

APPENDIX 1

- **DRT Technical Specification**
- **DRT Typical nutritional value**
 - **ITERG analytical report**



BETA SITOSTEROL

Nature

Mixture of plant sterols or PHYTOSTEROLS,
extracted from pine species.

Based on a very selective extraction, it is characterised by high purity and a constant quality. Due to its high percentage in Beta Sitosterol, the material is in accordance with European pharmacopeia.

Typical values

Aspect : White powder

Sterol title % (typical value) : 99

Typical chromatography pattern % :

Beta Sitosterol	75	Campesterol	10
Beta Sitostanol	11	Campestanol	2
Others sterols	3		

Specifications and analytical methods are available on request

Uses

The applications of Beta Sitosterol are very diverse :

Human pharmacy : Treatment against hypercholesterolaemia and prostatic adenoma.

Cosmetology : Its physicochemical properties make it a very good emulsifier. It has also an anti-inflammatory action on skin, valuable for formulators.

Dietetics : in diet foods against hypercholesterolaemia.

Tracing agent : In animal fats and industrial butters.

Synthesis : human steroid hormones and vegetal growing factors.

30, rue Gambetta - BP 206 - 40105 DAX Cédex (France)

Tel : + 33(0)5 58 56 62 00 - Fax : + 33(0)5 58 56 62 40

Web : <http://www.drt-france.com> / E-mail : drtsales@drt.fr



BETA SITOSTEROL

Other technical data

Raw formula : C₂₉ H₅₀ O
Molecular weight : 414
Melting point (°C) : 139 - 142
Desiccation loss (%) : < 3.5
Optical rotation (α)_D : - 24 to - 32° in a 2 % chloroform solution
Sulphuric ashes (%) : < 0.1
Solubility : Insoluble in water, slightly soluble in ethanol, soluble in chloroform, ether and carbon disulphide.

Regulatory status

N° CAS : 68555-08-8
N° EINECS : 271-413-3
TSCA registered
Kosher Certificate from BDP N° 6409156
N° CAS : 83-46-5
N° EINECS : 201-480-6
INCI registered
TSCA not registered

Customs tariff

29 06 13

Packaging

Available in packing of 20 kg and by pallets of 300 kg net.

Storage conditions

Room temperature in dry place.

Stability

Stable for 2 years under normal conditions of temperature, in its original sealed packaging.

Revision : 4

Date : 01/07/2005

The data herein are based on our knowledge about above product. They are without conditions or warranties, expressed or implied regarding the uses of the product.



LES DERIVES RESINIQUES ET TERPENIQUES

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BETA SITOSTEROL

It is a mixture of phytosterols extracted from pine trees.

TYPICAL NUTRITIONAL VALUE ON DRY MATTER

General composition :

Proteins	traces
Lipids	< 1 %
Carbohydrates	traces
Sterols	> 99 %
Minerals	traces

Sterol composition (%) :

Beta Sitosterol	75
Beta Sitostanol	11
Campesterol	10
Campestanol	2
Other minor sterols	3

DRT/June - 2005/Revision 1



INSTITUT DES CORPS GRAS
CENTRE TECHNIQUE INDUSTRIEL

Donneur d'Ordre :
DERIVES RESINIQUES ET
TERPENIQUES
A l'attention de M. Y. PIRIOU
Ingénieur R & D
40560 VIELLE-SAINT-GIRONS

Pessac,
Le 12 décembre 2002

v/réf. : Commande n°6711 du 11 décembre 2002
n/réf. : CP A 624/12/02 - [PR A 147/09/02]

RAPPORT D'ANALYSE

Dossier suivi par : Jean-Louis COUSTILLE

Méthodes :

→ DETERMINATION DE LA COMPOSITION DE LA FRACTION STEROLIQUE (D'APRES NF ISO 6799)
- DETERMINATION DE LA TENEUR EN STEROLS TOTAUX

