Health Canada Santé Canada

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

Substance: Benzonatate

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 those included in the Schedules to the CDSA.

Prepared by: _____ Date: September 23, 2011
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Veronique Lalonde

Drug Status Report

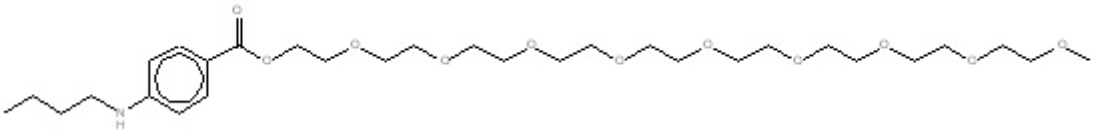
Drug: Benzonatate

Drug Name Status: Benzonatate is the proper name.

Chemical Name: Benzoic acid, 4-(butylamino)-, 2,5,8,11,14,17,20,23,26-nonaoxaoctacos-28-yl ester

Other Names: Benzononantin; Benzononatine; Benzoic acid, 4-(butylamino)-, 3,6,9,12,15,18,21,24,27-nonaoxaoctacos-1-yl ester; Benzoic acid, p-(butylamino)-, 2-(2-(2-(2-(2-(2-(2-(2-(2-methoxyethoxy)ethoxy)ethoxy)ethoxy)ethoxy)ethoxy)ethoxy)ethyl ester.

Chemical structure:



Molecular Formula: $C_{30}H_{53}NO_{11}$

Pharmacological class / Application: Non-opioid oral antitussive

CAS-RN: 104-31-4

International status:

US: Benzonatate is not listed in the Controlled Substances Act and is not mentioned anywhere on the DEA website as a controlled substance.

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: Benzonatate is not listed in the schedules to the CDSA. The substance has been reported to be a non-narcotic cough suppressor that has local anesthetic properties used mainly to treat acute and chronic respiratory diseases[1] and does not display any structural similarity to the substances listed in the Schedules to the CDSA.

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[1]Lin., W.-J. *et al.* (1999) Degradation kinetics of benzonatate in aqueous solutions. International Journal of Pharmaceutics, **176(2)**:179-186.

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

Date: Sept 23, 2011