Health Canada Santé Canada

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

Substance: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl

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 does not contain the core structural features of the fentanyls and therefore cannot be included under item 16 of Schedule I 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"

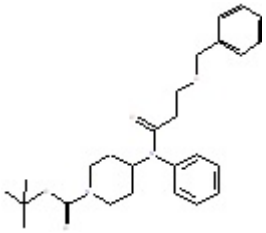
Drug Status Report

Drug: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl

Drug Name Status: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is the common name.

Chemical Name: 3-Benzyloxy-N-phenyl-N-4-(N-tert-butoxycarbonylpiperidinylpropanamide)

Chemical structure:



Molecular Formula: $C_{26}H_{34}N_2O_4$

Pharmacological class / Application: Pharmaceutical-related substance

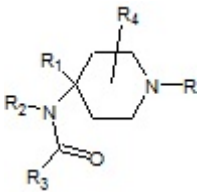
CAS-RN: NONE

International status:

US: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl 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: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is not listed in the CDSA. The substance is protected form of ω-hydroxy norfentanyl which was recently reviewed and concluded as not controlled under item 16 of Schedule I to the CDSA, on the basis that it does not have the the core structure of the fentanyls as shown below:



where 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

As such , O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is also considered not to fall under the heading “Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analouges, includng :” of item 16 of Schedule I to the CDSA.

Recommendation: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is not included in the schedules to the CDSA and is not a controlled substance.

Date: 27 April 2011