Health Canada
Santé Canada

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

Substance: rac Hydroxyethyl norfenfluramine hydrochloride

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

Controlled	X
Not Controlled	☐

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

- The substance is an analogue of N-(2-Hydroxyethyl)-alpha-methylbenzeneethanamine and is captured under sub-item 1(20) of Schedule III 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"

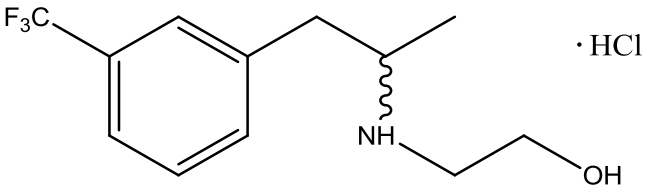
Drug: rac Hydroxyethyl norfenfluramine hydrochloride

Drug Name Status: rac Hydroxyethyl norfenfluramine hydrochloride is the common name.

Chemical Name: (+/-)-2-[[1-Methyl-2-[3-(trifluoromethyl)phenyl]ethyl]amino]ethanol Hydrochloride

Other Names: N-(2-Hydroxyethyl)norfenfluramine Hydrochloride; S 422-1; SE 422.

Chemical structure:



Molecular Formula: $C_{12}H_{17}ClF_3NO$

CAS-RN: 54779-69-0

Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: rac Hydroxyethyl norfenfluramine hydrochloride 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: rac Hydroxyethyl norfenfluramine hydrochloride is not listed in the schedules to the CDSA. The substance is a derivative of norfenfluramine, which is captured under Item 1 of Schedule III to the CDSA as an analogue of amphetamine. In addition, the substance has a substantially similar chemical structure to N-(2-Hydroxyethyl)-alpha-methylbenzeneethanamine which is listed as sub-item 1(20) in Schedule III to the CDSA, under the heading "Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues including". For the purpose of forming status decisions, a substance which displays substantial structural similarity to a controlled substance is considered an analogue. Therefore, rac Hydroxyethyl norfenfluramine hydrochloride must be included under sub-item 1(20) of Schedule III to the CDSA as an amphetamine analogue.

Recommendation: rac Hydroxyethyl norfenfluramine hydrochloride is included under sub-item 1(20) of Schedule III to the CDSA and is a controlled substance.

Date: May 7th, 2012.