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

Substance:  I- rac N-Acetyl-Pseudoephedrine  
II- rac O-Acetyl Pseudoephedrine  
III- rac N,O-Diacetyl Pseudoephedrine

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

- Controlled ☐
- Not Controlled X

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substances are derivatives of pseudoephedrine and are not captured under item 16 of Part 1 of Schedule VI to the CDSA.

Prepared by: ___________________________  Date: ______________
Evelyn 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- rac N-Acetyl-Pseudoephedrine  
II- rac O-Acetyl Pseudoephedrine  
III- rac N,O-Diacetyl Pseudoephedrine

Drug Name Status:
I- rac N-Acetyl-Pseudoephedrine  
II- rac O-Acetyl Pseudoephedrine  
III- rac N,O-Diacetyl Pseudoephedrine are the common names.

Chemical Names:
I - (R*,R*)-(±)-N-(2-Hydroxy-1-methyl-2-phenylethyl)-N-methylacetamide  
II - (αR)-rel-α-[1(1R)-1-(Methylamino)ethyl]benzenemethanol 1-Acetate  
III- (R*,R*)-N-[2-(Acetyloxy)-1-methyl-2-phenylethyl]-N-methylacetamide

Other Names:
I - rel-N-[(1R,2R)-2-Hydroxy-1-methyl-2-phenylethyl]-N-methylacetamide; threo-(±)-N-(β-Hydroxy-α-methylphenethyl)-N-methylacetamide;  
II - (R*,R*)-(±)-α-[1-(Methylamino)ethyl]benzenemethanol Acetate (Ester)

Chemical structure:

![Chemical Structures](image)

Pseudoephedrine

Molecular Formula: I- C_{12}H_{17}NO_2; II- C_{12}H_{18}NO_2Cl; III- C_{14}H_{19}NO_3;

Pharmacological class / Application: Pseudoephedrine derivatives

CAS-RN: I- 5878-95-5; II-N/A; III-144032-36-0

International status:
US: rac N-Acetyl-Pseudoephedrine, rac O-Acetyl Pseudoephedrine and rac N,O-Diacetyl Pseudoephedrine 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: rac N-Acetyl-Pseudoephedrine, rac O-Acetyl Pseudoephedrine Hydrochloride and rac N,O-Diacetyl Pseudoephedrine are not listed in the Schedules to the CDSA. These substances display substantial structurally similarity to pseudoephedrine and more specifically are acetyl derivatives of pseudoephedrine. Currently, pseudoephedrine is listed as item 16 in Part 1 of Schedule VI of the CDSA as “Pseudoephedrine (threo-2-(methylamino)-1-phenylpropan-1-ol), its salts and any plant containing pseudoephedrine or any of its salts”. As the substances are derivatives of pseudoephedrine, they cannot be captured under item 16 of Part 1 of Schedule VI to the CDSA. The salts of these pseudoephedrine derivatives are also not captured under item 16 of Part 1 of Schedule VI to the CDSA.

**Recommendation:** rac N-Acetyl-Pseudoephedrine, rac O-Acetyl Pseudoephedrine Hydrochloride and rac N,O-Diacetyl Pseudoephedrine are not included in the schedules to the CDSA and are not controlled substances nor precursor chemicals.

**Date:** November 22th, 2012.