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

Substance:  
I - 6-Desmethylpapaverine  
II - 4’,6-Didesmethylpapaverine

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 substances are metabolites of papaverine and are controlled under item 1 of Schedule I to the CDSA.

Prepared by: ______________________________ Date: Aug 29th, 2011
Evelyn C Soo

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:  I - 6-Desmethylpapaverine  
II - 4',6-Didesmethylpapaverine

Drug Name Status:  I - 6-Desmethylpapaverine  
II - 4',6-Didesmethylpapaverine are the common names.

Chemical Name:  I - 1-[(3,4-Dimethoxyphenyl)methyl]-7-methoxy-6-isoquinolinol  
II - 1-[4-Hydroxy-3-methoxyphenyl)methyl]-7-methoxy-6-isoquinolinol

Other Names:  I - 6-Demethylpapaverine; 7-methoxy-1-veratryl-6-isoquinolinol;  
isopacodine; 6-hydroxypapaverine; 1-(3,4-dimethoxybenzyl)-7-methoxyisoquinolin-6(2H)-one

Chemical structure:

Molecular Formula:  I - C_{19}H_{19}NO_4;  II - C_{18}H_{17}NO_4

CAS RN:  I - 18813-63-3;  II - 57170-09-9

Pharmacological class / Application:  Pharmaceutical-related substances

International status:

US: 6-Desmethylpapaverine and 4',6-Didesmethylpapaverine are not listed on the schedules to the US Controlled Substances Act and are not mentioned anywhere on the DEA website.

United Nations: The substances are 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: 6-Desmethypapaverine and 4',6-didesmethypapverine are not listed specifically in the CDSA. The substances have been reported in the scientific literature to be metabolites of papaverine\(^1\), which is currently listed as sub-item 1(36) under the “but not including” heading of item 1 of Schedule I to the CDSA. While papaverine is specifically excluded from item 1 of Schedule I to the CDSA, the derivatives of papaverine are not listed under the “but not including” heading and therefore are included under the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including” of Schedule I to the CDSA.

**Recommendation:** 6-Desmethypapaverine and 4',6-didesmethypapverine are included under item 1 of Schedule I to the CDSA and are controlled substances.

**Date:** 29 August, 2011