Health Canada Santé Canada

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

Substance: Polyaspartic acid

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 listed in the Schedules to the CDSA and is not considered to belong to any family or group listed in the Schedules.

Prepared by: _____ Date: June 24, 2011
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

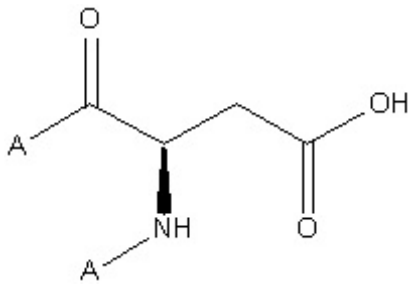
Drug: Polyaspartic acid

Drug Name Status: Polyaspartic acid is the common name.

Chemical Name: Poly(imino((1S)-1-(carboxymethyl)-2-oxo-1,2-ethanediyl))

Other Names: Poly(imino(1-(carboxymethyl)-2-oxo-1,2-ethanediyl)), (S)-

Chemical Structure:



Pharmacological class / Application: Polyamide

CAS-RN: 26063-13-8

International status:

US: Polyaspartic acid is not listed on 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: Polyaspartic acid is a polyamide based on aspartic acid used medically as synthetic bone[1] and is not listed in the Schedules to the CDSA. The substances is also not structurally similar to any of the substances listed in the schedules to the CDSA

[1]Thula. T.T., et al (2011). In vitro mineralization of dense collagen substrates: a biomimetic approach toward the development of bone-graft materials. Acta Biomater (Just accepted manuscript)

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

Date: June 24, 2011