Health Canada Santé Canada

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

Substance: Androsta-3,5-diene-7,17-dione

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):

- Androsta-3,5-diene-7,17-dione is not an anabolic steroid nor derived from an anabolic steroid and therefore is not included under item 23 of Schedule IV to the CDSA.

Prepared by: _____ Date: Dec 9rd 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"

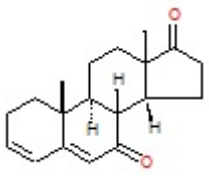
Drug Status Report

Drug: Androsta-3,5-diene-7,17-dione

Drug Name Status: Androsta-3,5-diene-7,17-dione is the common name.

Chemical Name: Androsta-3,5-diene-7,17-dione

Chemical structure:



Molecular Formula: $C_{17}H_{24}O_2$

CAS-RN: 1420-49-1

Pharmacological class / Application: Steroid

International status:

US: Androsta-3,5-diene-7,17-dione is not currently 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: Androsta-3,5-diene-7,17-dione is not listed specifically in the CDSA. The substance has been reported to be formed by the bioconversion of cholesta-3,5-dien-7-one found in wool wax by mycobateria[1] and produced by perchloric acid-induced hydrolysis of 7-oxo-DHEA-3beta-sulfate[2]. 7-oxo-DHEA is a metabolite of DHEA and is described in the scientific literature as a metabolite that is more active than DHEA in terms of inducing the thermogenic

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[1]Prome, D. et al. (1987) Conversion of sterols and triterpenes by mycobacteria. II. Transformation of 7-oxygenated sterols into androstane derivatives via a 7-deoxygenation, Biochim. Biophys. Acta, **921**:559-566.

[2]Marwah, A. et al. (2002) Ergosteroids VII: perchloric acid-induced transformations of 7-oxygenated steroids and their bio-analytical applications - a liquid chromatographic-mass spectrometry study, Bioorg. Chem. **30**:233-248.

enzymes, but which is not convertible to either testosterone or estrogens[2,3]. DHEA is currently listed as sub-item 23(26) "Prasterone (3β-hydroxyandrost-5-en-17-one) in Schedule IV to the CDSA. While 7-oxo-DHEA was considered controlled on the basis that it is a metabolite of DHEA (prasterone), androsta-3,5-diene-7,17-dione is not a metabolite of prasterone, but rather is formed by induced hydrolysis of 7-oxo-DHEA and therefore cannot be included under item 23(26) as a derivative of prasterone. In addition, there are no reports in the scientific literature that androsta-3,5-diene-7,17-dione displays anabolic activity and therefore, the substance is not considered to fall under the heading "Anabolic steroids and their derivatives including" of item 23 of Schedule IV to the CDSA.

Recommendation: Androsta-3,5-diene-7,17-dione is not included in the schedules to the CDSA and is not a controlled substance.

Date: 9 December 2010

[3]Lardy, H. et al. (1995) Erogsteroids: Induction of thermogenic enzymes in liver of rats treated with steroids derived from dehydroepiandrosterone, Proc. Natl. Acad. Sci. **92**:6617-6619.