

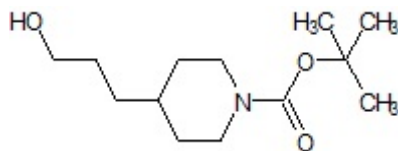
Drug Status Report

Drug: 4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester

Drug Name Status: 4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester is the chemical name

Chemical Name: 4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester

Chemical structure:



Molecular Formula: C₁₃H₂₅NO₃

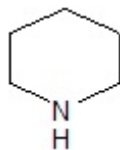
Pharmacological class / Application: fine chemical

International status:

US: The substance is not currently listed explicitly 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Piperidine (structure below) and its salts are Class A precursors in Canada. They were included in the list of precursors because piperidine is a precursor to phencyclidine¹. It is included in Table II to the UN's Red List.



Piperidine

4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester is not a salt of piperidine.

The piperidine radical is incorporated into several drug substances. Item 3 of Schedule I to the CDSA is "Phenylpiperidines, their intermediates, salts, derivatives and analogues and salts of

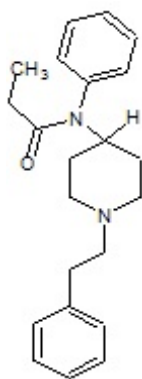
¹ See the Regulatory Impact Analysis Statement attached to SOR/2002-359.

intermediates, derivatives and analogues.” 4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester is not a phenylpiperidine.

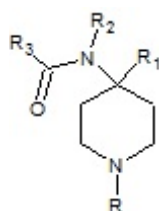
Item 5 of Schedule I is “Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives.” While some of these substances do contain the piperidine group, it is not characteristic of the class; other amine radicals such as dimethylamino and morpholino are incorporated, in place of piperidine, into these substances.

Only two of the three ampromides (item 12) specifically listed on Schedule I contain piperidine radicals so the presence of the piperidine cannot be considered essential or characteristic of this class of substances.

Item 16 of Schedule I is “Fentanyls, their salts, derivatives and analogues and salts of derivatives and analogues.” The structure of fentanyl is shown below. A review of the current family of fentanyls indicates that all members have one common root structure. This fentanyl root structure is shown below and must be considered essential in order to consider a substance a member of the fentanyl family of drugs and hence included in this item of Schedule I. The substituents R through R₃ may be hydrogen, alkyl or aryl groups.



Fentanyl



Fentanyl Root Structure

4-(3-Hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester does not contain the fentanyl root structure.

Recommendation: Based on this comparison with substances and families of substances currently included in the schedules to the CDSA, 4-(3-hydroxypropyl)-piperidine-1-carboxylic acid tert-butyl ester is not subject to the CDSA.

September 6, 2007