



LES DERIVES RESINIQUES ET TERPENIQUES

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**FOOD STANDARD AGENCY
ROOM 515B
AVIATION HOUSE
125 KINGSWAY
LONDON WC2B 6NH
GRANDE BRETAGNE**

Dax, 29 August 2006

O/ref. : JLA/FCD

Re. Pine Phytosterols

Dear Sirs,

DRT produces since more than 40 years pine phytosterols, sold in the market under the trade name : BETA SITOSTEROL.

On the 20th of December 2005, the ACNFP has given a positive opinion to Primapharm BV, about its phytosterol ingredient. Primapharm BV has notified the European commission, about its intention to market its phytosterols.

The producer DRT of the phytosterols marketed by Primapharm is as indicated in the technical part of the application of Primapharm BV. Primapharm BV is currently distributing our pine phytosterols in Europe.

We have compiled following information for your prompt review :

- ✓ Final opinion Primapharm BV
- ✓ Technical data sheet of BETA SITOSTEROL
- ✓ Page 5 of the application of Primapharm showing DRT as the supplier
- ✓ Invoices DRT-06-02389 and 06-02455 showing that Primapharm BV has purchased 2700 kg of pine phytosterols. These invoices have been paid by our customer on due issues.
- ✓ The labels under which the product will be marketed throughout Europe.

Having regard to the above information, we now seek confirmation that DRT's pine phytosterol is in every respect the same as supplied to Primapharm BV and the same product on which that company based its successful application.

Yours faithfully

JL ASSOUD

Mr M. Jaime Torres
Prima Pharm BV
2514BP Hague
Netherlands

20th December 2005

Reference: NFU 583

[By e-mail]

Dear Mr Torres,

**REQUEST FOR AN OPINION ON THE SUBSTANTIAL EQUIVALENCE OF
PHYTOSTEROLS FROM PRIMA PHARM**

The Advisory Committee on Novel Foods and Processes (ACNFP) has now finalised its assessment of your request for an opinion on the substantial equivalence of phytosterols from Prima Pharm as a food ingredient compared with the existing phytosterols marketed by Teriaka. The phytosterols are to be used in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks and fermented milk products.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, the UK Competent Authority for all novel food issues is content that your phytosterol ingredient meets the criteria for equivalence, as defined in Article 3(4) of Regulation (EC) 258/97.

You should ensure that all products containing phytosterols are marketed and labelled in



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accordance with European Community Law and any relevant national provisions, in particular with regards to (EC) 608/2004.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission of your intention to market your phytosterols when they are first marketed. This notification should be sent (with the UK opinion) to Mr Andreas Klepsch at the following address:

European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium

If you have any other queries please do not hesitate to contact me.

Yours sincerely

Dr Chris Jones
Novel Foods, Additives and Supplements Division

Enc: ACNFP's Opinion

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROLS CONSIDERED UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

Applicant **Prima Pharm BV**
 15, Nieuwe Uitleg
 2514BP Hague
 Netherlands

Responsible Person **Mr M. Jaume Torres**

Introduction

1. A request was submitted by Prima Pharm to the UK competent authority for an opinion on the equivalence of their phytosterols to the phytosterols marketed by Teriaka which were authorised by Commission Decision 2004/336/EC. In July 2004 and October 2004 Teriaka obtained opinions on equivalence from the Finnish competent authority that extended the range of foods that their phytosterol ingredient could be incorporated into. These are, yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks, and fermented milk products. Teriaka notified the Commission of the placing on the market of their products in accordance with Article 5 of regulation (EC) 258/97 on 16 July 2004 and 16 November 2004. Prima Pharm are therefore entitled to seek a view on equivalence for the use of their phytosterol ingredient in each of the food categories included in Teriaka's original authorisation and the two subsequent notifications granted by the Finnish competent authority.
2. According to Article 3(4) of (EC) 258/97, the notification procedure applies to, "foods or food ingredients... which on the basis of scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies.... are substantially equivalent to existing foods or food ingredients as regards their:
 - Composition
 - Nutritional value
 - Metabolism
 - Intended use
 - Level of undesirable substances contained therein."

Composition

3. The Applicant is claiming equivalence to the specification of phytosterols set out in Annex 2 of Commission Decision 2004/336/EC. Prima Pharm obtain their phytosterols from the company les Derives Resiniques et Terpeniques (DRT). It should be noted that the data on DRT's tall oil phytosterols were included in Teriaka's original novel food application, along with data from another supplier of phytosterols derived from vegetable oils. However, although DRT's phytosterols have been through the authorisation process they have not been used by Teriaka since gaining approval.

4. The product produced by the applicant is made from tall oil pitch from *Pinus maritima* (synonym *Pinus pinaster*) a species of pine tree. It is manufactured in the same way as the approved phytosterol product and involves extraction, crystallisation and drying. The specification of the product described by the applicant is consistent with that described in Commission Decision 2004/336/EC.
5. To comply with the conditions set out in Commission Decision 2004/336/EC for phytosterols and phytosteranols extracted from sources other than vegetable oil, all batches of the product will have a purity of more than 99%.

