

**Request for scientific evaluation of "Substantial Equivalence"
for Cargill, Incorporated phytosterols/phytostanols intended
to be used in
specified foods**

**With a view to support a notification under the procedure laid
down in Regulation (EC) No 258/97 of the European
Parliament and of the Council of 27 January 1997 concerning
novel foods and novel food ingredients**

APPENDIX 1

**Analysis Reports for Undesirable Substances
(as quoted in Table 3 of Proposal Document)**

**FINAL
16 August 2004**



The National Food Laboratory, Inc.

6363 CLARK AVENUE, DUBLIN, CA 94568
(925) 828-1440 FAX: (925) 829-8678

April 29, 2004

Shelly Howarth/ Lea Buerman
Cargill NutriProducts
1 Cargill Drive
Eddyville, IA 52553

Analytical Report No.: CL3265-9
PO#: 564466

Listed below are the results of our analyses for sample(s) received on April 26, 2004.

Sterols P11809304

NFL ID: AB87793

Heavy Metals Screen

Analyte	Result	Units
Chromium	1.5	ppm
Manganese	0.062	ppm
Iron	1.8	ppm
Cobalt	<0.01	ppm
Nickel	<0.01	ppm
Copper	0.018	ppm
Zinc	<0.01	ppm
Arsenic	<0.01	ppm
Selenium	<0.01	ppm
Cadmium	<0.01	ppm
Antimony	<0.01	ppm
Lead	<0.01	ppm
Mercury	<0.020	ppm

Sterols P11909604

NFL ID: AB87794

Heavy Metals Screen

Analyte	Result	Units
Chromium	1.3	ppm
Manganese	0.046	ppm
Iron	1.1	ppm
Cobalt	<0.01	ppm
Nickel	<0.01	ppm
Copper	<0.01	ppm
Zinc	<0.01	ppm
Arsenic	<0.01	ppm
Selenium	<0.01	ppm
Cadmium	<0.01	ppm
Antimony	<0.01	ppm
Lead	<0.01	ppm
Mercury	<0.020	ppm

April 29, 2004

Shelly Howarth/ Lea Buerman
Cargill NutriProducts

Analytical Report No.: CL3265-9

Sterols P12009904

NFL ID: AB87795
Heavy Metals Screen

Analyte	Result	Units
Chromium	1.7	ppm
Manganese	0.047	ppm
Iron	1.4	ppm
Cobalt	<0.01	ppm
Nickel	<0.01	ppm
Copper	0.011	ppm
Zinc	<0.01	ppm
Arsenic	<0.01	ppm
Selenium	<0.01	ppm
Cadmium	<0.01	ppm
Antimony	<0.01	ppm
Lead	<0.01	ppm
Mercury	<0.020	ppm

Sterols P12110204

NFL ID: AB87796
Heavy Metals Screen

Analyte	Result	Units
Chromium	1.9	ppm
Manganese	0.085	ppm
Iron	3.5	ppm
Cobalt	<0.01	ppm
Nickel	<0.01	ppm
Copper	<0.01	ppm
Zinc	<0.01	ppm
Arsenic	<0.01	ppm
Selenium	<0.01	ppm
Cadmium	<0.01	ppm
Antimony	<0.01	ppm
Lead	<0.01	ppm
Mercury	<0.020	ppm



CENTRAL SCIENCE
LABORATORY



1642

Test Report

Customer: Cantox Health Sciences International
The Science and Technology Centre
University of Reading
RG6 6BZ

Contact: Dr Nigel Baldwin

Report Reference Number: FSQE/PAH/M6FO - 1056

Date: 3rd August 2004.