ECHANTILLONS

Nature : STEROL CRISTALLISE PURIFIE (1)
Références : BETA-SITOSTEROL LOT 21036
Date de réception : 04 décembre 2002
Préparation : -

L'Institut des Corps Gras engage sa responsabilité pour ce qui est de la bonne conduite des essais qu'il réalise et l'exactitude des résultats qu'il fournit quant aux matières d'œuvre (contenus) analysées.
Il ne peut porter aucun avis sur l'authenticité des références, dénominations et emballages (contenants) des échantillons remis par le Donneur d'Ordre, mentions reprises dans les bulletins d'analyse seulement pour désigner lesdits échantillons.

L'accréditation du COFRAC atteste de la compétence des laboratoires pour les seuls essais couverts par l'accréditation, qui sont identifiés par le symbole (*).
La reproduction de ce rapport d'essai n'est autorisée que sous sa forme intégrale.
Ce rapport d'essai ne concerne que les objets soumis à l'essai.
Les résultats des déterminations COFRAC (*) sont accompagnés des incertitudes de mesure. Elles sont précisées en italique, directement dans le tableau de résultats ou reportées en annexe.

Il comporte 2 pages et 0 annexe.

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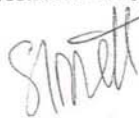
RESULTATS

**Composition (%) et Teneur (g/100g) en stérols
Beta sitostérol lot 21036**

STEROLS	%
CHOLESTEROL	0,1
BRASSICASTEROL	<0,1
24 METH. CHOLESTEROL	<0,1
CAMPESTEROL	8,8
CAMPESTANOL	1,4
STIGMASTEROL	0,2
Δ 7 CAMPESTEROL	0,5
Δ 5,23 STIGMASTADIENOL CLEROSTEROL	0,5
B SITOSTEROL	74,1
STIGMASTANOL	12,8
Δ 5 AVENASTEROL	0,2
Δ 5,24 STIGMASTADIENOL	0,3
Δ 7 STIGMASTEROL	0,4
Δ 7 AVENASTEROL	0,2
non identifié	0,5

Teneur (g/100g) en stérols totaux	100,0
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Le Responsable du Département
Prestations Analytiques



Stéphane MAZETTE

Le Directeur Général



Frédéric STAAT

APPENDIX 2

Manufacturing process



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BETA SITOSTEROL

BETA SITOSTEROL produced by DRT is exclusively extracted from pine species, mainly **Pinus pinaster**. It is in accordance with European legislation for use in food products.

The manufacturing process allows to extract **10 % of Beta Sitosterol from Tall oil**.

It includes 3 major steps :

1 – Extraction

The tall oil pitch is extracted at pH > 7 to obtain primary Beta Sitosterol crystals. The extraction solvent is a hydrocarbon solvent derived from petrol. These crystals are washed thoroughly with water in order to remove tall oil impurities, which are water soluble.

2 – Crystallisation

The primary Beta Sitosterol crystals are then redissolved and methanol is used to recrystallise the product. After cooling, the pure crystals of Beta Sitosterol are recovered by filtration.

3 – Drying

The recrystallised Beta Sitosterol is dried under vacuum milled and sieved to obtain pure crystalline Beta Sitosterol.

The process of extraction allows to obtain sterols of high purity.

No tall oil residues, terpenes, terpene alcohols, resins or resinic acids or any oxidized tall oil have been ever found. These compounds would appear on the GC chart.

The composition of Beta Sitosterol is as following :

	%
Phytosterol content	99
Beta Sitosterol	70 – 80
Beta Sitostanol	10 – 15
Campesterol	8 – 11
Campestanol	1 – 4
Total major sterols	> 95
Other minor sterols	< 3
Water	< 2

The composition of the minor sterols is : Stigmasterol, Delta 7 stigmasterol, Brassicasterol, Delta 5 avenasterol, Delta 7 avenasterol, Campestadiene, Sitostadiene (dehydrated form of campesterol and sitosterol).

