



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

Substance: Oxymorphone derivatives

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 substances are derivatives of oxymorphone and therefore included under item 1(29) of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Sept 20th 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:

**I** - 6beta-hydroxy oxymorphone beta-D-glucuronide

**II** - 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide

**III** - Oxymorphone-d3

### Drug Name Status:

**I** - 6beta-hydroxy oxymorphone beta-D-glucuronide

**II** - 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide

**III** - Oxymorphone-d3

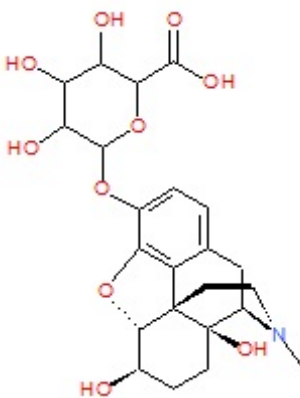
### Chemical Name:

**I** - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one 3-beta-D-glucopyranuronic acid

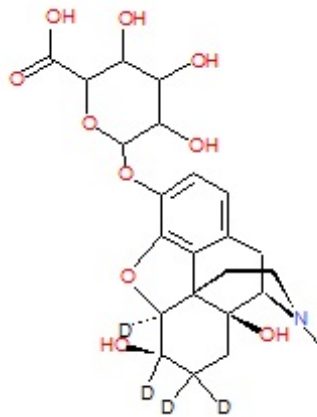
**II** - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one-d4 3-beta-D-glucopyranuronic acid

**III** - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one-d3

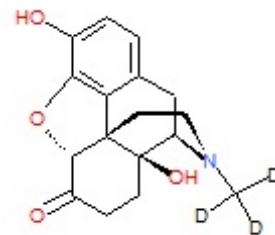
### Chemical structure:



**I**



**II**



**III**

**Molecular Formula:** **I** -  $C_{23}H_{29}NO_{10}$ ; **II** -  $C_{22}H_{25}D_4NO_{10}$ ; **III** -  $C_{21}D_3H_{18}NO_4$

**Pharmacological class / Application:** Pharmaceutical-related substances

**CAS-RN:** NONE

**International status:**

US: The substances are not listed specifically in the Controlled Substances Act and are not mentioned anywhere on the DEA website.

United Nations: The substances are 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: 6beta-hydroxy oxymorphone beta-D-glucuronide is a metabolite of oxymorphone and 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide, the corresponding deuterated form of the substance. Oxymorphone-d3 is a deuterated form of oxymorphone. The substances are not currently listed in the CDSA but oxymorphone is listed as sub-item 29 of item 1 of Schedule I under the heading "Opium Poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts including". Therefore as a metabolite and deuterated forms of oxymorphone, 6beta-hydroxy oxymorphone beta-D-glucuronide, 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide and oxymorphone-d3 are considered to be included under item 1(29) of Schedule I to the CDSA.

**Recommendation:** 6beta-hydroxy oxymorphone beta-D-glucuronide, 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide and oxymorphone-d3 are included under item 10 of Schedule I to the CDSA and are controlled substances.

**Date:** 20 September 2010