Sample: phytosterol

Date of receipt: 6th July 2004

Method used: Method FSQ5 SOP 10

Outline of Method: The samples are fortified with appropriate ¹³C Internal standards and subjected to saponification followed by liquid-liquid extraction. Cleanup is by DMF/cyclohexane partition followed by elution through a silica gel column. Analysis is by HRGC - LRMS

Issuing officer: Mr Shaun White, Technical Manager

Sand Hutton ■ York

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Results

CSL Sample No. Sample Details:	10134 Phytosterol, 3550-61-4	10135 Phytosterol, 3550-61-5	10136 Phytosterol, 3550-61-6	10137 Phytosterol, 3550-61-7
ug/kg whole weight				
acenaphthylene	<0.07	<0.07	<0.07	<0.07
acenaphthene	0.68	0.84	0.89	0.66
fluorene	0.90	1.25	1.46	0.87
phenanthrene	4.24	4.91	5.04	4.39
anthracene	0.12	0.17	0.13	0.14
fluoranthene	0.50	0.49	0.62	0.56
pyrene	0.26	0.23	0.32	0.24
Benzo[ghi]fluoranthene	<0.02	<0.02	<0.02	<0.02
benz (a) anthracene	<0.03	<0.03	<0.03	<0.03
Benzo[b]naphtho[2,1-d]thiophene	<0.03	<0.04	<0.04	<0.03
Cyclopenta[c,d]pyrene	<0.02	<0.02	<0.02	<0.02
chrysene	<0.05	<0.07	<0.09	<0.06
5-methylchrysene	<0.03	<0.03	<0.03	<0.03
benzo[b]fluoranthene	<0.05	<0.05	<0.05	<0.05
benzo[j]fluoranthene	<0.02	<0.02	<0.02	<0.02
benzo[k]fluoranthene	<0.03	<0.03	<0.03	<0.03
benzo[e]pyrene	<0.1	<0.09	<0.07	<0.11
benzo[a]pyrene	<0.08	<0.08	<0.08	<0.08
indeno[1,2,3-cd]pyrene	<0.05	0.08	<0.05	<0.05
dibenz[ah]anthracene	<0.05	<0.05	<0.05	<0.05
benzo-[g,h,i]perylene	0.18	ND	0.14	0.21
Anthanthrene	<0.1	ND	<0.1	<0.1
dibenzo[a,l]pyrene	<0.1	<0.1	<0.1	<0.1
dibenzo[a,e]pyrene	<0.1	<0.1	<0.1	<0.1
dibenzo[a,i]pyrene	<0.1	<0.1	<0.1	<0.1
dibenzo[a,h]pyrene	<0.1	<0.1	<0.1	<0.1
Coronene	<0.1	<0.1	<0.1	<0.1

ND = not determined



Quality Control Procedures

In order to demonstrate that adequate confidence can be placed in the results obtained, the following requirements were observed.

Each batch of samples analysed incorporated a certified reference material (CRM458), for which results are compared with certified or assigned data and laboratory performance (indicative) data [1]. The acceptable range of results and the results obtained for the batch CRM are tabulated below. Results for the batch RM all fall within the acceptable range. Each batch of samples analysed included a full reagent blank extract. The contribution from the batch blank was found to be negligible.

CRM458 PAHs in Coconut Oil

Compound	Certified Value(ug/kg)	Uncertainty (ug/kg)	Range (ug/kg)	Batch Reference px2333
Pyrene	9.40	1.5	7.9 - 10.9	9.22
Chrysene	4.90	0.4	4.5 - 5.3	4.47
Benzo[k]fluoranthene	1.87	0.18	1.69 - 2.05	1.74
Benzo[a]pyrene	0.93	0.09	0.84 - 1.02	1.01
Indeno[1,2,3-cd]pyrene	1.00	0.07	0.93 - 1.07	0.93
Benzo[ghi]perylene	0.97	0.07	0.90 - 1.04	0.93



References.

1. W. Luther, T. Win, H.A.M.G. Vaessen, C.G. Van de Kamp, A.A. Jekel, J. Jacob, A. Boenke, 1997, The certification of the mass fraction of Pyrene, Chrysene, Benzo[k]fluoranthene, Benzo[a]pyrene, Benzo[ghi]perylene and Indeno[1,2,3-cd]pyrene in two coconut oil reference materials (CRM458 and CRM459). Report EUR17545EN, Commission of the European Communities, Community Bureau of Reference.

This report has been prepared by CSL after exercise of all reasonable care and skill, but is provided without liability in its application and use. Opinions and interpretation are outside the scope of UKAS accreditation.

05/05/04

To: Lea Buerman
Cargill Nutri-Products, Inc.
Eddyville, IA.

From: Chris Marquardt
Cargill Research – Scientific Resources Center
Wayzata, MN.

