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

Substance: Bromfenac sodium

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 in structure to any of those listed in the CDSA.

Prepared by: _____________________________ Date: February 7th, 2012

Vincent Marleau

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:** Bromfenac sodium

**Drug Name Status:** Bromfenac sodium is the common name.

**Chemical Name:** 2-Amino-3-(4-bromobenzoyl)-benzeneacetic acid, , monosodium salt, sesquihydrate

**Other names:** Bromfenac ophthalmic; Duract; Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate; Benzeneacetic acid, 2-amino-3-(4-bromobenzoyl)-, monosodium salt, hydrate (2:3).

**Chemical structure:**

![Chemical structure of Bromfenac sodium](image)

**Molecular Formula:** C_{15}H_{12}BrNO_{3}·3/2H_{2}O·Na

**Pharmacological class / Application:** NSAID

**CAS-RN:** 120638-55-3

**International status:**

US: Bromfenac sodium is not listed in 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: Bromfenac sodium is not listed in the schedules to the CDSA. The substance is a non-steroidal anti-inflammatory drug which is generally used as an ophthalmic analgesic\(^1\) but has also been reported to be useful for the treatment of pain after surgical procedures such as oral surgery\(^2\). Bromfenac sodium is not similar in structure to any of the substances listed in the

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schedules to the CDSA.

**Recommendation:** Bromfenac sodium is not included in any of the Schedules to the CDSA and is not a controlled substance.

**Date:** February 7th, 2012.