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

Substance: 3β-Hydroxyandrost-5-en-17-one, 17-(1,3-dioxolane)

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):

• 3β-Hydroxyandrost-5-en-17-one, 17-(1,3-dioxolane) is a 
derivative of prasterone and therefore is included under item 
23(36) of Schedule IV to the CDSA.

Prepared by: ___________________________ Date: July 23rd 2010
Evelyn 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:** 3β-Hydroxyandrost-5-en-17-one, 17-(1,3-dioxolane)

**Drug Name Status:** 3β-Hydroxyandrost-5-en-17-one, 17-(1,3-dioxolane) is a common name

**Chemical Name:** Androst-5-en-17-one, 3-hydroxy, cyclic-1,2-ethandiyl acetate

**Chemical structure:**

![Chemical structure](image)

**Molecular Formula:** C_{21}H_{32}O_{3}

**Pharmacological class / Application:** Pharmaceutical intermediate

**CAS-RN:** 7745-40-6

**International status:**

US: The substance is not listed in the schedules to 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: The substance is one of the intermediates in the synthesis of 5-(1β-methyl-4β-hydroxy-2β-(2-(hydroxymethyl)cyclohexyl)-4α-methylamino-7αβ-methyl-1-methyleneoctahydroindene (A), a drug candidate that has shown potential as an anti-inflammatory drug for the treatment of acute and chronic inflammation of the bone and cartilage (e.g. in rheumatoid arthritis, ankylosing spondylitis, juvenile arthritis) as well as multiple sclerosis, Chrohn’s disease, psoriasis and dermatitis¹.

As shown in the synthetic route below, the substance is synthesized directly from prasterone, the 1,3-dioxolane being a common protecting group for carbonyl compounds in organic reactions\(^2\).

"third party information removed as per agreement with applicant"

Prasterone is currently listed under item 23(26) of Schedule IV to the CDSA under the heading “Anabolic steroids and their derivatives including”. Since the substance is a derivative of prasterone, it must be included under item 23(36) of Schedule IV to the CDSA.

**Recommendation:** 3\(\beta\)-Hydroxyandrost-5-en-17-one, 17-(1,3-dioxolane) is included under item 23(36) of Schedule IV to the CDSA and is a controlled substance.

**Date:** 23 July 2010