JL. ASSOUD
TERPENES AND NATURAL PRODUCTS
June, 2005

APPENDIX 3

STEROL PURITY: Analytical results on one year period

Fabrication	Sterol purity		Fabrication	Sterol purity
19/04/04	99.6		30/07/04	99.8
28/04/04	99.9		02/08/04	99.5
07/05/04	99.8		02/08/04	100
10/05/04	100		02/08/04	100
12/05/04	100		03/08/04	100
14/05/04	99.4		03/08/04	99
17/05/04	99.9		04/08/04	99.6
17/05/04	99.4		14/09/04	99.8
19/05/04	99.6		14/09/04	98.7
19/05/04	100		14/09/04	98.6
24/05/04	100		15/09/04	97.4
24/05/04	99.8		16/09/04	98.1
27/05/04	100		16/09/04	98.6
28/05/04	99.7		17/09/04	100
01/06/04	100		27/09/04	100
01/06/04	98.7		27/09/04	99.9
04/06/04	99.5		27/09/04	100
07/06/04	100		27/09/04	100
11/06/04	100		27/09/04	100
11/06/04	100		27/09/04	100
14/06/04	100		28/09/04	99
16/06/04	100		28/09/04	99.1
18/06/04	100		30/09/04	100
21/06/04	100		04/10/04	100
23/06/04	99.2		04/10/04	100
23/06/04	100		04/10/04	98.5
28/06/04	99.6		04/10/04	99.4
28/06/04	99.5		06/10/04	100
29/06/04	97.9		06/10/04	100
30/06/04	99.9		07/10/04	99.4
02/07/04	99.9		08/10/04	100
04/07/04	99.9		11/10/04	98.3
04/07/04	99.7		11/10/04	100
07/07/04	98.3		11/10/04	100
12/07/04	99.4		13/10/04	99.5
12/07/04	98.9		13/10/04	98.9
12/07/04	100		14/10/04	99.7
12/07/04	98.9		14/10/04	100
16/07/04	100		15/10/04	99.9
19/07/04	100		18/10/04	98.7
19/07/04	99.6		19/10/04	100
22/07/04	100		20/10/04	98.3
22/07/04	100		20/10/04	100
23/07/04	99.2		22/10/04	99.5
23/07/04	98.5		22/10/04	99.8
26/07/04	98.7		25/10/04	99.7
26/07/04	98		25/10/04	100
26/07/04	97.3		26/10/04	99.8
27/07/04	97.8		26/10/04	99.8
29/07/04	99.1		27/10/04	98.9
29/07/04	98.6		28/10/04	100

29/10/04	100
29/10/04	99.7
01/11/04	99.8
01/11/04	99.2
03/11/04	99.3
03/11/04	98.9
05/11/04	99.7
05/11/04	97.6
08/11/04	99.2
08/11/04	99.7
09/11/04	99.2
10/11/04	100
12/11/04	98.5
15/11/04	100
18/11/04	99.1
19/11/04	100
22/11/04	100
22/11/04	100
23/11/04	99.2
24/11/04	100
25/11/04	100
26/11/04	99.3
29/11/04	99.5
29/11/04	99.4
29/11/04	98.1
01/12/04	99.2
03/12/04	98.8
03/12/04	99.1
08/12/04	100
07/12/04	99
08/12/04	97.1
10/12/04	97.9
13/12/04	99.4
13/12/04	98
15/12/04	98.1
15/12/04	98.4
17/12/04	96.7
20/12/04	98.7
20/12/04	96.8
20/12/04	98.8
13/01/05	98.4
17/01/05	98.2
17/01/05	98.9
18/01/05	98.3
19/01/05	99.1
21/01/05	98.8
25/01/05	99
25/01/05	98.1
31/01/05	99.4
31/01/05	98.8
31/01/05	99.2
02/02/05	98.4
02/02/05	99.7

