Health Canada Santé Canada

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

Substance: N-tert-butoxycarbonyl-4-anilinopiperidine

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 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

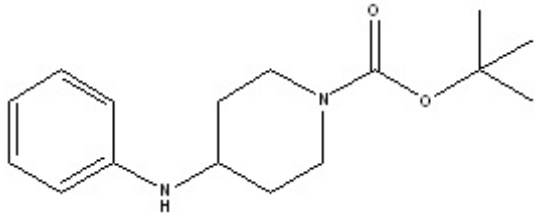
Drug: N-tert-butoxycarbonyl-4-anilinopiperidine

Drug Name Status: N-tert-butoxycarbonyl-4-anilinopiperidine is the common name.

Chemical Name: 4-(Phenylamino)-1-piperidinecarboxylic acid 1,1-dimethylethyl ester

Other Names: 4-Phenylaminopiperidine-1-carboxylic acid tert-butyl ester; 1-(tert-butyloxycarbonyl)-4-(phenylamino)piperidine

Chemical structure:



Molecular Formula: $C_{16}H_{24}N_2O_2$

Pharmacological class / Application: Pharmaceutical-related substance

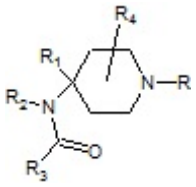
CAS-RN: 125541-22-2

International status:

US: N-tert-butoxycarbonyl-4-anilinopiperidine 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: N-tert-butoxycarbonyl-4-anilinopiperidine is not listed in the CDSA. The substance is reported to be an intermediate in the synthesis of various fentanyl derivatives but the substance does not contain the core structure of the fentanyls, as shown below



Fentanyl root structure

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 , N-tert-butoxycarbonyl-4-anilinopiperidine is not captured by 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: N-tert-butoxycarbonyl-4-anilinopiperidine is not included in the schedules to the CDSA and is not a controlled substance.

Date: 27 April 2011