



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

Substance: Ambroxol

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 similar to any of the substances included in the Schedules to the CDSA.

Prepared by: _____
Evelyn C Soo

Date: Nov 19th 2010

Verified by: _____
Marianne Tang

Date: _____

Approved by: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

Date: _____

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

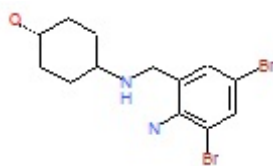
Drug: Ambroxol

Drug Name Status: Ambroxol is the common name.

Chemical Name: Trans-4-(((2-amino-3,5-dibromophenyl)methyl)amino)-cyclohexanol

Other Names: E-4-((2-amino-3,5-dibromobenzyl)amino)-cyclohexanol; trans-4-((2-amino-3,5-dibromobenzyl)amino)-cyclohexanol

Chemical structure:



Molecular Formula: C₁₃H₁₈Br₂N₂O

Pharmacological class / Application: Expectorant

CAS-RN: 18683-91-5

International status:

US: The substance is not listed specifically in the CSA 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: Ambroxol is not currently listed in the CDSA. The substance is an active metabolite of bromhexine and is used as a mucolytic agent and cough-suppressant in the treatment of respiratory conditions such as asthma and chronic obstructive pulmonary disease (COPD)¹. The substance is not structurally similar to any substances included under the Schedules to the CDSA.

Recommendation: Ambroxol is not included in the schedules to the CDSA and is not a controlled substance.

Date: November 19th 2010

¹Ren, YC et al. (2009) Pulmonary selectivity in local pharmacokinetics of ambroxol hydrochloride dry powder inhalation in rat, J. Pharm. Sci. **98**:1797-1803.