Health Canada
Santé Canada

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

Substance: beta-Hydroxythiofentanyl

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 is an analogue of fentanyl and is included under item 16 of Schedule I to the CDSA.

Prepared by: _____ Date: _____
Zack Li

Verified by: _____ Date: _____
Mark Kozlowski

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

This status was requested by: Evelina Rutkowski, OCS

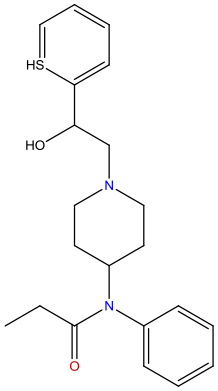
Drug Status Report

Drug: beta-Hydroxythiofentanyl

Drug Name Status: beta-Hydroxythiofentanyl is the common name.

Chemical Name: N-{1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl}-N-phenylpropanamide

Chemical structure:



Molecular Formula: $C_{20}H_{26}N_2O_2S$

Pharmacological class / Application: Fentanyl

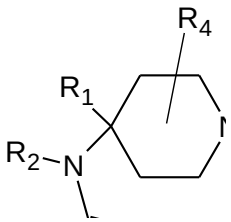
CAS-RN: 1474-34-6

International status:

US: beta-Hydroxythiofentanyl is not listed specifically in the Schedules to the US *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: beta-Hydroxythiofentanyl is not currently listed in the CDSA. The substance is an analogue of Fentanyl which is currently listed as item 16 of Schedule I to the CDSA under the heading "Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, including." A review of the current family of fentanyls revealed that substances included under item 16 of Schedule I to the CDSA all contain the following root structure:



R=ethyl group substituted variously at the 1 and 2 position
R_1=hydrogen, methoxymethyl or carboxylate alkyl ester
R_2=phenyl or substituted phenyl
R_3=alkyl
R_4=hydrogen or alkyl

Note, however, that the pharmacological activities of the substances were not considered in the earlier reviews.

According to above root structure, beta-hydroxythiofentanyl would be considered to contain all the essential structural elements. Given that the substance contains the core structure of the fentanyls, beta-hydroxythiofentanyl must be included under the heading “Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, including” of item 16 of Schedule I to the CDSA.

Recommendation: beta-Hydroxythiofentanyl is included in item 16 of Schedules I to the CDSA and is a controlled substance.

Date: June 18, 2012.