Health Canada
Santé Canada

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

Substance:
(R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea

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 substance contains the core benzodiazepine structure and is captured under item 18 of Schedule IV to the CDSA.

Prepared by: _____ Date: 12 April, 2012
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

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

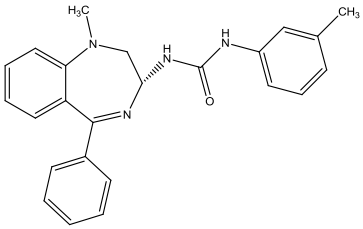
Drug: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea

Drug Name Status: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea is the common name.

Chemical Name: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea

Other Names: [(3R-(+)-2,3-dihydro-1-methyl-2-oxo-5-phenyl-1H-1,4- benzodiazepin-3-yl)-N'-(3-methylphenyl)urea]

Chemical structure:



Molecular Formula: $C_{24}H_{24}N_4O$

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: 118101-09-0

International status:

US: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea is not listed specifically in the Schedules to the US *Controlled Substances Act* (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, 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: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea is not listed in the Schedules to the CDSA. The substance is a nonpeptide antagonist of gastrin/CCKB receptors and was developed for the treatment of peptic ulcers.[1] However, the substance has the core structure of the 1,4-benzodiazepines, which are listed under item 18 of Schedule IV to the CDSA under the heading "Benzodiazepine, their salts and derivatives,

[1] Pendley, E.C. *et* al. (1993) The Gastrin/Cholecystokinin-B Receptor Antagonist L-365,260 Reduces Basal Acid Secretion and Prevents Gastrointestinal Damage Induced by Aspirin, Ethanol and Cysteamine in the Rat. J. Pharmacol. Expt. Ther. **265**(3): 1348-1354.

including". Accordingly, the substance must be included under Item 18 of Schedule IV to the CDSA.

Recommendation: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea is included under Item 18 of Schedule IV to the CDSA and is a controlled substance.

Date: April 12th, 2012.