Health Canada Santé Canada

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

Substance: 3-Hydroxy papaverine

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 substance is a metabolite of papaverine and included under item 1 of Schedule I to the CDSA.

Prepared by: _____ Date: June 23, 2011
Zack Li

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

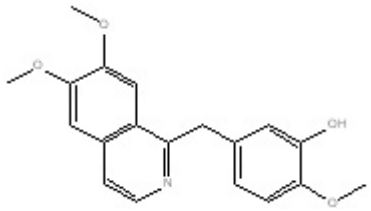
Drug: 3-Hydroxy papaverine

Drug Name Status: 3'-Demethyl papaverine is the common name.

Chemical Name: 5-((6,7-Dimethoxy-1-isoquinolinyl)methyl)-2-methoxyphenol

Other Names: alpha-(6,7-Dimethoxy-1-isoquinolyl)-6-methoxy-m-cresol; 3'-desmethylpapaverine; Palaudine: Ro 20-0518

Chemical structure:



CAS RN: 18694-10-5

Molecular Formula: $C_{19}H_{19}NO_4$

Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: The substance is not currently listed on the schedules to the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The substance is 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: 3-Hydroxy papaverine is not currently listed in the CDSA. The substance is reported in the scientific literature to be a metabolite of papaverine[1] which is listed under the 'but

[1]Peng, Z. et al. (2007) Chromatographic tandam mass spectrometric detectin of papaverine and its major metabolites in rat urine, Int J Mass Spectrometr. **266**:114-121.

not including' provision of Schedule I as sub-item 1(36) and is not a controlled substance. However, as the metabolites of papaverine are not mentioned in the provision, the substance is included as a derivative of papaverine under the heading "Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts including" of item 1 of Schedule I to the CDSA.

Recommendation: 3-Hydroxy papaverine is included in the schedule I to CDSA and is a controlled substance.

Date: June 23, 2011