



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

Substance: Codeine dimer

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):

- Based on the interpretation of item 1 of Schedule I to the CDSA and recent status decisions in regard to similar substances, codeine dimer is included in item 1 of Schedule I to the CDSA and is a controlled substance.

Supporting document(s) attached: X

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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: Codeine dimer

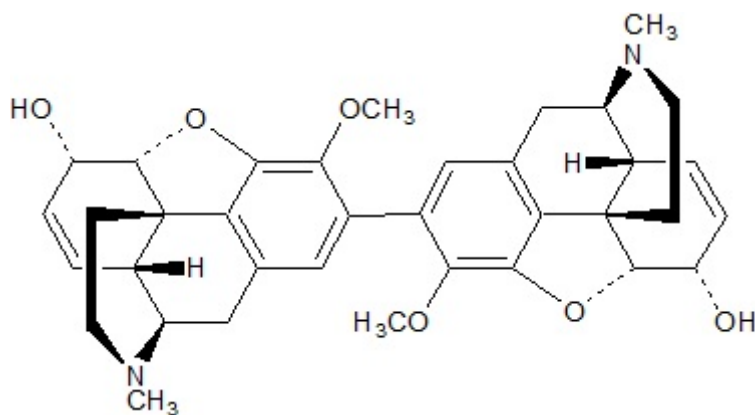
Drug Name Status: Codeine dimer is a trivial name.

Chemical Name: (5 α ,6 α)-
(5' α ,6' α)-7,7',8,8'-tetrahydro-4,5:4',5'-diepoxy-3,3'-dimethoxy-17,17'-dimethyl-
[2,2'-bimorphinan]-6,6'-diol

Other Names: Dicodeine; 2,2'-bicodeine

Molecular Formula: C₃₆H₄₀N₂O₆

Chemical structure:



Pharmacological class / Application: Drug impurity

International status:

US: The drug is not currently listed on the US Controlled Substances Act 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 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 specifically 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-

hydroxycodone, codeine N-oxide, isocodeine and pseudomorphine. See the list of administrative List of Controlled Substances. The last substance is related to morphine in exactly the same way that codeine dimer is related to codeine.

Recommendation: Based on the interpretation of item 1 of Schedule I to the CDSA and recent status decisions in regard to similar substances, codeine dimer is included in item 1 of Schedule I to the CDSA and is a controlled substance.

June 15, 2005