



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

Substance: Midazolam N-β-D-Glucuronide

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 substance is a metabolite of midazolam and contains the structural features of the benzodiazepines and therefore is included under item 18 of Schedule IV to the CDSA.

Prepared by: Evelyn Soo Date: 28 July 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"

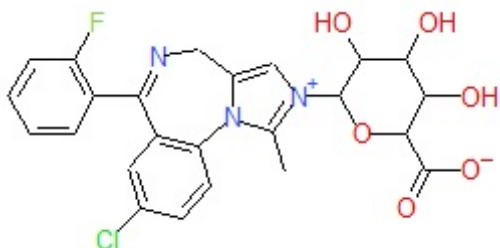
Drug Status Report

Drug: Midazolam N-β-D-glucuronide

Drug Name Status: Midazolam N-β-D-glucuronide is a common name.

Chemical Name: 8-Chloro-6-(2-fluorophenyl)-2-β-D-glucopyranuronosyl-1-methyl-4H-imidazo[1,5-A][1,4]benzodiazepinium

Chemical structure:



Molecular Formula: C₂₄H₂₁ClFN₃O₆

Pharmacological class / Application: metabolite of midazolam

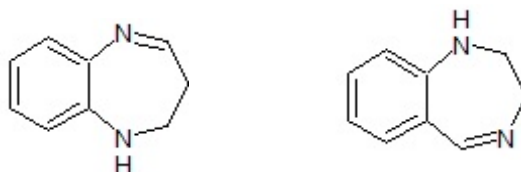
CAS-RN: 1033824-50-8

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: Midazolam N-β-D-glucuronide is claimed to be a metabolite of midazolam, which is listed as sub-item 22.1 under item 18 of Schedule IV to the CDSA under the heading “Benzodiazepines, their salts and derivatives, including:”. With the exception of brotizolam, the benzodiazepines have a characteristic core structural feature, the two variations of the which are shown below:



As can be seen from its chemical structure, midazolam N- β -D-glucuronide also contains the core structure of the benzodiazepines and therefore the substance is included under item 18(22.1) of Schedule IV to the CDSA.

Recommendation: Midazolam N- β -D-glucuronide is 18(22.1) of Schedule IV to the CDSA and is considered a controlled substance.

Date: 27th July 2010