



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

Substance: Erythro [(R\*,S\*)] methylphenidate

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

Controlled X
Not Controlled [ ]

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- Methylphenidate is included in Schedule III as item 2, "Methylphenidate (a-Phenyl-2-piperidineacetic acid methyl ester) and any salt thereof."
The name methylphenidate includes all of the isomers of methylphenidate.

Supporting document(s) attached:

Prepared by: SHEREEN KHAN Date:

Verified by: See email MICHAEL LEBELLE Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

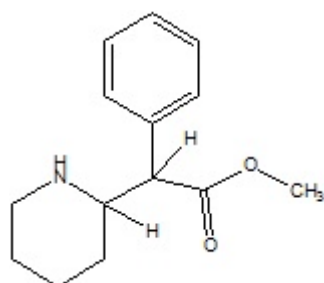
## Drug Status Report

**Drug:** Erythro [(R\*,S\*)] methylphenidate

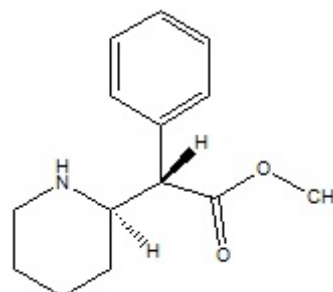
**Drug Name Status:** Erythro [(R\*,S\*)] methylphenidate is a common name; methylphenidate hydrochloride is USAN and JAN; methylphenidate is INN

**Chemical Name:** (R,S)-alpha-phenyl-2-piperidineacetic acid methyl ester

**Chemical structure:**



Methylphenidate



(R,S)-Methylphenidate

**Molecular Formula:** C<sub>14</sub>H<sub>19</sub>NO<sub>2</sub>

**Pharmacological class / Application:** methylphenidate related compound

**International status:**

US: Methylphenidate is listed on Schedule II to the US Controlled Substances Act.

United Nations: Methylphenidate is listed on Schedule II to the 1971 Convention.

Canadian Status: Methylphenidate is included in Schedule III as item 2, "Methylphenidate (α-Phenyl-2-piperidineacetic acid methyl ester) and any salt thereof." Methylphenidate is a substance with two optically active (chiral) carbon atoms. These atoms have four different substituents attached to each. As two different isomers are possible at each chiral atom, two chiral atoms results in four optical isomers. Optical isomers are most rigorously designated by using the absolute stereochemical designations R and S at each chiral atom. The erythro R,S isomer of methylphenidate is shown above on the right. The other possible isomers are R,R, S,S and S,R.

When methylphenidate was developed in the 1950s, it was marketed as a mixture of all four possible isomers. The name methylphenidate then includes all of the

isomers of methylphenidate. This interpretation is supported in regulatory approaches in other jurisdictions including the 1971 Convention and the US CSA.

Recommendation: Erythro [(R\*,S\*)] methylphenidate is included in item 2 of Schedule III to the CDSA and is a controlled substance.

February 9, 2006