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

Substance: Oripavine

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):

- Oripavine is not listed on the schedules to the CDSA. Item 1 of Schedule I to the CDSA is “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:

  (1) Opium
  (2) Codeine (methylmorphine)
  (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”.

Subitem 1(4) of Schedule I to the CDSA is thebaine (structure below).
Based on the structural similarity of oripavine to thebaine, it must be considered to be included in item 1 of Schedule I.

Item 10 of Schedule I to the CDSA is, “Morphinan, their salts, derivatives and salts of derivatives.” Structurally, oripavine is a morphinan and could also be considered to be included in this item of Schedule I.

Supporting document(s) attached: Drug Status Report by Mr. LeBelle

Prepared by: ___________________________ Date: Sept. 26, 2006

Xiao Peng Feng

Drug Status Report by: Mr. M. LeBelle Date: Sept. 26, 2006

Approved by: ___________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES
Drug Status Report

**Drug:** Oripavine

**Drug Name Status:** Oripavine is the common name

**Chemical Name:**
(5a)-6,7,8,14-Tetrahydro-4,5-epoxy-6-methoxy-17-methylmorphinan-3-ol

**Chemical structure:**

![Chemical Structure of Oripavine](image)

**Molecular Formula:** \(C_{18}H_{19}NO_3\)

**Pharmacological/chemical class / Application:** fine chemical

**International status:**

US: Oripavine is not listed on the US Controlled Substances Act and is not mentioned on the DEA website. 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.” Confirmation of the status of the substance in the US would need to be obtained from the DEA.

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. However, it is recognized as an ingredient in some poppy straws and must be reported on Form C, Annual Statistics of Production, Manufacture, Consumption, Stocks and Seizures of Narcotic Drugs in accordance with the Single Convention.

Canadian Status: Oripavine is not listed on the schedules to the CDSA. Item 1 of Schedule I to the CDSA is “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:
(1) Opium
(2) Codeine (methylmorphine)
(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”.

Subitem 1(4) of Schedule I to the CDSA is thebaine (structure below).

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Based on the structural similarity of oripavine to thebaine, it must be considered to be included in item 1 of Schedule I.

Item 10 of Schedule I to the CDSA is, “Morphinans, their salts, derivatives and salts of derivatives.” Structurally, oripavine is a morphinan and could also be considered to be included in this item of Schedule I.

Recommendation: Oripavine is included in Schedule I to the CDSA and is a controlled substance.

September 26, 2006