



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

Substance: Tiletamine

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 drug is currently not listed specifically on the CDSA.
There are similar substances listed on the Schedules to the CDSA. Item 14 of Schedule I to the CDSA is, "Phencyclidine (1-(1-phenylcyclohexyl)piperidine), its salts, derivatives and analogues and salts of derivatives and analogues."
The four analogues of phencyclidine currently listed as items 13-16 of Schedule III (CDSA) are: N-(1-phenylcyclohexyl)ethylamine (PCE), 1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP), 1-Phenyl-N-propylcyclohexanamine and Rolicyclidine (1-(1-phenylcyclohexyl)pyrrolidine). From these examples of substances considered to be within the family of phencyclidine and its analogues, the two structural fragments that appear to be considered characteristic of phencyclidine are the phenylcyclohexyl and the cyclohexylpiperidine
As the structure of tiletamine contains neither a phenylcyclohexyl nor a cyclohexylpiperidine moiety, it should not be considered an analogue of phencyclidine.

Supporting document(s) attached: X

Prepared by: TIANA BRANCH Date: 2005-07-04

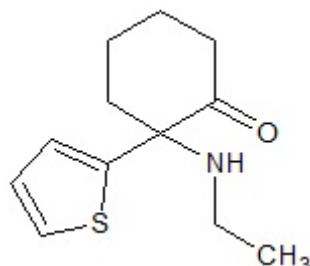
Verified by: See email Date: 2005-07-04
MICHAEL LABELLE

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

Drug Name Status: Tiletamine is INN, USAN and BAN

Chemical Name: 2-(Ethylamino)-2-(2-thienyl)cyclohexanone

Chemical structure:



Molecular Formula: C₁₂H₁₇NOS

Pharmacological class / Application: anticonvulsant; dissociative anesthetic

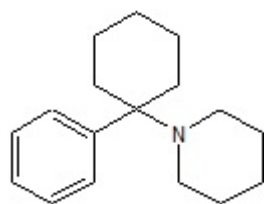
International status:

US: The combination product containing tiletamine and zolazepam is listed on Schedule III to the CSA.

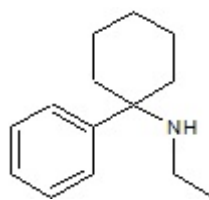
United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control

Canadian Status: The drug is currently not listed specifically on the CDSA. There are similar substances listed on the Schedules to the CDSA. Item 14 of Schedule I to the CDSA is, "Phencyclidine (1-(1-phenylcyclohexyl)piperidine), its salts, derivatives and analogues and salts of derivatives and analogues." Four analogues of phencyclidine are currently listed as items 13-16 of Schedule III to the CDSA. They are: N-(1-phenylcyclohexyl)ethylamine (PCE), 1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP), 1-Phenyl-N-propylcyclohexanamine and Rolicyclidine (1-(1-phenylcyclohexyl)pyrrolidine). The structures of these five substances are shown on the next page.

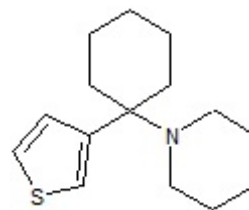
In May, 2005, OCS interpreted "analogues" of phencyclidine in giving notice that ketamine is "an analogue of phencyclidine (PCP), and is, therefore, captured as item 14 in Schedule I of the CDSA". The structure of this ketamine is also shown on the next page.



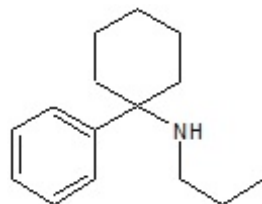
Phencyclidine



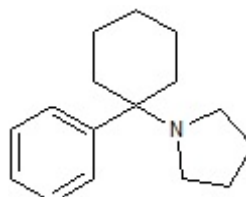
PCE



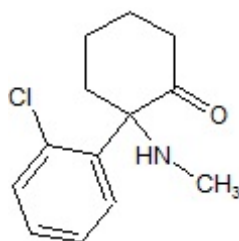
TCP



1-Phenyl-N-propyl-
cyclohexanamine

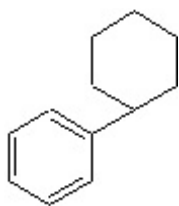


Rolicyclidine

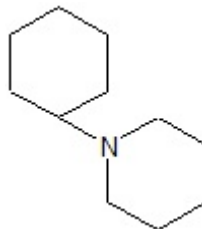


Ketamine

From these examples of substances considered to be within the family of phencyclidine and its analogues, two structural fragments appear to be considered characteristic of phencyclidine. They are the phenylcyclohexyl and the cyclohexylpiperidine. These fragments are shown below.



Phenylcyclo-
hexyl moiety



Cyclohexyl-
piperidine
moiety

It should be noted that only ketamine contains an oxygen in the cyclohexane ring.

As the structure of tiletamine contains neither a phenylcyclohexyl nor a cyclohexylpiperidine moiety, it should not be considered an analogue of phencyclidine.

The use of the analogue provision of the CDSA should be tempered by prudence. The extension of items under the analogue provisions was intended to capture new hazardous chemicals with pharmacological properties attractive to recreational drug users. This provided for the immediate control of “designer” drugs to protect the general public. The inclusion of new substances within an item using the analogue provision of the CDSA logically extends the scope of the item of the schedule thereby accidentally including unnecessary substances.

Recommendation: Tiletamine is not currently included in the schedules to the CDSA and is not a controlled substance.

July 4, 2005