

Drug Status Report

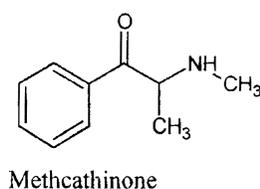
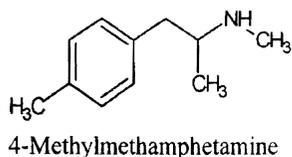
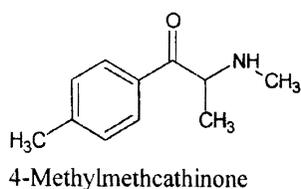
Drug: 4-Methylmethcathinone

Drug Name Status: 4-Methylmethcathinone is the common name

Other Names: Mephedrone; 2-methylamino-1-p-tolylpropan-1-one

Chemical Name: 2-Methylamino-1-(4-methylphenyl)-1-propanone

Chemical structure:



Molecular Formula: C₁₁H₁₅NO

Pharmacological class / Application: stimulant

International status:

US: The substance is not currently listed on the US Controlled Substances Act and is not mentioned on the DEA website. However, 4-methylmethcathinone is controlled¹ in the US due to the analogue provisions in the CSA.

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: Item 1 of Schedule III to the CDSA is, "Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues." Although not listed specifically in item 1 of Schedule III, 4-methylmethamphetamine (structure above) is an amphetamine. 4-Methylmethcathinone is analogous to 4-methylmethamphetamine in that it contains the same structure with an additional oxygen. 4-Methylmethcathinone is therefore an analogue of 4-methylmethamphetamine and is included in item 1 of Schedule III to the CDSA.

A similar rationale was used to recommend that 2-methylamino-1-(3,4-methylenedioxy)-propiophenone be included in item 1 of Schedule III. That report is appended for information.

¹ http://www.usdoj.gov/dea/programs/forensicsci/microgram/journal_v5_num14/pg1.html

The substance is also structurally similar to 2-methylamino-1-phenyl-1-propanone (methcathinone) which is listed as item 21 of Schedule III to the CDSA.

Recommendation: 4-Methylmethcathinone is included in item 1 of Schedule III to the CDSA and is a controlled substance.

June 19, 2008

STATUS

Standard Operating Procedures

All correspondence must be done through the STATUS account and not your personal Lotus account.

Prepared by Amira Sultan
Reviewed by Alanna Maloney

BACKGROUND

Objective: To determine whether a particular substance of interest is controlled under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations.

Requests are received from within the Office of Controlled Substances (OCS) – Licenses and Permits Division, Evaluation and Authorization Division, Policy and Regulatory Affairs Division or from external clients such as the Royal Canadian Mounted Police, Canadian Border Services Agency, Health Products and Food Branch Inspectorate, pharmaceutical and chemical companies and individuals.

STANDARD OPERATING PROCEDURES

1. A status request may be received by the Evaluation and Authorization Division (EAD) through a variety of ways:
 - via e-mail (status@hc-sc.gc.ca)
 - via telephone ((613) 941-9582)
 - via fax ((613) 952-8576)

** requests made in person by members in the office should be avoided, please request that the person send a formal e-mail to the STATUS account.

2. Check the urgency of all status requests and process those of an urgent nature first. An example of an urgent status would be a status request from a Border Services Officer, in which a package is being detained.
3. Once the request is received, what is known as a **preliminary search** is to be performed. See Appendix A for a copy of "Status Decision: Preliminary Search Checklist" (L:\OCS\EAD\EAD Status\StatusDecision\STATUS PRELIMINARY CHECKLIST- 2007).

A number of resources and online search engines are to be consulted during the preliminary search.

Please note: In order to perform an effective preliminary search it is recommended that once a request for a substance is received, that you verify the correct spelling of

this substance. One suggestion would be to put the name into a search engine such as GOOGLE.

1. Verify whether the substance is listed in the CDSA, the most up to date version may be found online at the following link:

<http://laws.justice.gc.ca/en/ShowFullDoc/cs/C-38.8//en>

2. Verify the STATUS account "all documents" folder to determine if there have been any previous e-mails sent on this substance as to whether the substance was controlled or not controlled.

- In the Status account window go to views > all documents – then click on the magnifying loop icon (found at the top of the window), a search field will appear, type in the substance of interest and hit enter.

Please note: some status e-mails date from a few years back, so if the e-mail is not relatively recent, it would be a good idea to ensure that the status of the substance has not changed.

