Health Canada Santé Canada

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

Substance: Rilpivirine

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

Controlled ☐
Not Controlled ✓

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

- The substance is not listed in the Schedules to the CDSA and is not similar to any of the substances included in the CDSA.

Prepared by: _____ Date: June 30, 2011
Zack Li

Verified by: _____ Date: _____
Mark Kozlowski

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

This status was requested by: Ali Feroz, OCS

Drug Status Report

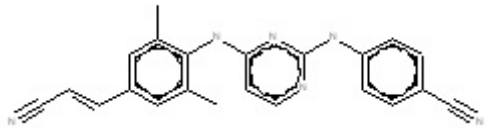
Drug: Rilpivirine

Drug Name Status: Rilpivirine is proper (INN) name.

Chemical Name: Benzonitrile, 4-((4-((4-((1E)-2-cyanoethenyl)-2,6-dimethylphenyl)amino)-2-pyrimidinyl)amino)-

Other Names: Edurant; 4-((4-((4-((1E)-2-Cyanoethenyl)-2,6-dimethylphenyl)amino)-2-pyrimidinyl)amino)benzonitrile; R 278474; TMC 278

Chemical structure:



Molecular Formula: $C_{22}H_{18}N_6$

CAS RN: 500287-72-9

Pharmacological class / Application: Antiviral

International status:

US: The substance is not currently listed on the schedules to the US Controlled Substances Act and is not mentioned 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: Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) used in HIV treatment[1]. It is not listed in the CDSA and is not structurally similar to any of the

[1]Miller. C.D., et al (2011). Rilpilvirine: a new addition to the anti-HIV-1 armamentarium. Drugs Today (Barc). **47:**5-15

substances included in the Schedules to the CDSA. Its analogue and fellow reverse transcriptase, 4-((6-amino-5-bromo-2-((4-cyanophenyl)amino)-4-pyrimidinyl)oxy)-3,5-dimethyl-benzonitrile (Etravirine), was also previously reviewed and was found not controlled under the CDSA. Etravirine is currently regulated under Schedule F to the *Food and Drug Regulations*.

Recommendation: Ripilvirine is not included in the schedules CDSA and is not a controlled substance.

Date: June 30, 2011