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

Substance: Temazepam Related Compound G

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):

- The substance is an impurity of temazepam and contains the core structure of the 1,4-benzodiazepines and therefore is captured under Item 18 of Schedule IV to the CDSA.

Prepared by: ________________________________ Date: ______________
Evelyn C Soo

Verified by: ________________________________ Date: ______________
Mark Kozlowski

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:** Temazepam Related Compound G

**Drug Name Status:** Temazepam Related Compound G is the common name.

**Chemical Name:** 7-chloro-1,4-dimethyl-5-phenyl-4,5-dihydro-1H-1,4-benzodiazepine-2,3-dione

**Chemical structure:**

![Chemical structure](image)

**Molecular Formula:** $C_{17}H_{15}ClN_2O_2$  
**CAS-RN:** 93329-92-1

**Pharmacological class / Application:** Pharmaceutical-related impurity

**International status:**

US: Temazepam Related Compound G is not listed specifically 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: Temazepam Related Compound G is not listed specifically in the schedules to the CDSA. The substance is a synthetic impurity of temazepam, which is currently listed as sub-item 18(30) in Schedule IV to the CDSA under the heading “Benzodiazepines and their derivatives”. The substance also contains the core structure of the 1,4-benzodiazepines and therefore is considered captured under sub-item 18(30) of Schedule IV to the CDSA. A number of synthetic impurities relating to temazepam were reviewed previously and also considered captured under item 18 of Schedule IV to the CDSA.

**Recommendation:** Temazepam Related Compound G is included under item 18 of Schedule IV to the CDSA and is a controlled substance.

**Date:** August 29th, 2012.