Substance: 5-Methyl zolpidem

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

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<td>Controlled</td>
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<td>Not Controlled</td>
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under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The substance is a related impurity of zolpidem is not captured under the heading of item 25 of Schedule IV to the CDSA.

Prepared by: ____________________________ Date: April 27th 2011

Evelyn Soo

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:** 5-Methyl zolpidem

**Drug Name Status:** 5-Methyl zolpidem is the common name.

**Chemical Name:** N,N,5-Trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide

**Chemical structure:**

![Chemical structure of 5-Methyl zolpidem](image)

**Molecular Formula:** C\textsubscript{19}H\textsubscript{21}N\textsubscript{3}O

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

**CAS-RN:** NONE

**International status:**

US: 5-Methyl zolpidem is not listed 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, 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: 5-Methyl zolpidem is reported to be a related impurity of zolpidem which is currently listed as item 25 in Schedule IV to the CDSA as “Zolpidem (N,N,6-trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide) and any salt thereof”. Since 5-methyl zolpidem is not a salt of the parent drug, it does not fall under item 25 of Schedule IV to the CDSA. It is noteworthy that a review of another related impurity of zolpidem, namely 7-methyl zolpidem) also found that the substance could not be included under item 25 of Schedule IV to the CDSA.

**Recommendation:** 5-Methyl zolpidem is not included in the schedules to the CDSA and is not a controlled substance.

**Date:** 27 April 2011