Discussion: *The Committee noted that data provided on the composition of Prima Pharm's phytosterols complied with the specification of phytosterols in Commission Decision 2004/336/EC.*

Nutritional value and metabolism

6. The nutritional value and metabolism of Prima Pharm phytosterols are expected to be the same as those marketed by Teriaka. Anticipated intake of phytosterols is not likely to be increased as the ingredient is to be used in the same range of products already approved.

Intended use

7. The applicant intends the ingredient to be used in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks, and fermented milk products. These products are the same as existing products on the market containing Teriaka phytosterols that were authorised in Commission Decision 2004/336/EC and the two subsequent notifications issued by the Finnish competent authority in July and October 2004.

Discussion: *The Committee is content that the applicant's product is to be consumed at the same level and in the same range of products as the existing product.*

Level of undesirable substances

8. The applicant gave detailed information on the levels of a number of classes of potential contaminants including dioxins, polycyclic hydrocarbons, herbicides, pesticides and heavy metals. All contaminants measured are within acceptable levels in compliance with EU regulations.

Further Information

9. In accordance with the guidelines on substantial equivalence the applicant also submitted data from some studies carried out with DRT's phytosterols. These studies addressed acute toxicity, skin irritation and skin sensitisation. These studies were evaluated as part of the earlier application from Teriaka. No adverse results were reported in any of these studies.

Conclusion

10. The Committee is content that the applicant's approach to demonstrating the equivalence of their phytosterols with the existing phytosterol ingredient is consistent with the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.
11. Therefore phytosterols marketed by Prima Pharm can be considered to be substantially equivalent to the existing phytosterol ingredient marketed by Teriaka.
12. Prima Pharm should ensure that the labelling of products containing their phytosterols comply with Commission Regulation (EC) 608/2004 concerning the labelling of foods with added phytosterols, and more specifically to Article 2 of this regulation.

December 2005



BETA SITOSTEROL

Nature

Mixture of plant steroids or PHYTOSTEROLS,
extracted from pine species.
Based on a very selective extraction, it is characterised by
high purity and a constant quality.
Sterol composition is in conformity with EEC regulation for food.

Typical values

Aspect : White powder

Sterol title % : 99

Typical chromatography pattern % :

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

Specifications and analytical methods are available on request

Uses

The applications of Beta Sitosterol are very diverse :

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 and nutraceuticals.

Tracing agent : In animal fats and industrial butters.



BETA SITOSTEROL

Other technical data

Raw formula : $C_{29}H_{50}O$

Molecular weight : 414

White index : 65
Melting point (°C) : 139 - 142
Desiccation loss (%) : < 3.5
Sulphuric ashes (%) : < 0.1

Solvent residue : Methanol 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

N° CAS : 83-46-5
N° EINECS : 201-480-6

TSCA registered
Kosher Certificate from BDP

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 : 11

Date : 07/03/06

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.

2-ADMINISTRATIVE INFORMATION

The applicant is:

PRIMA PHARM Bv

15, Nieuwe Uitleg
2514BP Hague
Netherlands

Tel: + 31 703 640 900

Fax: + 31 703 635 795

Contact Person: M. Jaume Torres
jaumetorres@prima-pharm.com

The supplier of Prima Pharm's product is:

Les Dérivés Résiniques et Terpéniques (DRT)

30 rue Gambetta BP206
40105 DAX Cedex (France)

Tel + 33 5 58 56 62 00

Fax + 33 5 58 56 62 40

Prima Pharm's product is manufactured by DRT under the brand name of « Beta Sitosterol ».

3-COMPOSITION

The Prima Pharm's phytosterol is isolated from tall oil from *Pinus maritima L.*

According to SCF opinion⁽⁸⁾, Teriaka proposed to obtain their sterols from Tall oil (*Pinus maritima*) or vegetable oil. *Pinus maritima* (Synonym *Pinus Pinaster*) is a Mediterranean tree and can neither be found in Finland nor in Northern European countries. The biggest forest of *Pinus maritima* is located in the south west of France (Landes) where DRT is based.

