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: ___________________________  Date: Nov 19th 2010

Evelyn C 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: Ambroxol

Drug Name Status: Amboroxol 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:

\[
\begin{align*}
\text{Molecular Formula: } & C_{13}H_{18}Br_2N_2O \\
\text{Pharmacological class / Application: } & \text{Expectorant} \\
\text{CAS-RN: } & 18683-91-5 \\
\text{International status:} & \\
\text{US: } & \text{The substance is not listed specifically in the CSA and is not mentioned anywhere on the DEA website.} \\
\text{United Nations: } & \text{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.} \\
\text{Canadian Status: } & \text{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). The substance is not structurally similar to any substances included under the Schedules to the CDSA.} \\
\text{Recommendation: } & \text{Amboroxol is not included in the schedules to the CDSA and is not a controlled substance.} \\
\text{Date: } & \text{November 19th 2010}
\end{align*}
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\[\text{Ren, YC et al. (2009) Pulmonary selectivity in local pharmacokinetics of ambroxol hydrochloride dry power inhalation in rat, J. Pharm. Sci. 98:1797-1803.}\]