



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

Substance: Midazolam 5-Oxide and Midazolam 2-Oxide

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

Controlled [checked]
Not Controlled [unchecked]

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

- The substances are derivatives of midazolam and therefore included under item 18(22.1) of Schedule IV to the CDSA.

Prepared by: Evelyn Soo Date: Sept 24th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

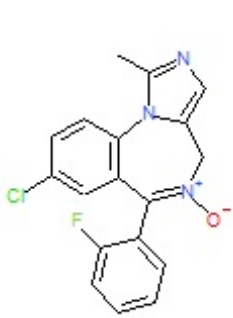
Drug: I- Midazolam 5-oxide
II - Midazolam 2-oxide

Drug Name Status: I- Midazolam 5-oxide
II - Midazolam 2-oxide are the common names

Chemical Name:

I - 8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5- a][1,4]benzodiazepine, 5-oxide
II -8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5- a][1,4]benzodiazepine, 2-oxide

Chemical structure:



I



II

Molecular Formula: I - C₁₈H₁₃ClFN₃O; II - C₁₈H₁₃ClFN₃O

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: I - 59468-83-6; II - 59468-86-9

International status:

US: The substances are not listed specifically in the 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Midaxolam 5-oxide and midazolam 2-oxide are by-products relating to the synthesis of midazolam 2,5-dioxide from midazolam. The substances derivatives of midazolam, which is presently listed under as item 18(22.1) in Schedule IV to the CDSA under the item heading “Benzodiazepines, their salts and derivatives, including:”, and therefore must be included under item 18(22.1) of Schedule IV to the CDSA.

Recommendation: Midaxolam 5-oxide and midazolam 2-oxide are included under item 18(22.1) of Schedule IV to the CDSA and are controlled substances.

Date: 24th September 2010