04/02/05	97.6
07/02/05	99.6
09/02/05	99.2
09/02/05	99.3
09/02/05	98.9
11/02/05	99.4
14/02/05	98.8
14/02/05	97.7
14/02/05	98.5
16/02/05	98.6
17/02/05	99.8
21/02/05	99.3
21/02/05	99.4
23/02/05	98.3
23/02/05	98.8
24/02/05	100
25/02/05	99.1
25/02/05	98.6
28/02/05	99.4
02/03/05	99.2
02/03/05	99.1
03/03/05	98.7
04/03/05	100
07/03/05	99.7
09/03/05	99.2
09/03/05	97.6
10/03/05	98.6
11/03/05	99.2
15/03/05	99.9
16/03/05	99.8
17/03/05	98.9
18/03/05	99.6
21/03/05	99.3
21/03/05	100
22/03/05	99.8
23/03/05	100
25/03/05	100
29/03/05	99.4
29/03/05	99.7
29/03/05	99.4
30/03/05	99.4
30/03/05	100
01/04/05	99.1
01/04/05	100
04/04/05	100
04/04/05	98.9
05/04/05	100
06/04/05	100
07/04/05	99
08/04/05	99.1
11/04/05	98.6
11/04/05	100
11/04/05	100

04/02/05	98.8
13/04/05	99.5
15/04/05	99.1
18/04/05	98.8
18/04/05	100
20/04/05	99.7
21/04/05	100
25/04/05	100
25/04/05	100
25/04/05	100
27/04/05	99.8
28/04/05	100
29/04/05	100
29/04/05	99.7
02/05/05	100
04/05/05	100
06/05/05	99.9
06/05/05	99.4
08/05/05	100
09/05/05	100
10/05/05	99.4
10/05/04	99.4
10/05/04	97.5
12/05/04	99.9
17/05/04	100
04/06/04	99.5
07/06/04	100
18/06/04	99.1
18/06/04	100
21/06/04	100
21/06/04	100
02/07/04	99.4
04/07/04	100
07/07/04	100
07/07/04	99.8
12/07/04	99
28/09/04	99.7
28/09/04	98.8
28/09/04	99.3
28/09/04	99.2
30/09/04	99.7
15/11/04	99.4
15/11/04	99.5
14/12/04	99.5
25/01/05	98
28/01/05	100
17/02/05	99.4
17/02/05	99.3
18/02/05	98.6
18/02/05	99.6
21/02/05	100
02/03/05	99.2
02/03/05	100

13/04/05	100
09/03/05	100
09/03/05	100
11/03/05	100
11/03/05	99.2
13/03/05	98.4
15/03/05	99.2
16/03/05	99.6
13/04/05	100
18/04/05	99.4
18/04/05	100
18/04/05	99
20/04/05	99.8
21/04/05	99.3
21/04/05	100
21/04/05	100
22/04/05	99.8
25/04/05	100
25/04/05	100
26/04/05	100
26/04/05	100
02/05/05	100
02/05/05	100
02/05/05	100
04/05/05	98.5
29/06/04	100
05/05/04	100
12/05/04	100
17/05/04	100
21/05/04	98.6
24/05/04	100
26/05/04	99.3
26/05/04	100
01/06/04	100
01/06/04	99.8
14/06/04	98.4
18/06/04	99.1
19/07/04	99.8
19/07/04	98.8
30/09/04	98
18/10/04	100
22/02/05	100
14/03/05	100
23/03/05	99.5
23/03/05	100
06/05/05	98.5
14/01/04	98.7
16/03/04	99.7
16/03/04	96.6
18/06/04	100
06/12/04	98.8
06/12/04	99.3
06/12/04	99.2

07/03/05	100	25/04/05	99.3
07/03/05	99		
Mean	99.3851735		
Mean (rounded)	99.4		
Standard deviation	0.703293148		
Number of samples	317		
Nber samples >= 99	245		
% samples >= 99%			
purity	77.3		

