of Sample	CELANESE CORPORATION, CELANESE PLASTICS COMPANY DIVISION	
Technique	KBr WAFER	
Viscosity Data	Melt Index= 27.0	
Comments	Chemical Description= ACETAL COPOLYMER	
Classification	POLYMERS - POLYETHERS	
Density	0.0507 LB/CU IN(Specific Gravity)= (23/23C) 1.41	
Volume Data	19.7 CU IN/LB	



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