Health Canada
Santé Canada

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

Substance: 4-Fluoroephedrine

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 not a salt of ephedrine and therefore cannot be included under item 4 in Part 1 of Schedule VI 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

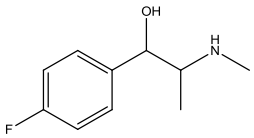
Drug: 4-Fluoroephedrine

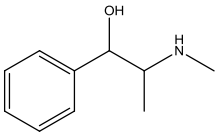
Drug Name Status: 4-Fluoroephedrine is the common name.

Chemical Name: 1-(4-fluorophenyl)-2-(methylamino)propan-1-ol

Other Names: 4-Fluoro-α-[1-(methylamino)ethyl]benzenemethanol

Chemical structure:





Ephedrine

Molecular Formula: $C_{10}H_{14}FNO$ **CAS-RN:** 63009-92-7

Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: 4-Fluoroephedrine 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: 4-Fluoroephedrine is not listed in the Schedules to the CDSA. The substance has been proposed to be a metabolite of flephedrone but a recent study has shown that flephedrone is metabolised to form its N-demethylated and hydroxylation products, and unlike similar substances such as methylethcathinone, methylone and pentylone, a reduction of its keto group does not occur during Phase I metabolism[i]. Accordingly, 4-fluoroephedrine cannot be captured under item 19 of Schedule I to the CDSA as a derivative of flephedrone. It is noteworthy that the substance also displays substantial structural similarity to ephedrine, which is currently listed as item 4 in Part 1 of Schedule VI to the CDSA as "Ephedrine (erythro-2-(methylamino)-1-phenylpropan-1-ol), its salts and any plant containing ephedrine or any of its salts". However, since 4-fluoroephedrine is not a salt of ephedrine, it cannot be included under item 4 in Part 1 of Schedule VI to the CDSA.

Recommendation: 4-Fluoroephedrine is not included under item 4 in Part 1 of Schedule VI to the CDSA and is not a controlled substance or a precursor chemical.

Date: November 19th, 2012.

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[i] Mueller, DM et al. (2012) Generation of metabolites by an automated online metabolism method using human liver microsomes with subsequent identification by LC-MS(n), and metabolism of 11 cathinones, Anal. Bioanal. Chem. **402**:2141-2151.