



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

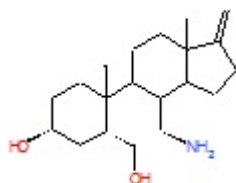
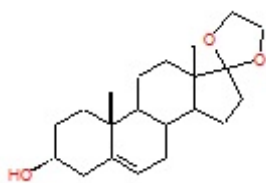
This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

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

Drug Name Status: 3 β -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:

A

Molecular Formula: C₂₁H₃₂O₃

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-(1 β -methyl-4 β -hydroxy-2 β -(2-(hydroxymethyl)cyclohexyl)-4 α -methylamino-7 α β -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, Crohn's disease, psoriasis and dermatitis¹.

¹Raymond, JR. et al. (2004) Indene derivatives as pharmaceutical agents, WIPO Patent WO2004/92100 .

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 reactions².

“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: 3β -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

²Green TW and Wuts PGM. 1,3-dioxolanes in Protective Groups, In: Organic Synthesis, Wiley-Interscience, New York, 1999, pp724-272.