Re: Pesticide results for sterol sample

Following are the results of multiresidue pesticide testing on the sterol sample submitted. The screen includes the usual “Luke II” pesticide list (excluding TCMTB) plus some chlorophenoxy acid herbicides including 2,4-D.

Sample ID/description: P11809304, Tall Oil Pitch Sterols
CAS LIMS #: 2407586

No pesticides on the list were found

Sample ID/description: P11909604, Tall Oil Pitch Sterols
CAS LIMS #: 2407587

No pesticides on the list were found

Sample ID/description: P12009904, Tall Oil Pitch Sterols
CAS LIMS #: 2407588

No pesticides on the list were found

Sample ID/description: P12110204, Tall Oil Pitch Sterols
CAS LIMS #: 2407589

No pesticides on the list were found

Spike data:

<u>Pesticide spiked</u>	<u>% Recovery</u>
Atrazine	91
Cyanazine	99
Heptachlor epoxide	101
Dieldrin	94
Bifenthrin	81
Permethrin	83
Phorate	83
Terbufos	80
Chlorpyrifos	85
Malathion	100
Profenophos	108
MCPP	73
MCPA	67
Dichloroprop	77
2,4 - D	76
2,4,5 - TP	81
2,4,5 - T	87
2,4 - DB	79
Methomyl	82
Carbaryl	2

Cargill, Health & Food Technologies

TLI Project: **63144Ar1**
 Client Sample: **P11809304**

Toxicity Equivalents Report
 Analysis File: **S041852**

Client Project: DIOXIN & PCB TESTING	Date Received: 05/21/04	Spike File: SP161B2S
Sample Matrix: SOLID	Date Extracted: 05/27/04	ICal: SF5129B
TLI ID: 383-46-1	Date Analyzed: 06/02/04	ConCal: SB41841
Sample Size: 10.020 g	Dilution Factor: 1	% Moisture: n/a
Dry Weight: n/a	Blank File: S041851	% Lipid: n/a
GC Column: DB-5	Analyst: JSY	% Solids: n/a

Analytes	Conc. (pg/g)		TEF		Equivalent
2,3,7,8-TCDD	{0.07}	x	1	=	0.07
1,2,3,7,8-PeCDD	{0.08}	x		=	0.08
1,2,3,4,7,8-HxCDD	{0.09}	x	0.1	=	0.009
1,2,3,6,7,8-HxCDD	{0.08}	x	0.1	=	0.008
1,2,3,7,8,9-HxCDD	{0.09}	x	0.1	=	0.009
1,2,3,4,6,7,8-HpCDD	{0.2}	x	0.01	=	0.002
1,2,3,4,6,7,8,9-OCDD	{1.1}	x	0.0001	=	0.00011
2,3,7,8-TCDF	{0.05}	x	0.1	=	0.005
1,2,3,7,8-PeCDF	{0.05}	x	0.05	=	0.003
2,3,4,7,8-PeCDF	{0.06}	x	0.5	=	0.03
1,2,3,4,7,8-HxCDF	{0.05}	x	0.1	=	0.005
1,2,3,6,7,8-HxCDF	{0.05}	x	0.1	=	0.005
2,3,4,6,7,8-HxCDF	{0.05}	x	0.1	=	0.005
1,2,3,7,8,9-HxCDF	{0.08}	x	0.1	=	0.008
1,2,3,4,6,7,8-HpCDF	{0.08}	x	0.01	=	0.0008
1,2,3,4,7,8,9-HpCDF	{0.2}	x	0.01	=	0.002
1,2,3,4,6,7,8,9-OCDF	{0.5}	x	0.0001	=	0.00005

Total WHO Dioxin TEFs for Humans	TEQ	0.24 pg/g
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{...} indicates that the value is that of a Detection Limit.

