



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

Substance: Hydrocodonediol

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):

- Item 1 of Schedule I to the CDSA is "Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts ... and the salts, derivatives and salts of derivatives of the substances set out in subitems (1) to (4)". There then follows a list of 27 substances to illustrate the types of substances included in the item of the schedule.
Item 1 of Schedule I has been interpreted to include a broad range of substances related to the opium alkaloids and the substances included specifically in item 1.
In assessing the status of substances in the past four years, no substance similar to any of the opium related substances has been determined to be "non-controlled", i.e., outside the application of the CDSA. During the same period, nine substances related to the opium alkaloids have been declared to be "controlled". One of these, hydrocodone related substance A, was declared to be controlled as it is a derivative of codeine.
Due to the similarity of the structures of hydrocodonediol and hydrocodone related substance A, the former should be considered to be included in item 1 of Schedule I to the CDSA.

Supporting document(s) attached: X

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Verified by: See email MICHAEL LEBELLE Date: 2005-06-24

Approved by: DIRECTOR, OFFICE OF Date:

CONTROLLED SUBSTANCES

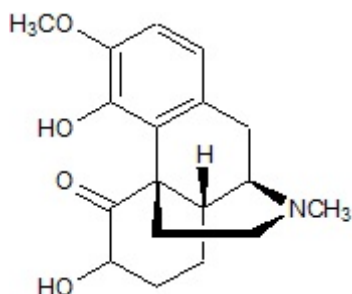
Drug Status Report

Drug: Hydrocodonediol

Drug Name Status: Hydrocodonediol is the trivial name

Chemical Name: 4,6-dihydroxy-3-methoxy-5-oxo-17-methylmorphinan

Chemical structure:



Molecular Formula: C₁₈H₂₃NO₄

Pharmacological class / Application: unknown

International status:

US: The Controlled Substances Act is broad in its specification of opiates: The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." The "capable of conversion" could be interpreted to include hundreds of chemical substances. It is likely that the subject substance would be considered to be included in the CSA; confirmation of the status of the substance in the US would need to be obtained from the DEA.

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. The drug is not likely considered to be covered by the 1971 Convention as the list of substances included is extended beyond those specifically listed by only specific related substances, for example, ethers, esters, etc. The title substance does fall into this extension.

Canadian Status: Item 1 of Schedule I to the CDSA is "Opium Poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts, including:

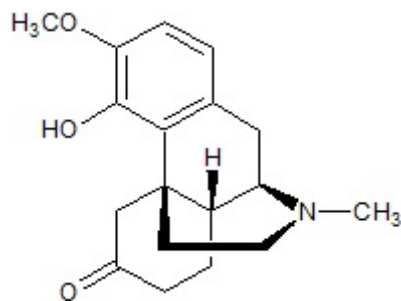
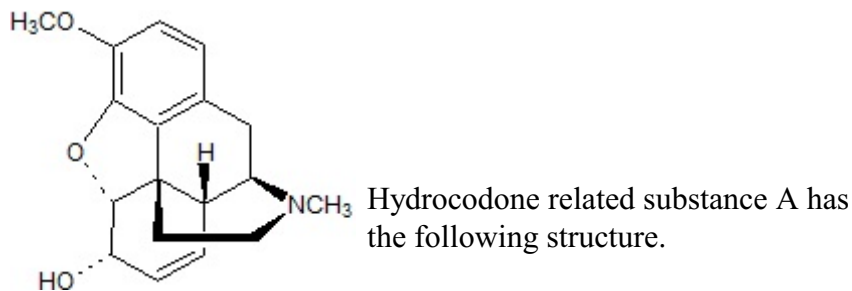
- (1) Opium
- (2) Codeine (methylnorphine)

(3) Morphine (7,8--didehydro--4,5--epoxy--17 --methylmorphinan--3,6--diol)
(4) Thebaine (paramorphine)
and the salts, derivatives and salts of derivatives of the substances set out in subitems (1) to (4), including:”

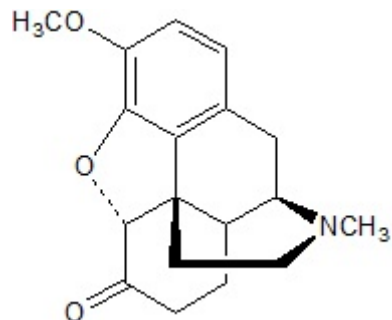
There then follows a list of 27 substances to illustrate the types of substances included in the item of the schedule. This list has been interpreted to include, as well, the salts, derivatives and salts of derivatives of the substances.

Item 1 of Schedule I has been interpreted to include a broad range of substances related to the opium alkaloids and the substances included specifically in item 1. In assessing the status of substances in the past four years, no substance similar to any of the opium related substances has been determined to be “non-controlled”, i.e., outside the application of the CDSA. During the same period, nine substances related to the opium alkaloids have been declared to be “controlled”. One of these, hydrocodone related substance A, was declared to be controlled as it is a derivative of codeine.

Codeine has the following structure.



For reference the structure of hydrocodone is shown on the next page.



Hydrocodone

Due to the similarity of the structures of hydrocodonediol and hydrocodone related

substance A, the former should be considered to be included in item 1 of Schedule I to the CDSA.

Recommendation: Hydrocodonediol is included in item 1 of Schedule I to the CDSA and is a controlled substance.

June 24, 2005