Health Canada
Santé Canada

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

Substance: Palmidrol

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 substance is an endocannabinoid and does not show any cannabinoid receptor agonist activity.

Prepared by: _____ Date: _____
Zack Li

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

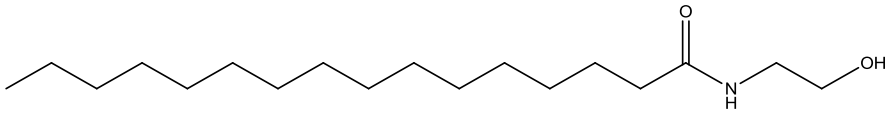
Drug: Palmidrol

Drug Name Status: Palmidrol is the INN name.

Chemical Name: Hexadecanamide, N-(2-hydroxyethyl)-

Other Names: Palmitoylethanolamide; PEA; palmidrolum; N-(2-Hydroxyethyl)palmitamide; monoethanolamine palmitic acid amide; hydroxyethylpalmitamide; loramine P 256; palmitinsaeure-beta-hydroxyethylamid

Chemical structure:



Molecular Formula: $C_{18}H_{37}NO_2$

Pharmacological class / Application: Endocannabinoid

CAS-RN: 544-31-0

International status:

US: Palmidrol 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: Palmidrol is not listed in the schedules to the CDSA. The substance is an endocannabinoid and in studies evaluating its anti-inflammatory potential, palmidrol has been found to demonstrates no activity at the CB_1 or CB_2 cannabinoid receptors[1]. "Cannabis, its preparations, derivatives and similar synthetic preparations" are currently listed as item 1 in Schedule II to the CDSA. Given that palmidrol does not demonstrate any cannabinoid receptor agonist activity, it cannot be included in item 1 of Schedule II to the CDSA.

Recommendation: Palmidrol is not included in the Schedules to the CDSA and is not a controlled substance.

Date: May 24th, 2012.

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[1] O'Sullivan, SE et al. (2010) Cannabinoid activation of peroxisome proliferator-activated receptors: potential for modulation of inflammatory disease, Immunobiology **215:** 611-616