



25 August 2015

(15-4284)

Page: 1/2

Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Notifying Member: <u>ARGENTINA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, ANMAT (National Drug, Food and Medical Technology Administration) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: National enquiry point
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Chemical substances
5.	Title, number of pages and language(s) of the notified document: Sustancias químicas: gamma butirolactona (GBL) y cloruro de etilo (Chemical substances: gamma-butyrolactone (GBL) and ethyl chloride) (2 pages, in Spanish)
6.	Description of content: The substances gamma-butyrolactone (GBL) and ethyl chloride have been included in the latest update of the "Lists of narcotic drugs, psychotropic substances and other substances that may cause physical or psychological dependence". The National Drugs, Food and Medical Technology Administration (ANMAT) has established an authorization system for the importation of gamma-butyrolactone (GBL) and ethyl chloride intended for the production of medicines, food or cosmetics. The sectors of the pharmacy, food and cosmetics industries, which are regulated by National Drugs, Food and Medical Technology Administration (ANMAT), will be able to obtain authorization justifying their lawful use of these substances. The authorization procedure for the importation of gamma-butyrolactone (GLB) will be initiated by the National Food Institute (INAL) or by the National Institute of Medicines (INAME), depending on whether it applies to the food or cosmetics industry. The authorization procedure for the importation of ethyl chloride will be initiated by the National Institute of Medicines (INAME). Both institutes are attached to the National Drugs, Food and Medical Technology Administration (ANMAT). For all cases, the administrative procedures will be dealt with by the Directorate for the Surveillance of Substances Subject to Special Control, attached to the National Institute of Medicines (INAME) which issues the import authorization.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of public health

8.	Relevant documents: Decreto PEN N° 722/1991 (texto actualizado 2015) "Listas de Estupefacientes, Psicotrópicos y demás sustancias susceptibles de producir dependencia física o psíquica, a los efectos establecidos en el último párrafo del artículo 77 del Código Penal" (National Executive Branch Decree No. 722/1991 (text updated in 2015) "Lists of narcotic drugs, psychotropic substances and other substances that may cause physical or psychological dependence, for the purposes laid down in the final paragraph of Article 77 of the Criminal Code")
9.	Proposed date of adoption: 7 August 2015 (Official Journal No. 33188) Proposed date of entry into force: 15 August 2015
10.	Final date for comments:
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: Punto Focal de la República Argentina Dirección Nacional de Comercio Interior Avda. Julio A. Roca 651, Piso 4°, Sector 2 (C1067ABB) Ciudad Autónoma de Buenos Aires Fax: (+54) 11 4349-4072; Tel. (+54) 11 4349-4067 Email: focalotc@mecon.gov.ar Text available at: http://www.puntofocal.gov.ar/formularios/registro_arg10.php https://members.wto.org/crnattachments/2015/TBT/ARG/15_3263_00_s.pdf

" 2015. Arjo BICENTENARY CONGRESS OF THE FREE PEOPLE '
CffiCULARN °

or

OO 6

t

Ministry of

Bless you

•

Presidency la.Nación

I

Import authorization / Decree 772/15

On the 6th of May this year by Decree 772/15 was substituted Annex 1

Decree 299 / 10, including further substances to the list of narcotics for the purpose set out in Article 77 of the Penal Code of Argentina.

Of the 49 substances added by the mentioned decree raises two that under certain uses

,

fall within the lawful scope of the powers of the control referred ANMAT

and control of the quality and safety of products, substances, elements and materials consumed or used in medicine, food and human cosmetics, established by Decree 1490-1492 creation of this Administration.

On one hand, the substance GAMMA BUTffiOLACTONA (GBL) endogenous precursor ACID

Gamma hydroxybutyric acid (GHB). GHB is a substance included in Schedule IV of the Act

Psychotropic 19,303, easily synthesized from GBL by pH change.

The substance GBL has no therapeutic value and therefore has not spread Registration Pharmaceutical product (REM) with the active ingredient to date. Nevertheless, it has licit use as a flavoring and flavoring in food industry

Y

in cosmetics

(ANMAT powers according art.3 subsection b) and c) Decree 1490/92 respectively).

Furthermore, ethyl chloride, could be used as a topical anesthetic in the pharmaceutical aerosol; however, the health authority to date has not extended Specialty Medical Registration (REM) any substance with ethyl chloride as a principle active.

