



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

Substance: **I - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine**  
**II - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4**

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 mazindol and are not included under item 15 of Schedule IV to the CDSA.

Prepared by: \_\_\_\_\_ Date: July 17<sup>th</sup> 2010  
Evelyn Soo

Verified by: \_\_\_\_\_ Date: \_\_\_\_\_  
Marianne Tang

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** - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine  
**II** - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4

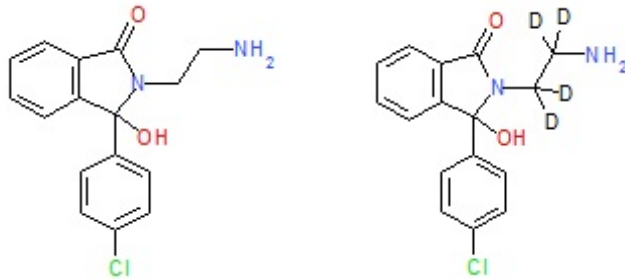
### Drug Name Status:

**I** - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine  
**II** - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4

### Chemical Name:

**I** - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-2,3-dihydro-3-hydroxy-1H-isoindol-1-one  
**II** - 2-(2-Aminoethyl-D4)-3-(4-chlorophenyl)-2,3-dihydro-3-hydroxy-1H-isoindol-1-one

### Chemical structure:



**Molecular Formula: I** -  $C_{16}H_{15}ClN_2O_2$ ; **II** -  $C_{16}H_{11}D_4ClN_2O_2$

**Pharmacological class / Application:** pharmaceutical related substances

**CAS-RN: I** - 13473-53-5; **II** - N/A

### International status:

US: The substance is not listed specifically in the CSA and is not mentioned anywhere on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine (**I**) is a metabolite of mazindol, and 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4 (**II**) is the deuterated form of the same metabolite. Mazindol (5-(p-chlorophenyl)-2,5-dihydro-3H-imidazo[2,1-a]isoindol-5-ol) is currently listed as item 15 in Schedule IV to the CDSA. Since the derivatives of mazindol are not included under item 15 of Schedule IV, substances **I** and **II** are also not included.

**Recommendation:** 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine and 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4 are not included in the schedules to the CDSA and are not controlled substances.

**Date:** 27 July 2010