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

Substance: 3-(4-amino-2-methylpyrimidin-5-ylmethyl)-5-(2-hydroxyethyl)-4-
methylthiazole-2(3H)-thione

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 a related impurity of thiamine (vitamin B1) and is not similar to any of the substances included in the CDSA.

Prepared by: ________________________________ Date: Sept 9th 2010

Evelyn Soo

Verified by: ________________________________ Date: __________

Marianne Tang

Approved by: ________________________________ Date: ______________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Eva Roig on behalf of a company importing the substance.
Drug Status Report

**Drug**: 3-(4-amino-2-methylpyrimidin-5-ylmethyl)-5-(2-hydroxyethyl)-4-methylthiazole-2(3H)-thione

**Drug Name Status**: EP Thiamine Impurity E is the common name.

**Chemical Name**: 3-(4-amino-2-methylpyrimidin-5-ylmethyl)-5-(2-hydroxyethyl)-4-methylthiazole-2(3H)-thione

**Chemical structure:**

![Chemical Structure](image)

**Molecular Formula**: C_{12}H_{16}N_{4}OS_{2}

**Pharmacological class / Application**: Pharmaceutical-related substance

**CAS-RN**: 299-35-4

**International status**:  
US: The substance is not listed specifically in the CSA 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: 3-(4-amino-2-methylpyrimidin-5-ylmethyl)-5-(2-hydroxyethyl)-4-methylthiazole-2(3H)-thione is a related impurity of thiamine, which is more commonly known as vitamin B1. The substance is not currently listed in the CDSA and is not similar to any of the substances included in the Schedules to the CDSA.

**Recommendation**: 3-(4-amino-2-methylpyrimidin-5-ylmethyl)-5-(2-hydroxyethyl)-4-methylthiazole-2(3H)-thione is not included in the Schedules to the CDSA and is not a controlled substance.

**Date**: 9 September 2010