



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

Substance: Dienogest

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

Controlled	<input type="checkbox"/>
Not Controlled	<input checked="" type="checkbox"/>

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

- The substance is not an anabolic steroid nor a derivative of an anabolic steroid.

Prepared by: \_\_\_\_\_  
Evelyn C Soo

Date: Nov 19<sup>th</sup> 2010

Verified by: \_\_\_\_\_  
Marianne Tang

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_  
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

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

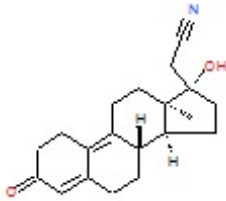
## Drug Status Report

**Drug:** Dienogest

**Drug Name Status:** Dienogest is the proper (INN) name.

**Chemical Name:** 17-Hydroxy-3-oxo-19-nor-17alpha-pregna-4,9-diene-21-nitrile

**Chemical structure:**



**Molecular Formula:** C<sub>20</sub>H<sub>25</sub>NO<sub>2</sub>

**Pharmacological class / Application:** Steroid

**CAS-RN:** 65928-58-7

**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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Dienogest is a drug used in oral contraceptives and for the treatment of endometriosis<sup>1,2</sup>. The drug is not currently listed in the CDSA and has not been reported in the scientific literature to display any anabolic activity, nor derived from an anabolic steroid. Accordingly, dienogest cannot be included under item 23 of Schedule IV to the CDSA.

**Recommendation:** Dienogest is not included in the schedules to the CDSA and is not a controlled substance.

**Date:** November 19<sup>th</sup> 2010

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<sup>1</sup>Jensen, JT. (2010) Evaluation of a new estradiol oral contraceptive: estradiol valerate and dienogest, *Expert Opin Pharmacother.* **11**:1147-1157.

<sup>2</sup>McCormack, PL (2010) Dienogest: A review of its use in the treatment of endometriosis, *Drugs*, **70**:2073-2088.