



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

Substance: Zearalenol (alpha and beta)

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):

- Neither alpha-zearalenol nor beta-zearalenol are on the schedules to the CDSA.
A structurally related substance, zeranol, is listed as item 24 of Schedule IV. However, the listing of zeranol is not extended beyond the listed substance.

Supporting document(s) attached: [X]

Prepared by: TIANA BRANCH Date: 2005-07-06

Verified by: See email MICHAEL LEBELLE Date: 2005-07-06

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

Drug: Zearalenol (alpha and beta)

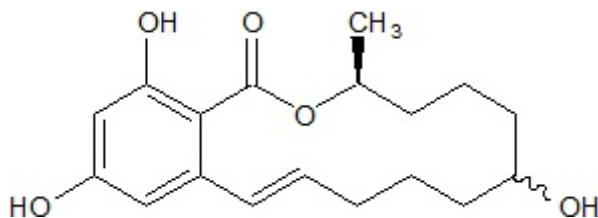
Drug Name Status: alpha-Zearalenol and beta-zearalenol are common names.

Chemical Name: The alpha isomer: (3S,7R,11E)- 3,4,5,6,7,8,9,10-octahydro-7,14,16-trihydroxy-3-methyl-1H-2-Benzoxacyclotetradecin-1-one

The beta isomer: (3S,7S,11E)- 3,4,5,6,7,8,9,10-

octahydro-7,14,16-trihydroxy-3-methyl-1H-2-Benzoxacyclotetradecin-1-one,

Chemical structure:



The structure is applicable to both alpha-zearalenol and beta-zearalenol in that the hydroxyl is alpha for the alpha isomer and beta for the beta isomer.

Molecular Formula: C₁₈H₂₄O₅

Pharmacological class / Application: metabolite of mycotoxin zearalenone.

International status:

US: The drug is not currently listed specifically on the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control

Canadian Status: Neither alpha-Zearalenol nor beta-zearalenol are on the schedules to the CDSA. A structurally related substance, zeranol, is listed as item 24 of Schedule IV. However, the listing of zeranol is not extended beyond the listed substance.

Recommendation: alpha-Zearalenol; beta-zearalenol are not included in the schedules to the CDSA and neither is a controlled substance.

July 5, 2005