Health Canada Santé Canada

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

Substance: N-(2-Hydroxyethyl) pseudoephedrine

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 is not listed in the Schedules to the CDSA and is not considered to belong to any family or group listed in the Schedules.

Prepared by: _____ Date: June 6, 2011
Zack Li

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"

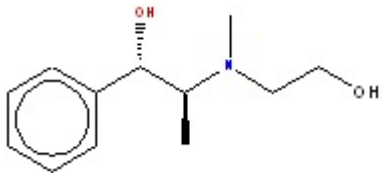
Drug Status Report

Drug: N-(2-Hydroxyethyl) pseudoephedrine

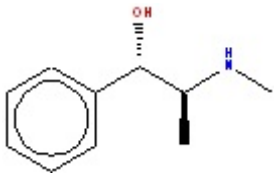
Drug Name Status: N-(2-Hydroxyethyl) pseudoephedrine is the common name.

Chemical Name: (αaS)-αa-[(1S)-1-[(2-Hydroxyethyl)methylamino]ethyl]benzenemethanol

Chemical structure:



N-(2-hydroxyethyl) pseudoephedrine



Pseudoephedrine

CAS RN: 54275-43-3

Pharmacological class / Application: Pseudoephedrine derivative

International status:

US: N-(2-hydroxyethyl) pseudoephedrine is not listed on 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: N-(2-hydroxyethyl) pseudoephedrine is a derivative of pseudoephedrine[1] and is not listed specifically in the CDSA. Currently, pseudoephedrine is listed as item 16 in Part 1 of Schedule VI of the CDSA as "Pseudoephederine (threo-2-(methylamino)-1-phenylpropan-1-ol), its salts and any plant containing pseudoephedrine or any of its salts". However, as a derivative of pseudoephedrine, N-(2-hydroxyethyl) pseudoephedrine is not captured under item 16 of Schedule VI to the CDSA and is not considered a controlled substance.

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[1]Maizel. E.B., et al (1978). Ephedrine, salsoline and cystisine derivatives as substrates and inhibitors of cholinesterases. Biokhimiya **43:**1150-1156.

Recommendation: N-(2-hydroxyethyl) pseudoephedrine is not included in the Schedules to the CDSA and is not a controlled substance.

Date: June 4, 2011