Notification Number: 2010/21/F

Pro Pharmacopoeia technical notes subject to public inquiry (texts attached) N° 1200: Mould for allergen products N° 1201: Bonain's Mixture N° 1202: Lead (acetate) trihydrate N° 1203: Lead (monoxyde) N° 1204: Potion gommeuse N° 1205: Basic lead acetate solution N° 1206: Basic lead acetate suspension for veterinary usage N° 1207: Grosso lavender essential oil (Rev. 10th)

Date received : 11/01/2010 End of Standstill : 12/04/2010

# Message

Message 002

Communication from the Commission - SG(2010) D/50084

Directive 98/34/EC

Translation of the message 001

Notification: 2010/0021/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Мääräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201000084.EN)

#### 1. Structured Information Line

MSG 002 IND 2010 0021 F EN 12-04-2010 11-01-2010 F NOTIF 12-04-2010

## 2. Member State

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## 3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot – 75572 Paris Cedex 12 d9834.france@finances.gouv.fr

tél: 01 53 44 98 24 - fax: 01 53 44 98 88

## 3. Originating Department

Agence française de Sécurité Sanitaire des Produits de Sante – DLC/Unité Pharmacopée – 143-147, boulevard Anatole France – F-93285 SAINT-DENIS CEDEX pharmacopeefrançaise@afssaps.sante.fr tél. 01 55 87 41 41 – fax. 01 55 87 41 32

#### 4. Notification Number

2010/0021/F - C30P

#### 5. Title

Pro Pharmacopoeia technical notes subject to public inquiry (texts attached)

N° 1200: Mould for allergen products

N° 1201: Bonain's Mixture

N° 1202: Lead (acetate) trihydrate

N° 1203: Lead (monoxyde)

N° 1204: Potion gommeuse

N° 1205: Basic lead acetate solution

N° 1206: Basic lead acetate suspension for veterinary usage

N° 1207: Grosso lavender essential oil (Rev. 10th)

## 6. Products Concerned

Draft monographs

#### 7. Notification Under Another Act

-

## 8. Main Content

French pharmacopoeia, 10th edition. The texts will be published by Order in the Official Journal of the French Republic with the wording: "In view of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, and in particular Notification No. ..."

#### 9. Brief Statement of Grounds

-

## 10. Reference Documents - Basic Texts

-

# 11. Invocation of the Emergency Procedure

NO
12. Grounds for the Emergency
13. Confidentiality NO
14. Fiscal measures NO
15. Impact assessment -
16. TBT and SPS aspects
TBT aspect a) NO b) i°) The draft is not a technical regulation or a compliance evaluation procedure, in the sense of Annex 1 to the TBT Agreement
SPS aspect a) NO b) i°) The draft is not a sanitary or phytosanitary measure, in the sense of Annex A to the SPS Agreement.
Catherine Day Secrétaire général Commission européenne
Point de contact Directive 98/34 Fax: (32-2) 296 76 60 email: dir83-189-central@ec.europa.eu
sent to:
Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1 Frau MARKL Iris
Työ- ja elinkeinoministeriö Ms. Leila Vilhunen



Malta standards Authority Sarah Jane Meli

Kommerskollegium Ms Gunnel Fälth

Office of standards, metrology & Testing Kralikova Dana

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BundesMinisterium für Wirtschaft und Technologie (Referat EB2) Frau Kathrin Lettgen

Représentation Permanente de la France

.

Ministerio dell'industria Sr. CASTIGLIONI Enrico

Ministry of Economy Dept for Economic Regulations Mrs Barbara H. Kozlowska

Ministry of Economy and Commerce Division for Internal Market Catalina Groza

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1 Frau Brigitte WIKGOLM

Représentation Permanente de la Belgique auprès de l'Union européenne

.

Ministerio de Asuntos Exteriores y Coop. DG de Coordinación del Mercado Interior Juan Carlos Calvo Huerta

Min. of Economic Affairs & Communication Mr. Karl Stern

Délégation Interministérielle aux Normes Mme PORTOU-DUPIN

Min. of Industry, Energy & Technology Mr K. Polychronidis

CU N Lovseth Hanne Leen

.

Ministerie van Financiën Belastingsdienst - Douane Noord / CDIU De Heer IJ.G. van der Heide

Instituto Portugês da Qualidade Sra Eng<sup>a</sup>. Anete Freitas

Bundesministerium für Wirtschaft und Bund Arbeit - Abteilung C2/1

Franz BORTH

Institut Belge de Normalisation

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**European Free Trade Association** 

Mr. Robert Murphy

EU internal market coordination (Ministry of Economics)

Mr. Dainis Matulis

BELNotif (Qualité et Sécurité) SPF Economie, PME, Classes moyennes, Energ

M. Paul Caruso

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M. Antonis Ioannou

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Mr Philip Plumb

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1



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Institut luxembourgeois de la normalisat (ILNAS) Mr Manuel Turmes
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Représentation Permanente du Luxembourg .
Office of standards, metrology & Testing Director of the department of European I Mrs Kvetoslava STEINLOVA
sent to :
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Malta standards Authority Sarah Jane Meli
Ministry of Economy and Commerce Division for Internal Market Catalina Groza
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European Free Trade Association Mr. Robert Murphy
AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena Mª Luisa Aguilar Zambalamberri



# EUROPEAN COMMISSION GROWTH DIRECTORATE-GENERAL

Single Market for goods Prevention of Technical Barriers

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Undersecretariat of Foreign Trade General Directorate of Standardisation Mr Mehmet COMERT

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