



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

Substance: I - 4-Dimethylamino-2,2-diphenylvaleric acid
II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled [checked]
Not Controlled [unchecked]

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are metabolites of methadone. As such these substances are included under item 5(4) of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Nov 23rd 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"

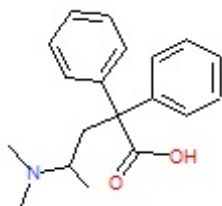
Drug Status Report

Drug: I - 4-Dimethylamino-2,2-diphenylvaleric acid
II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

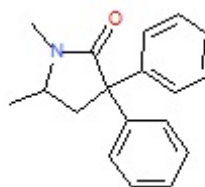
Drug Name Status: I - 4-Dimethylamino-2,2-diphenylvaleric acid
II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone are the common names.

Chemical Name: I - 4-Dimethylamino-2,2-diphenylvaleric acid
II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

Chemical structure:



I



II

Molecular Formula: I - C₁₇H₁₈N₂; II - C₁₈H₁₉NO

Pharmacological class / Application: Methadone-related

CAS-RN: I - 5348-94-7; II - 30223-75-7

International status:

US: 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are not listed specifically in the US Controlled Substances Act and are not mentioned on the DEA website.

United Nations: The substances are 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: 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are not listed specifically in the CDSA. The substances have both been reported in

the scientific literature to be minor urinary metabolites of methadone¹, and in the case of 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone, is also claimed to be a synthetic intermediate of methadone.

Methadone (6-dimethylamino-4,4-diphenyl-3-heptanone) is currently listed as item 5(4) in Schedule I under the heading “Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives including”. Given that both the substances are metabolites of methadone (and in the case of 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone, also a synthetic intermediate of methadone), 4-dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone must be included under item 5(4) of Schedule I to the CDSA.

Recommendation: 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are included under item 5(4) of schedule I to the CDSA and are controlled substances.

Date: 23 November 2010

¹Sullivan, HR. and Due, SL. (1973) Urinary metabolites of dl-methadone in maintenance subjects, J. Med. Chem. **16**:909-913.