Health Canada Santé Canada

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

Substance: rac Norphenylephrine hydrochloride

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 similar to any of the substances in the CDSA.

Prepared by: _____ Date: February 2nd, 2012
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

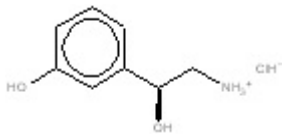
Drug: rac Norphenylephrine hydrochloride

Drug Name Status: rac Norphenylephrine hydrochloride is the common name.

Chemical Name: Benzenemethanol, alpha-(aminomethyl)-3-hydroxy-, hydrochloride (9CI)

Other Names: Benzyl alcohol, alpha-aminomethyl-3-hydroxy-, hydrochloride; Norfenefrine HCl; Norphenephrine hydrochloride;Norphenylephrine hydrochloride; WIN 5501; Norfenefrine hydrochloride.

Chemical structure:



Molecular Formula: $C_8H_{11}NO_2$. HCl

Pharmacological class / Application: Fine Chemicals

CAS-RN: 4779-94-6

International status:

US: rac Norphenylephrine hydrochloride is not listed in 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 Norphenylephrine hydrochloride is not specifically listed in the schedules to the CDSA. It is the desmethylated form of phenylephrine, which is listed as a Schedule F substance under the *Food and Drugs Regulation* under the heading "Phenylephrine and its salts in preparations for ophtalmic or parenteral use in concentrations greater than 2.5%". Since the substance does not display any similarity to those listed in the CDSA, it is not considered a controlled substance.

Recommendation: rac Norphenylephrine hydrochloride is not included in any of the Schedules to the CDSA and is not considered a controlled substance.

Date: February 2nd, 2012.