



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

Substance: Tofisopam Diketone

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 a starting material used in the synthesis of tofisopam but does not contain the core structure of the benzodiazepines.

Prepared by: Evelyn Soo Date: Oct 21st 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: Wissam Sader

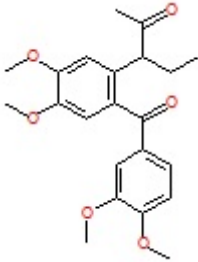
Drug Status Report

Drug: Tofisopam diketone

Drug Name Status: Tofisopam diketone is the common name.

Chemical Name: 3-[2-(3,4-dimethoxybenzoyl)-4,5-dimethoxy-phenyl]pentan-2-one

Chemical structure:



Molecular Formula: C₂₁H₂₆O₆

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: None

International status:

US: The substance not listed specifically in the 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Tofisopam diketone is a starting material used in the synthesis of tofisopam, a 2,3-benzodiazepene¹. The status of tofisopam was reviewed in 2003 and the substance was considered to be included under item 18 of Schedule IV to the CDSA, under the heading "Benzodiazepines, their salts and derivatives, including:". However, tofisopam diketone does not contain the core structure of the benzodiazepenes and is not derived from tofisopam and therefore, the substance is not included under item 18 of Schedule IV to the CDSA.

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

¹Gyogyszergyart E. *et al.* (2003) Process for the Preparation of Tofisopam and new intermediates, WIPO No WO 03/050092.

Date: 20 October 2010