Health Canada / Santé Canada

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no. (given by the issuing regulatory authority): 12245297

1. Name and address of site (including building number, where applicable): Delmar Chemicals Inc./Les Products Chimiques Delmar Inc., 9321 Airlie St., LaSalle, Quebec, H8R 2B2, Canada

2. Manufacturer's licence number(s):[1] 101989

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s):[2]	Activity(ies):[3]
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
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	Chemical synthesis
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	Chemical synthesis
Propinox (J-20)	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis

[1] Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.

[2] Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).

[3] For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.

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Active substance(s):[2]	Activity(ies):[3]
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.[4]

Date of inspection of the plant under (1): Name of inspecting authority if different from the issuing regulatory authority:

- Health Canada inspected the facility on January 17 – 20, 2017

This written confirmation remains valid until January 17, 2020.

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:
Jeanne Mance Building, 13th Floor, 200 Eglantine Driveway, Address Locator #1913-A, Ottawa, Ontario, Canada, K1A 0K9

Name and function of responsible person:
Etienne Ouimette, Director, Health Product Inspection and Licensing, Health Canada

E-mail, Telephone no.:
Etienne.Ouimette@hc-sc.gc.ca
Tel. no.: 613-954-2996

Signature *Date*

MAR 16 2017

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[4] qdefect@ema.europa.eu.

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