Cargill, Health & Food Technologies

TLI Project: **63144Ar1**
 Client Sample: **P11909604**

Toxicity Equivalents Report
 Analysis File: **S041853**

Client Project:	DIOXIN & PCB TESTING		
Sample Matrix:	SOLID	Date Received:	05/21/04
TLI ID:	383-46-2	Date Extracted:	05/27/04
		Date Analyzed:	06/02/04
		Spike File:	SP161B2S
		ICal:	SF5129B
		ConCal:	SB41841
Sample Size:	10.000 g	Dilution Factor:	1
Dry Weight:	n/a	Blank File:	S041851
GC Column:	DB-5	Analyst:	JSY
		% Moisture:	n/a
		% Lipid:	n/a
		% Solids:	n/a

Analytes	Conc. (pg/g)		TEF		Equivalent
2,3,7,8-TCDD	{0.1}	x		=	0.1
1,2,3,7,8-PeCDD	{0.1}	x		=	0.1
1,2,3,4,7,8-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,6,7,8-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,7,8,9-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,4,6,7,8-HpCDD	{0.6}	x	0.01	=	0.006
1,2,3,4,6,7,8,9-OCDD	{1.6}	x	0.0001	=	0.00016
2,3,7,8-TCDF	{0.07}	x	0.1	=	0.007
1,2,3,7,8-PeCDF	{0.07}	x	0.05	=	0.004
2,3,4,7,8-PeCDF	{0.10}	x	0.5	=	0.050
1,2,3,4,7,8-HxCDF	{0.09}	x	0.1	=	0.009
1,2,3,6,7,8-HxCDF	{0.10}	x	0.1	=	0.010
2,3,4,6,7,8-HxCDF	{0.1}	x	0.1	=	0.01
1,2,3,7,8,9-HxCDF	{0.3}	x	0.1	=	0.03
1,2,3,4,6,7,8-HpCDF	{0.4}	x	0.01	=	0.004
1,2,3,4,7,8,9-HpCDF	{0.5}	x	0.01	=	0.005
1,2,3,4,6,7,8,9-OCDF	{1.2}	x	0.0001	=	0.00012

Total WHO Dioxin TEFs for Humans	TEQ	0.4 pg/g
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{...} indicates that the value is that of a Detection Limit.

Cargill, Health & Food Technologies

TLI Project: **63144Ar1**
 Client Sample: **P12009904**

Toxicity Equivalents Report
 Analysis File: **S041854**

Client Project: DIOXIN & PCB TESTING			
Sample Matrix: SOLID	Date Received: 05/21/04	Spike File: SP161B2S	
TLI ID: 383-46-3	Date Extracted: 05/27/04	ICal: SF5129B	
	Date Analyzed: 06/02/04	ConCal: SB41841	
Sample Size: 10.010 g	Dilution Factor: 1	% Moisture: n/a	
Dry Weight: n/a	Blank File: S041851	% Lipid: n/a	
GC Column: DB-5	Analyst: JSY	% Solids: n/a	

Analytes	Conc. (pg/g)	TEF			Equivalent
2,3,7,8-TCDD	{0.1}	x		=	0.1
1,2,3,7,8-PeCDD	{0.1}	x		=	0.1
1,2,3,4,7,8-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,6,7,8-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,7,8,9-HxCDD	{0.2}	x	0.1	=	0.02
1,2,3,4,6,7,8-HpCDD	{0.6}	x	0.01	=	0.006
1,2,3,4,6,7,8,9-OCDD	{2.5}	x	0.0001	=	0.00025
2,3,7,8-TCDF	{0.07}	x	0.1	=	0.007
1,2,3,7,8-PeCDF	{0.07}	x	0.05	=	0.004
2,3,4,7,8-PeCDF	{0.09}	x	0.5	=	0.05
1,2,3,4,7,8-HxCDF	{0.09}	x	0.1	=	0.009
1,2,3,6,7,8-HxCDF	{0.09}	x	0.1	=	0.009
2,3,4,6,7,8-HxCDF	{0.1}	x	0.1		0.01
1,2,3,7,8,9-HxCDF	{0.3}	x	0.1	=	0.03
1,2,3,4,6,7,8-HpCDF	{0.4}	x	0.01		0.004
1,2,3,4,7,8,9-HpCDF	{0.5}	x	0.01	=	0.005
1,2,3,4,6,7,8,9-OCDF	{1.5}	x	0.0001	=	0.00015

Total WHO Dioxin TEFs for Humans	TEQ	0.4 pg/g
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{...} indicates that the value is that of a Detection Limit.

