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

Substance: Everolimus

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

<table>
<thead>
<tr>
<th>Controlled</th>
<th>Not Controlled</th>
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<tbody>
<tr>
<td></td>
<td>X</td>
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under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substance is not similar in structure to any of those included in the schedules to the CDSA.

Prepared by: ________________________________  Date: ______________

Evelyn C Soo

Verified by: ________________________________  Date: ______________

Mark Kozlowski

Approved by: ________________________________  Date: ______________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Evelina Rutkowski, OCS
Drug Status Report

Drug: Everolimus

Drug Name Status: Everolimus is the common name.

Chemical Name: \[(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-Dihydroxy-12-((1R)-2-((1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl)-1-methylethyl)-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxo-4-azatricyclo(30.3.1.0_{4,9})hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentaone\]

Other Names: 42-O-(2-Hydroxyethyl)-rapamycin

Chemical structure:

![Chemical structure](image)

Molecular Formula: \(C_{53}H_{83}NO_{14}\)

CAS-RN: 159351-69-6

Pharmacological class / Application: Immunosuppressant

International status:

US: Everolimus 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: Everolimus is not listed in the schedules to the CDSA. The substance is an inhibitor of rapamycin (mTOR) and has been shown to be effective for the treatment of
neuroendocrine tumours¹, and is used as an immunosuppressive drug following organ transplantation². Everolimus phthalate does not display structural similarity to any of the substances listed in the CDSA.

**Recommendation:** Everolimus is not included in the schedules to the CDSA and is not a controlled substance.

**Date:** April 13th, 2012.

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