Expues.to It is appropriate to frame these substances under a system of licensing import the industry sectors covered by this National Authority

You! ' (+ 54-11)

4340-0800 [http://www.anmat.gov.a r](http://www.anmat.gov.ar) A.rgentina Republic

Medical Products

Av. Belgrano 1480

(CI093AAP)

CABA

INAME

Av. Caseros 2161

(C1264AAD)

CABA

WIRELESS

USA 25

(Cn01AAA)

CABA

See Alsina

Alsina 665/671

(CI087AAI)

CABA

Headquarters

Av. De Mayo 869

(C1084AAD)

CABA

"2015 - year of the Bicentennial of Congress UDDERS PEOPLES "

t

Ministry of

Bless you

Presidency of the Nation

I

they can use it to justify their legal use within the powers of the ANMAT.

In this sense when you try to gamma butyrolactone the authorization process will start,

as applicable to the food industry or cosmetics, for the Desk of the Institute National Food applying the Free Movement of Foodstuffs

.

for industrial use (UPEI), or the Desk of the Foreign Trade

National Institute of Drug Directorate to intervene Surveillance Products

Health import request processed by note, the pending authorization

import ethyl chloride was initiated by the Bureau of the National Institute of Posts Medicines.

Met the formal requirements, in all cases the proceedings shall be sent to the address Surveillance Substances Subject to Special Control under the National Institute of Drugs that issued the Authorization Import / Decree 772/15 within the fields

exclusive competence of the ANMAT (see attached model).
Contact the National Food Institute, the National Institute of medicines,
Surveillance Directorate Health Products, the Directorate General of Customs.
Take to the National Official Register for publication in the Official Gazette.

Autonomous City of Buenos Aires,

O 3 AGO 2015

In9 ROGELIO THE FISH

Admlnl.trsdor

National

ANMAT

You! ' (+ 54-11) 4340-0800 - <http://www.anmat.gov.ar>-

Argentinian republic

Products

Doctors

Av Belgrano 1480 •

(C1093AAP) CABA

INAME

Av. Caseros 2161

(C1264AAD) CABA

WIRELESS

USA 25

(C1101AAA)

CABA

See Alsina

Alsina 665/671

(C1087AAI)

CABA

Headquarters

Av de Mayo 869

(C1084AAD)

CABA

I

I

DECREE 772 115

We certify

for pre, scntc the Ministry of SaluQ. commissioned by the laws of the production controller.

industry, commerce and sale of narcotics and substances p5icotrópicas.

He has authorized of the importacion

GAMMA substances butyrolactone (GBL) YLO ethyl chloride exclusively for applications, "lan

cnmarcados in the area of competitions ANMAT.

Importer.

Exporter:

Fabricante:

Manufactured:

l dt

rt

ro uc or lm or ar:

.-....- -.!1

-

Name

Cantidlld

Shape

Presentation

Total of matter

Total material

—

..

-

..

—

.....

Farmllcéuticfl

based lrima

. orima salt

i

I

Oestinados for:

.-: .-----

----- . . . ----- .---

..--

j

. VI "of income:

—
i

Custom "dc Input:

....

—
Is

autori7J.lción

from

Import You 1

It is valid for] 80

days

Vence:

..:~—

..:~·

· ·,

..:~ J

i With Cerltfj_cado esle refers back! same, making

S11

Lienen cOJlocimienlo that the

1

obligation to report this inslituto when lugger ,, c the goods, indicating. the number of

j

office number medlame lafecha and gluttony losformularios (ificiales desarrallados "lalfin.

I

If not used must be returned to

Sil

to / immediate ulation.

JI

I

Valid for

IIIn

single shipment

—·

·—·

—

·:~:~· . . . ----- L

,

,

,

,

f-----; "" IR-m -.-'-. - "U-d" ", " "1

"O " ir'rt' "T-y._.

"IMPORTANT"

E.lusuario tíenc S presenrar working days to claim the corresponding error, -

Original

Mr. R

LOPEZ

amlnlstrador

National

Tel. (+ 54-11)

43110-; O &.: Rñhttp: //www.anmat.gov.ar '

Argentinian republic

Products

Doctors

Av. Belgrano 1480

(C1093AAP) CABA

INAME

Av Caseros 2161

(C1264AAD)

CABA

WIRELESS

USA 25

(C110 \ AAA)

CABA

See Alsina

Alsina 665/671

(C10S7AAI)

HOME

Headquarters

Av. De Mayo 869

(C10S4AAD), 'CABA