Cargill, Health & Food Technologies

TLI Project: 63144Ar1
Client Sample: P12110204

Toxicity Equivalents Report
Analysis File: S041855

Client Project:	DIOXIN & PCB TESTING	Date Received:	05/21/04	Spike File:	SP161B2S
Sample Matrix:	SOLID	Date Extracted:	05/27/04	ICal:	SF5129B
TLI ID:	383-46-4	Date Analyzed:	06/02/04	ConCal:	SB41841
Sample Size:	10.020 g	Dilution Factor:	1	% Moisture:	n/a
Dry Weight:	n/a	Blank File:	S041851	% Lipid:	n/a
GC Column:	DB-5	Analyst:	JSY	% Solids:	n/a

Analytes	Conc. (pg/g)	TEF	Equivalent
2,3,7,8-TCDD	{0.09}	x =	0.09
1,2,3,7,8-PeCDD	{0.1}	x 1. =	0.1
1,2,3,4,7,8-HxCDD	{0.2}	x 0.1 =	0.02
1,2,3,6,7,8-HxCDD	{0.1}	x 0.1 =	0.01
1,2,3,7,8,9-HxCDD	{0.2}	x 0.1 =	0.02
1,2,3,4,6,7,8-HpCDD	{0.3}	x 0.01 =	0.003
1,2,3,4,6,7,8,9-OCDD	{2.0}	x 0.0001 =	0.00020
2,3,7,8-TCDF	{0.06}	x 0.1 =	0.006
1,2,3,7,8-PeCDF	{0.06}	x 0.05 =	0.003
2,3,4,7,8-PeCDF	{0.07}	x 0.5 =	0.04
1,2,3,4,7,8-HxCDF	{0.07}	x 0.1 =	0.007
1,2,3,6,7,8-HxCDF	{0.07}	x 0.1 =	0.007
2,3,4,6,7,8-HxCDF	{0.09}	x 0.1 =	0.009
1,2,3,7,8,9-HxCDF	{0.2}	x 0.1 =	0.02
1,2,3,4,6,7,8-HpCDF	{0.2}	x 0.01 =	0.002
1,2,3,4,7,8,9-HpCDF	{0.3}	x 0.01 =	0.003
1,2,3,4,6,7,8,9-OCDF	{0.9}	x 0.0001 =	0.00009

Total WHO Dioxin TEFs for Humans	TEQ	0.3 pg/g
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{...} indicates that the value is that of a Detection Limit.

Cargill, Health & Food Technologies

TLI Project: **63144Ar1**
 Client Sample: **Blank**

Toxicity Equivalents Report
 Analysis File: **S041851**

Client Project:	DIOXIN & PCB TESTING		
Sample Matrix:	SOLID	Date Received:	05/21/04
TLI ID:	Blank	Date Extracted:	05/27/04
		Date Analyzed:	06/02/04
Sample Size:	10.000 g	Dilution Factor:	1
Dry Weight:	n/a	Blank File:	S041851
GC Column:	DB-5	Analyst:	JSY
		Spike File:	SP161B2S
		ICal:	SF5129B
		ConCal:	SB41841
		% Moisture:	n/a
		% Lipid:	n/a
		% Solids:	n/a

Analytes	Conc. (pg/g)		TEF		Equivalent
2,3,7,8-TCDD	{0.2}	x	1	=	0.2
1,2,3,7,8-PeCDD	{0.08}	x		=	0.08
1,2,3,4,7,8-HxCDD	{0.07}	x	0.1	=	0.007
1,2,3,6,7,8-HxCDD	{0.06}	x	0.1	=	0.006
1,2,3,7,8,9-HxCDD	{0.07}	x	0.1	=	0.007
1,2,3,4,6,7,8-HpCDD	{0.09}	x	0.01	=	0.0009
1,2,3,4,6,7,8,9-OCDD	0.42	x	0.0001	=	0.000042
2,3,7,8-TCDF	{0.1}	x	0.1	=	0.01
1,2,3,7,8-PeCDF	{0.06}	x	0.05	=	0.003
2,3,4,7,8-PeCDF	{0.06}	x	0.5	=	0.03
1,2,3,4,7,8-HxCDF	{0.05}	x	0.1	=	0.005
1,2,3,6,7,8-HxCDF	{0.05}	x	0.1	=	0.005
2,3,4,6,7,8-HxCDF	{0.04}	x	0.1	=	0.004
1,2,3,7,8,9-HxCDF	{0.05}	x	0.1	=	0.005
1,2,3,4,6,7,8-HpCDF	{0.05}	x	0.01	=	0.0005
1,2,3,4,7,8,9-HpCDF	{0.07}	x	0.01	=	0.0007
1,2,3,4,6,7,8,9-OCDF	{0.2}	x	0.0001	=	0.00002

