



STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)

Substance: Naloxol 3-beta-D-Glucuronide

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled [checked]
Not Controlled [unchecked]

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substance is a derivative of naloxol and included under item 1 of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Nov 22nd 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: "third party information removed as per agreement with applicant"

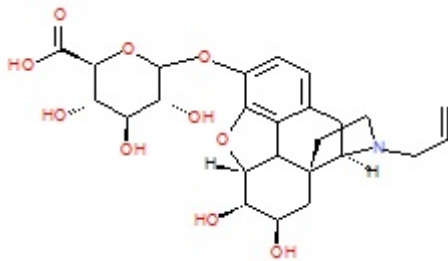
## Drug Status Report

**Drug:** Naloxol 3-beta-D-glucuronide

**Drug Name Status:** Naloxol 3-beta-D-glucuronide is the common name.

**Chemical Name:** (5alpha)-4,5-Epoxy-6,14-dihydroxy-17-(2-propenyl)morphinan-3-yl beta-D-glucopyranosiduronic acid

**Chemical structure:**



**Molecular Formula:**  $C_{25}H_{31}NO_{10}$

**Pharmacological class / Application:** Metabolite of naloxol

**CAS-RN:** 24326-39-4

**International status:**

US: Naloxol 3-beta-D-glucuronide is not listed specifically in the schedules to the US Controlled Substances Act.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Naloxol 3-beta-D-glucuronide is not listed specifically in the CDSA. However, the substance is a metabolite of naloxol<sup>1</sup> which is included under item 1 of Schedule I to the CDSA under the heading "Opium Poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts, including:". Accordingly, the substance must be included under item 1 of Schedule I on the basis that it is a metabolite of naloxol.

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<sup>1</sup>Kumagai, Y. et al. (1990) Stimulation mechanism of guinea pig liver-mediated reduction of naloxone by morphine, *Drug Met. Dis.* **18**:462-466.

**Recommendation:** Naloxol 3-beta-D-Glucuronide is included under item 1 of Schedule I to the CDSA and is a controlled substance.

**Date:** 22 November 2010