



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

Substance: Norgestrel

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 not reported in the scientific literature to display any anabolic activity and is not a derivative of an anabolic steroid.

Prepared by: Evelyn C Soo Date: Nov 19th 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

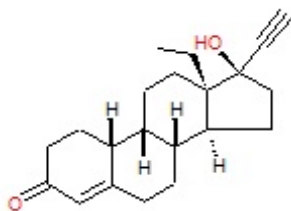
Drug: Norgestrel

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

Chemical Name: (±)-13-Ethyl-17-hydroxy-18,19-dinor-17alpha-pregn-4-en-20-yn-3-one

Other Names: Methylnorethindrone; dl-13-beta-ethyl-17alpha-ethynyl-17beta-hydroxygon-4-en-3-one

Chemical structure:



Molecular Formula: C₂₁H₂₈O₂

Pharmacological class / Application: Steroid

CAS-RN: 6533-00-2

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: Norgestrel is not listed specifically in the CDSA. The substance is used as an oral contraceptive¹ and the *l*-isomer, levonorgestrel, is regulated as a Schedule F drug under the *Food and Drugs Regulations*. Norgestrel is claimed to be a starting material in the synthesis of norbolethone, which is controlled as item 23(29) in Schedule IV to the CDSA but the substance has not been reported in the scientific literature to display any anabolic activity and is not a derivative of an anabolic steroid. Accordingly, norgestrel is not included under the heading "Anabolic steroids and their derivatives" of item 23 of Schedule IV CDSA.

¹Belle, DJ. *et al.* (2002) The effects of an oral contraceptive containing ethinylloestradiol and norgestrel on CYP3A activity, *Br. J. Clin. Pharmacol.* **53**:67-74.

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

Date: November 19th 2010