Health Canada Santé Canada

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

Substance: Nimesulide

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

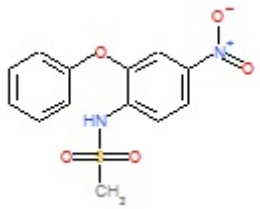
Drug: Nimesulide

Drug Name Status: Nimesulide is the common name.

Chemical Name: 4'-Nitro-2'-phenoxymethanesulfonanilide

Other Names: 4-Nitro-2-phenoxy-methanesulfonanilide; N-(4-Nitro-2-phenoxyphenyl)methanesulfonamide

Chemical structure:



Molecular Formula: $C_{13}H_{12}N_2O_5S$

Pharmacological class / Application: Analgesic

CAS-RN: 51803-78-2

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: Nimesulidel is not currently listed in the CDSA. The substance is used as an an anti-inflammatory and analgesic drug for the treatment of musculoskeletal disorder, dyemenorrhoea, thrombophlebitis and dental pain[1]. The substance is not structurally similar to any substances included under the Schedules to the CDSA.

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

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[1]Battu, PR (2009) Determinations of Nimesulide in phrmaceutical formulations and in human serum by reverse-phase high-performance liquid chromatography, Int. J. Pharm. Tech. Res. **1**:206-209.

Date: November 19th 2010