Health Canada
Santé Canada

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

Substance: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole)

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

Controlled	☐
Not Controlled	X

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

- The substance is an impurity in the synthesis of telmisartan and is not structurally similar to any of those listed in the Schedules to the CDSA.

Prepared by: _____ Date: _____
Evelyn C Soo

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Bruno Lafontaine, OCS

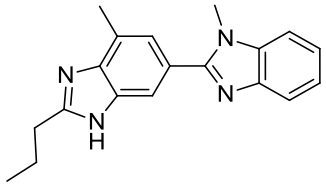
Drug Status Report

Drug: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole)

Drug Name Status: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole) is the common name.

Chemical Name: 1,7'-Dimethyl-2'propyl-1H,3'H-2,5'-bibenzo[d]imidazole

Chemical structure:



Molecular Formula: $C_{19}H_{20}N_4$ **CAS-RN:** 152628-02-9

Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole) is not listed specifically in the Schedules to the US *Controlled Substances Act* and is not mentioned anywhere on US 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: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole) is not listed in the schedules to the CDSA. The substance has been reported to be an impurity relating to the synthesis of telmisartan, which is a drug used to treat hypertension and currently listed under Schedule F to the *Food and Drugs Regulations*. The substance is not structurally similar to any of those listed in the CDSA.

Recommendation: (2-n-propyl-4-methyl-6-(1-methylbenzimidazole-2-yl)benzimidazole) is not included in the Schedules to the CDSA and is not a controlled substance.

Date: September 13th, 2012.