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

Substance: I- 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan
II- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal
III- 14-Hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal
IV- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal

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 derivatives of oxycodone and are captured under sub-item 1(28) of Schedule I to the CDSA.

Prepared by: ______________________________ Date: ______________
Vincent Marleau

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- 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan
II- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal
III- 14-Hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal
IV- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal

Drug Name Status:
I- 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan
II- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal
III- 14-Hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal
IV- 14-Hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal are the common names.

Chemical Name:
I- (4bR,8aS,9R)-8a-hydroxy-3-methoxy-11-methyl-4-phenoxy-8,8a,9,10-tetrahydro-5H-9,4b-(epiminoethano)phenanthen-6(7H)-one
II- (4bR,8aS,9R)-3-methoxy-11-methyl-5,7,8,8a,9,10-hexahydrospiro[9,4b-(epiminoethano)phenanthrene-6,2’-[1,3]dioxolan]-8a-ol
III- (4bR,8aS,9R)-3-methoxy-5,7,8,8a,9,10-hexahydrospiro[9,4b-(epiminoethano)phenanthrene-6,2’-[1,3]dioxolan]-8a-ol
IV- (4bR,8aS,9R)-3-methoxy-11-methyl-4-phenoxy-5,7,8,8a,9,10-hexahydrospiro[9,4b-(epiminoethano)phenanthrene-6,2’-[1,3]dioxolan]-8a-ol

Chemical structure:

Molecular Formula: I- C_{24}H_{27}NO_{4}; II- C_{20}H_{27}NO_{4}; III- C_{19}H_{25}NO_{4}; IV- C_{26}H_{31}NO_{5}.

CAS-RN: I- 21030-81-9; II- 21020-35-9; III- 1612-45-9; IV- 21020-34-8.

Pharmacological class / Application: Oxycodone derivatives

International status:
US: 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan, 14-hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal, 14-hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal and 14-hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal are not listed specifically in 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: 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan, 14-hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal, 14-hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal and 14-hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal are not listed specifically in the Schedules to the CDSA. These substances are derivatives of oxycodone, which is currently listed as sub-item 1(28) of Schedule I to the CDSA under the heading: “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:”. As a derivative of oxycodone, 14-hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan, 14-hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan, 14-hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal, 14-hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal and 14-hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal must be included under sub-item 1(28) of Schedule I to the CDSA.

**Recommendation:** 14-Hydroxy-3-methoxy-N-methyl-6-oxo-4-phenoxy-morphinan, 14-hydroxy-3-methoxy-17-methyl-6-oxo-morphinan 6-ethylene ketal, 14-hydroxy-3-methoxy-6-oxo-morphinan 6-ethylene ketal and 14-hydroxy-3-methoxy-17-methyl-6-oxo-4-phenoxy-morphinan 6-ethylene ketal are included under sub-item 1(28) of Schedule I to the CDSA and are controlled substances.

**Date:** August 10th, 2012.