



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

Substance: Fluorometholone acetate

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled []
Not Controlled [x]

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substance is an anti-inflammatory drug and does not display any anabolic activity nor a derivative of an anabolic steroid.

Prepared by: Evelyn C Soo Date: October 29th 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

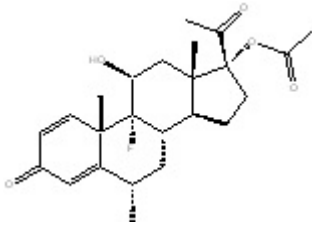
Drug: Fluorometholone acetate

Drug Name Status: Fluorometholone acetate is the common name.

Chemical Name: 9-Fluoro-11beta,17-dihydroxy-6alpha-methylpregna-1,4-diene-3,20-dione 17 acetate

Other Names: Fluorometholone 17-acetate; Pregna-1,4-diene-3,20-dione, 17-(acetyloxy)-9-fluoro-11-hydroxy-6-methyl-, (6alpha,11beta)-; tobrasone

Chemical Structure:



Molecular Formula: C₂₄H₃₁FO₅

CAS-RN: 3801-06-7

Pharmacological class / Application: steroid

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: Fluorometholone acetate is not currently listed in the CDSA. The substance is a synthetic corticosteroid and used as an anti-inflammatory drug, particularly in ocular applications¹. The substance has not been reported in the scientific literature to display any anabolic activity and is not a derivative of an anabolic steroid. It is therefore not included

¹Vetrugno, M. *et al.* (2000) A randomized, comparative study of fluorometholone 0.2% and fluorometholone 0.1% acetate after photorefractive keratectomy, *Eur. J. Ophthalmol.* **10**:39-45.

under item 23 of Schedule IV to the CDSA.

Recommendation: Fluorometholone is not included in Schedule IV to the CDSA and is not a controlled substance.

Date: October 29th 2010