Health Canada
Santé Canada

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

Substance:
I – 8-Chloro-3a,4-dihydro-6-(2-fluorophenyl)-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine
II - 8-Chloro-6-(fluorophenyl)-3a,4,5,6-tetrahydro-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine, dihydrochloride

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

| | |
|---|---|
| Controlled | X |
| Not Controlled | ☐ |

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

- The substances are impurities of midazolam and captured under item 18 of Schedule IV to the CDSA.

Prepared by: _____ Date: _____
Evelyn C Soo

Verified by: _____ Date: _____
Mark Kozlowski

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

**This status was requested by:** Nacer Silarbi, OCS

**Drug Status Report**

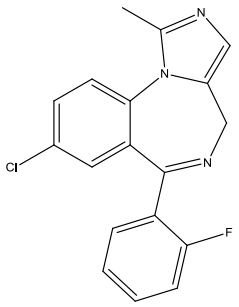
**Drug:**
I – 8-Chloro-3a,4-dihydro-6-(2-fluorophenyl)-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine
II - 8-Chloro-6-(fluorophenyl)-3a,4,5,6-tetrahydro-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine

**Drug Name Status**:
I - 8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f]imidazo[1,5-a][1,4]diazepine
II - 8-Chloro-6-(2-fluorophenyl)-1-methyl-5,6-dihydro-4H-benzo[f]imidazo[1,5-a][1,4]diazepine
are the common names.

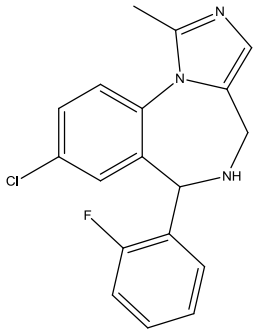
**Chemical Name**:
I - 8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f]imidazo[1,5-a][1,4]diazepine
II - 8-Chloro-6-(2-fluorophenyl)-1-methyl-5,6-dihydro-4H-benzo[f]imidazo[1,5-a][1,4]diazepine

**Other Names:**
I – RMID
II –RRMID

**Chemical structure:**




**I**




**II**

**Molecular Formula:** I – $C_{18}H_{13}ClFN_3$; II – $C_{18}H_{15}ClFN_3$

**Pharmacological class / Application:** Pharmaceutical-related substances

**CAS-RN: I, II –** N/A

**International status**:
US: 8-Chloro-3a,4-dihydro-6-(2-fluorophenyl)-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine and 8-chloro-6-(fluorophenyl)-3a,4,5,6-tetrahydro-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine 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: 8-Chloro-3a,4-dihydro-6-(2-fluorophenyl)-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine and 8-chloro-6-(fluorophenyl)-3a,4,5,6-tetrahydro-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine are not listed specifically in the Schedules to the CDSA. The substances are impurities of midazolam which is currently listed as sub-item 18(22.1) under the heading "Midazolam (8-chloro-6-(o-fluorophenyl)-1-methyl-4H-imidazo[1,5a][1,4]benzodiazepine)" in Schedule IV to the CDSA. The substances also contain the core structure of the 1,4-benzodiazepines. Therefore they are considered captured under the heading "Benzodiazepines, their salts and derivatives including" of item 18 of Schedule IV to the CDSA.

**Recommendation:** 8-Chloro-3a,4-dihydro-6-(2-fluorophenyl)-1-methyl-3H-imidazo-[1,5a][1,4]- benzodiazepine and 8-chloro-6-(fluorophenyl)-3a,4,5,6-tetrahydro-1-methyl-3H-imidazo-[1,5a][1,4]-benzodiazepine are included under item 18 of Schedule IV to the CDSA and are controlled substances.

**Date:** November 1st, 2012.