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

Substance: 10-hydroxycodeine

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

Controlled  X
Not Controlled  □

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

• The drug is currently not listed on the CDSA. However, item 1 of Schedule I to the CDSA is an inclusive listing of opium derivatives and alkaloids. This section has been interpreted to include a broad range of chemicals similar to the three main opium alkaloids: codeine, morphine and thebaine. In recent years, several substances similar to the title substance have been declared to be controlled substances. These include 14-hydroxycodeine, codeine N-oxide and isocodeine.

Supporting document(s) attached: X

Prepared by: TIANA BRANCH Date: 2005-06-13
Verified by: See email MICHAEL LEBELLE Date: 2005-06-15
Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date: 2005-06-16
Drug Status Report

Drug: 10-Hydroxycodeine

Drug Name Status: 10-Hydroxycodeine is the common name.

Chemical Name: (5a,6a)-7,8-Didehydro-4,5-epoxy-10-hydroxy-3-methoxy-17-methylmorphinan-6-ol

Chemical structure:

\[
\text{\includegraphics{chemical_structure.png}}
\]

Molecular Formula: \(C_{18}H_{21}NO_4\)

Pharmacological class / Application: opiate

International status:

US: The drug is not currently listed on the US Controlled Substances Act (CSA) and is not mentioned on the DEA website. The “analogue”, “narcotic drug” and “opiate” definitions included in the CSA likely provide for inclusion of 10-hydroxycodeine in the CSA.

United Nations: The drug is not listed specifically on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: The drug is currently not listed on the CDSA. However, item 1 of Schedule I to the CDSA is an inclusive listing of opium derivatives and alkaloids. This section has been interpreted to include a broad range of chemicals similar to the three main opium alkaloids: codeine, morphine and thebaine. In recent years, several substances similar to the title substance have been declared to be controlled substances. These include 14-hydroxycodeine, codeine N-oxide and isocodeine. See the list of administrative List of Controlled Substances.
Recommendation: Based on the interpretation of item 1 of Schedule I to the CDSA and recent status decisions in regard to similar substances, 10-hydroxycodeine is included in item 1 of Schedule I to the CDSA and is a controlled substance.

June 15, 2005