According to DRT, the source of Prima Pharm's product ("Beta-Sitosterol" product manufactured by DRT) is also one of the sources of Teriaka's product, reinforcing thus the substantial equivalence claimed.



les dérivés résiniques et terpéniques

30, rue Gambetta - B.P. 206 - 40105 DAX Cedex (FRANCE)
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 Web : <http://www.drt-france.com> - E-mail : ddsales@drt.fr

Société anonyme au
 capital de 13 408 000 euros
 Siret 985 520 154 00016
 R.C.S. Dex
 N° TVA FR 86985520154

FACTURE INVOICE

NUMERO / N°	DATE / DATE	CLIENT N° CUSTOMER N°	O.C. / ORDER N°
F-DRT-06-02389	09/05/2006	4256	OC-DRT-06-02900

LIVRAISON A / DELIVERY TO :

PRIMA PHARM B.V
 C/O LIPOFOODS
 POLIGONO INDUSTRIAL CAMI RAL
 C/GALILEU 17
 08850 GAVA
 ESPAGNE

FACTURATION A / INVOICE TO :

PRIMA PHARM B.V
 NIEUWE UITLEG 15

 2514 BP DEN HAAG
 PAYS BAS

MODE D'ACHEMINEMENT : CAMION PLATEAU
 MEANS OF DELIVERY : LORRY

DESIGNATION PRODUIT GOODS DESCRIPTION	QUANTITE QUANTITY	PRIX UNITAIRE UNIT PRICE	MONTANT HORS TVA AMOUNT EXC VAT
REF. CODE CLIENT / AGENT : FODS/GR/60103 CUSTOMER REF. / AGENT MP00097 BETA SITOSTEROL 60 SAC(S) SUR 4 PALETTE(S) 290613100000N	1 200 KG	EUR / KG	EUR
Exonération TVA, Art 262 TER I du C.G.I. VAT Exemption, Art 262 TER I of C.G.I. Mwst. Befreling, Art. 262 TER I des C.G.I. FR86985520154 NL810170814B01			

CONDITIONS DE FACTURATION : PACKED DDU GAVA
 CONDITIONS OF SALES

CONDITIONS DE PAIEMENT : VIREMENT BANCAIRE SWIFT à 60 jours net
 CONDITIONS OF PAYMENT : SWIFT BANK TRANSFER et 60 days from invoice date

ECHEANCE PAIEMENT : 08/07/2006
 DATE OF PAYMENT

DOMICILIATION BANCAIRE : BNP DAX
 BANK DETAILS

NET A PAYER TOTAL AMOUNT TO PAY
EUR



les dérivés résiniques et terpéniques

30, rue Gambetta – B.P. 206 – 40105 DAX Cedex (FRANCE)
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Société anonyme au
capital de 13 408 000 euros
Siret 985 520 154 00016
R.C.S. Dax
N° TVA FR 86985520154

FACTURE INVOICE

NUMERO / N°	DATE / DATE	CLIENT N° CUSTOMER N°	O.C. / ORDER N°
F-DRT-06-02455	12/05/2006	4256	OC-DRT-06-00781

LIVRAISON A / DELIVERY TO :

PRIMA PHARM B.V
C/O LIPOFOODS
POLIGONO INDUSTRIAL CAMI RAL
C/GALILEU 17
08850 GAVA
ESPAGNE

FACTURATION A / INVOICE TO

PRIMA PHARM B.V
NIEUWE UITLEG 15

2514 BP DEN HAAG
PAYS BAS

MODE D'ACHEMINEMENT : CAMION PLATEAU
MEANS OF DELIVERY LORRY

DESIGNATION PRODUIT GOODS DESCRIPTION	QUANTITE QUANTITY	PRIX UNITAIRE UNIT PRICE	MONTANT HORS TVA AMOUNT EXC VAT
REF. CDE CLIENT / AGENT : FODSGR / 60032 CUSTOMER REF. / AGENT MP00097 BETA SITOSTEROL 75 SAC(S) SUR 5 PALETTE(S) 29061310000N	1 500 KG	EUR	EUR
Exonération TVA, Art 262 TER I du C.G.I. VAT Exemption, Art 262 TER I of C.G.I. Mwst. Befreiung, Art. 262 TER I des C.G.I. FR86985520154 NLB10170814B01			

CONDITIONS DE FACTURATION : LOGE DDU BARCELONA
CONDITIONS OF SALES

CONDITIONS DE PAIEMENT : VIREMENT BANCAIRE COMPTANT
CONDITIONS OF PAYMENT BANK TRANSFER cash

ECHEANCE PAIEMENT : 12/05/2006
DATE OF PAYMENT

COORDONNEES BANCAIRES : BNP DAX
BANK DETAILS

BIC	IBAN	Banque Bank	Guichet Sort code	N° Compte Account N°	Clé Key

NET A PAYER
TOTAL AMOUNT TO PAY

EUR

Conditions d'escompte pour règlement antérieur aux conditions générales de vente au verso : Taux de base bancaire en vigueur le jour du paiement.
Conditions of discount for anticipated payment outside general conditions of sales : French legal rate in force at the date of payment.

COPIE A / COPY TO :



1-00020185

BETA-SITOSTEROL

S122/BOX121/P995/FILM C/INT984

PROD 008100

BRUT APPROX.: 321,5 KG

TARE APPROX.: 21,5 KG

LOT 047137

NET 300 KG



1-00020185

BETA-SITOSTEROL

S122/BOX121/P995/FILM C/INT984

PROD 008100

BRUT APPROX.: 321,5 KG

TARE APPROX.: 21,5 KG

LOT 047137

NET 300 KG