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

Substance:  I - Dextromethorphan Impurity C  
            II – Dextromethorphan Impurity D

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

- Controlled ✓
- Not Controlled □

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

- The derivatives of dextromethorphan are not excluded from item 10 of Schedule I to the CDSA.

Prepared by: ____________________________ Date: ________________
Evelyn C Soo

Verified by: ____________________________ Date: ________________
Mark Kozlowski

Approved by: ____________________________ Date: ________________
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Wissam Sader, OCS
Drug Status Report

**Drug:** I - Dextromethorphan Impurity C  
II – Dextromethorphan Impurity D

**Drug Name Status:**  
I - Dextromethorphan Impurity C  
II – Dextromethorphan Impurity D are the common names.

**Chemical Name:**  
I - *ent*-3-methoxy-17-methylmorphinan-10-one  
II - *ent*-(14S)-3-methoxy-17-methylmorphinan

**Chemical structure:**

![Chemical structure image](image-url)

**Molecular Formula:** I - C$_{18}$H$_{23}$NO$_2$, II - C$_{18}$H$_{25}$NO;  
**CAS-RN:** I, II – unknown

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

**International status:**

US: Dextromethorphan Impurity C and Dextromethorphan Impurity D are not listed specifically in the Schedules to the US *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, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances under International Control.

Canadian Status: Dextromethorphan Impurity C and Dextromethorphan Impurity D are not listed specifically in the schedules to the CDSA. The substances are impurities of dextromethorphan and contain the core morphinan structure. Although dextromethorphan is specifically excluded from the CDSA and listed as sub-item 10(10) in Schedule I to the CDSA under the “but not including” heading, the related substances of dextromethorphan are not captured under that provision. Accordingly, the substances must be included under item 10 of Schedule I to the CDSA.
**Recommendation:** Dextromethorphan Impurity C and Dextromethorphan Impurity D included under item 10 of Schedule I to the CDSA and are controlled substances.

**Date:** August 29th, 2012.