Health Canada Santé Canada

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

Substance: D-phenylalaninol and N,O-Ditosyl D-Phenylalaninol

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 substances cannot be considered derivatives nor analogues of an amphetamine and therefore are not included in the schedules to the CDSA..

Prepared by: _____ Date: Feb 23rd 2011
Evelyn Soo

Verified by: _____ Date: _____
Marianne Tang

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: I - D-Phenylalaninol
II - N,O-Ditosyl D-Phenylalaninol

Drug Name Status: I - (S)-Beta-aminobenzenepropanol
II - II - N,O-Ditosyl D-Phenylalaninol are the common names.

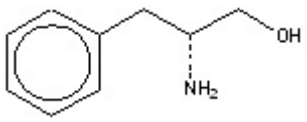
Chemical Name:

I - L-2-amino-3-phenyl-1-propanol

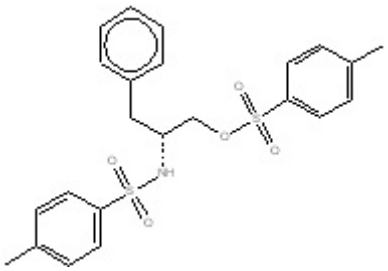
II - (S)-4-Methyl-N-[1-[[[(4-methylphenyl)sulfonyl]oxy]methyl]-2-phenylethyl]benzenesulfonamide

Other Names: I - (S)-2-Benzylethanolamine; L-2-amino-3-phenyl-propan-1-ol; L-phenylalaninol; S-phenylalaninol

Chemical structure:



I



II

Molecular Formula: I - $C_9H_{13}NO$; II - $C_{23}H_{25}NO_5S_2$

Pharmacological class / Application: Amino alcohols

CAS-RN: I - 3182-95-4; II - 63328-00-7

International status:

US: D-Phenylalaninol and its ditosyl protected derivative are not listed specifically in the Schedules to the US *Controlled Substances Act* and is not mentioned anywhere on the DEA website.

United Nations: The substances are 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: D-Phenylalaninol and its ditosyl protected derivative are not listed specifically in the CDSA and are claimed to be used in the synthesis of lisdexamphetamine. While the D-phenylalaninol displays structural similarity to amphetamine, which is listed as sub-item 1(1) of Schedule III to the CDSA, the substance does not contain a methyl group in the alpha-position. Therefore, the substance and its ditosyl protected derivative cannot be considered to be analogues of amphetamine and are not included under item 1 of Schedule III to the CDSA.

Recommendation: D-Phenylalaninol and N,O-ditosyl D-phenylalaninol are not included in the schedules to the CDSA and are not controlled substances.

Date: 23 February 2011