Health Canada
Santé Canada

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

Substance: 5-Phenyloxazolidine-2,4-dione

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 a metabolite of pemoline and is not captured under Item 25.1 of Schedule IV to the CDSA.

Prepared by: _____ Date: _____
Vincent Marleau

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

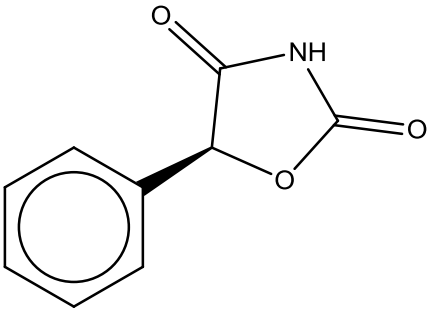
Drug: 5-Phenyloxazolidine-2,4-dione

Drug Name Status: 5-Phenyloxazolidine-2,4-dione is the common name.

Chemical Name: 2,4-Oxazolidinedione, 5-phenyl-

Other Names: 4-27-00-03335 (Beilstein Handbook Reference); 5-Phenyl-2,4-oxazolidinedione; Pemoline-dione.

Chemical structure:



Molecular Formula: $C_9H_7NO_3$ **CAS-RN:** 5841-63-4

Pharmacological class / Application: Pemoline metabolite

International status:

US: 5-Phenyloxazolidine-2,4-dione 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: 5-Phenyloxazolidine-2,4-dione is not listed in the CDSA. The substance is a metabolite of pemoline, which is listed as item 25.1 in Schedule IV to the CDSA under the heading "Pemoline (2-amino-5-phenyl-oxazolin-4-one) and any salt thereof". Since 5-Phenyloxazolidine-2,4-dione is a metabolite of pemoline, it cannot be included under item 25.1 of Schedule IV to the CDSA.

Recommendation: 5-Phenyloxazolidine-2,4-dione is not included under item 25.1 of Schedule II to the CDSA and is not a controlled substance.

Date: August 28th, 2012.