Total WHO Dioxin TEFs for Humans	TEQ	0.4 pg/g
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{...} indicates that the value is that of a Detection Limit.

Prepared for: Cargill, Health & Food Technologies
Reference ID: DIOXIN & PCB TESTING

Project Summary 63144B

Method 1668

Concentrations shown in pg/g

	Blank	P11809304	P11909604	P12009904
Analytes				
3,4,4',5-TetraCB (#81)	< 8.7	< 16.8	< 22.6	< 21.0
3,3',4,4'-TetraCB (#77)	< 9.1	< 17.7	< 23.8	< 22.2
2',3,4,4',5-PentaCB (#123)	< 14.3	< 57.6	< 73.3	< 97.7
2,3',4,4',5-PentaCB (#118)	67.2 J	< 56.6	< 72.1	< 96.1
2,3,4,4',5-PentaCB (#114)	< 14.7	< 59.3	< 75.5	< 101
2,3,3',4,4'-PentaCB (#105)	< 16.3	< 65.9	< 84.0	< 112
3,3',4,4',5-PentaCB (#126)	< 19.7	< 79.5	< 101	< 135
2,3',4,4',5,5'-HexaCB (#167)	< 22.9	< 161	< 196	
2,3,3',4,4',5-HexaCB (#156)	< 25.8	< 181	< 220	
2,3,3',4,4',5-HexaCB (#157)	< 25.0	< 175	< 214	
3,3',4,4',5,5'-HexaCB (#169)	< 35.6	< 250	< 305	
2,3,3',4,4',5,5'-HeptaCB (#189)	< 24.2	< 212	< 229	< 396
Extraction Date	5/26/2004	5/26/2004	5/26/2004	5/26/2004
Analysis Date	6/3/2004	6/3/2004	6/3/2004	6/3/2004
Primary Filename	W095101	W095102	W095103	W095104
Confirm Filename	N/A	N/A	N/A	N/A
Dilution Filename	N/A	N/A	N/A	N/A

mcw 8/11/04

Data Flag Descriptions:
< Not detected -Sample Specific Detection Limits reported
[.] EMPC Value
B Analyte detected in Blank

C Value reported from Confirmatory Analysis
D Value reported from Dilution Analysis
E Estimated Value - Above Calibration Range
J Estimated Value- Below Calibration Range

N/A Not Applicable
Q Quantitative Interference Present
S Analyte saturated
X Interference from Diphenyl Ethers

Prepared for: Cargill, Health & Food Technologies
Reference ID: DIOXIN & PCB TESTING

Project Summary 63144B

Method 1668

Concentrations shown in pg/g

P12110204

Analytes

3,4,4',5-TetraCB (#81)	< 27.6
3,3',4,4'-TetraCB (#77)	< 29.1
2',3,4,4',5-PentaCB (#123)	< 35.7
2,3',4,4',5-PentaCB (#118)	< 35.1
2,3,4,4',5-PentaCB (#114)	< 36.7
2,3,3',4,4'-PentaCB (#105)	< 40.9
3,3',4,4',5-PentaCB (#126)	< 49.3
2,3',4,4',5,5'-HexaCB (#167)	
2,3,3',4,4',5-HexaCB (#156)	
2,3,3',4,4',5'-HexaCB (#157)	
3,3',4,4',5,5'-HexaCB (#169)	
2,3,3',4,4',5,5'-HeptaCB (#189)	< 272

Extraction Date	5/26/2004
Analysis Date	6/3/2004
Primary Filename	W095105
Confirm Filename	N/A
Dilution Filename	N/A

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summary 2

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