



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

Substance: 7-Chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione

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 related impurity of temazepam and contains the core structure of the benzodiazepenes. Therefore, it is included under item 18 of Schedule IV to the CDSA.

Prepared by: Evelyn Soo Date: Sept 10th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: Nacer Silarbi

Drug Status Report

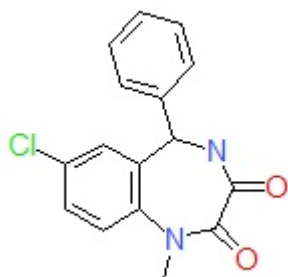
Drug: 7-Chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione

Drug Name Status: 7-Chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione

Chemical Name: (5R,S)-7-Chloro-1-methyl-5-phenyl-4,5-dihydro-1H-1,4-benzodiazepine-2,3-dione

Other Names: EP Temazepam Impurity F

Chemical structure:



Molecular Formula: C₁₆H₁₃ClN₂O₂

Pharmacological class / Application: Pharmaceutical-related impurity

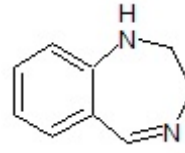
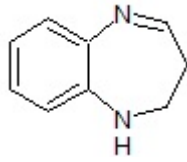
CAS-RN: 3294-96-0

International status:

US: The substance is not listed specifically in the Controlled Substances Act 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: 7-Chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione is an impurity related to temazepam and is not listed specifically in the CDSA. Temazepam is currently listed under Item 18 (30) of Schedule IV to the CDSA, under the heading "Benzodiazepines, their salts and derivatives". With the exception of brotizolam, the benzodiazepines have a characteristic core structural feature, two variations of which are shown below:



Given that 7-chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione contains the core structure of the benzodiazepines, the substance must be included under item 18 of Schedule IV to the CDSA.

Recommendation: 7-Chloro-4,5-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2,3-(1H)-dione is included under item 18(30) of Schedule IV to the CDSA and is a controlled substance.

Date: 10 September 2010