3. Verify the Office OCS list of controlled and non-controlled substances

pathways are:

L:\OCS\EAD\EAD Status\StatusDecision>List of Controlled Substances

L:\OCS\EAD\EAD Status\StatusDecision>List of Non-Controlled Substances

4. Verify the *Food and Drugs Act, Food and Drugs Regulations*

Food and Drugs Act - <http://laws.justice.gc.ca/en/showtdm/cs/F-27//en>

Food and Drugs Regulations - <http://laws.justice.gc.ca/en/showtdm/cr/C.R.C.-c.870>

5. Verify "The Compendium of Pharmaceuticals and Specialties (CPS)" reference and "Martindale – The Complete Drug Reference". EAD has their own copies of these references.

- *make sure to note any pertinent information found in these references on the "Preliminary Search Checklist".*

6. Verify the Therapeutic Product Directorate (TPD) Drug Products Database:

<http://cpe0013211b4c6d->

cm0014e88ee7a4.cpe.net.cable.rogers.com/dpdonline/startup.do

4. Based on all the information gathered during the preliminary check, the officer must make a recommendation as to whether the substance is controlled or not.

Unless the status of substance is obvious (i.e. over-the-counter drug, common substance, prescription drug or already on the OCS list of controlled/non-controlled substances) a formal status will need to be requested.

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[REDACTED]@rogers.com), our chemist consultant must be issued an e-mail through the STAIUS account requesting a "status decision" on the substance in question. All information gathered during the preliminary check should also be provided to the chemist.

5. [REDACTED] will evaluate the substance and prepare a formal Drug Status Report and will send it to the STATUS account.
5. Once the drug status report is received from [REDACTED] the officer will then prepare a status decision folder (green folder) which will contain the following items: (*do not staple any documentation in the folder*)
 - a) a status decision form (see Appendix B) for signature by the Director, pathway:
L:\OCS\EAD\EAD Status\StatusDecision\StatusForm(updated2007).wpd
 - b) the status report prepared by the chemist and any pertinent e-mails or correspondence
 - c) a blue Office of Controlled Substances tracking sheet (see Appendix C) is to filled out and appended to the outside of the green folder:
 - date the form
 - check off "To Director"
 - sign your name where it says reply – prepared by and date it
6. The green folder with the appended blue sheet will then be given to the assistant to the EAD manager. The assistant to the EAD manager will then ensure that the manager approves it before going to the Director for signature.
6. Once the Director has signed the status decision form, the status report is received back by the officer, the officer will then reply by e-mail, fax or phone to the original requestor notifying them of the decision.

This standard response may be found in the STATUS account "sent items":

Status/HC-SC/GC/CA
Sent by: YOU (the officer) To Jane Doe/HC-SC/GC/CA
2007-08-31 02:34 PM cc
Subject: status of: methyl phenylacetate⁽¹⁾
t

Hello **ORIGINAL REQUESTOR**,

Based on the current information available to the Office of Controlled Substances, methyl phenylacetate is **not a controlled substance** under the schedules to the *Controlled Drugs and Substances Act*.

Thank you,
YOU, the officer
Evaluation and Authorization Officer
Office of Controlled Substances
Healthy Environments and Consumer Safety Branch
Health Canada

7. The status request track sheet (internal tracking of number of requests and from whom) is to be completed by the officer and can be found at:
L:\OCS\EAD\EAD Status\StatusDecision\Status Track Sheet.XLS

8. A copy of every drug status report must be maintained on the LAN. Go to the STATUS account where the e-mail with the attached drug status report from Mr. Lebelte may be found and open the attachment. Save the attachment under:

L:\OCS\EAD\EAD Status\StatusDecision

In the "save as" field, type the following if the substance is controlled:

C-substance name- YYYY/MM/DD status report was signed by Director.wpd

And if the substance is not controlled:

NC-substance name-YYYY/MM/DD status report was signed by Director.wpd

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9. The e-mail from [redacted] is to then be filed in the appropriate folder in the STATUS account (Folders > Approved Controlled or Approved Not Controlled). The original requestor e-mail (if the request was made by e-mail is also to be filed in the appropriate folder in the STATUS account (Folders > Internal Questions and Responses or External Questions and Responses)

10. Remove the signed drug status report from the green folder. Discard the green folder and the blue tracking sheet. Staple the status decision form and the drug status report along with any other pertinent information that was in the folder.
This status drug report is now ready for filing.

APPENDIX A

STATUS DECISION: Preliminary Search Checklist

File Number:	Substance:		
1. PRELIMINARY SEARCH			
Is the substance listed in any of the following?	YES	NO	If yes, Schedule (if applicable):
1. <i>Controlled Drugs and Substances Act (CDSA)</i>	<input type="checkbox"/>	<input type="checkbox"/>	
2. STATUS account inbox <input type="checkbox"/>	<input type="checkbox"/>		
3. OCS List of Controlled/Non-Controlled Substances	<input type="checkbox"/>	<input type="checkbox"/>	
4. <i>Food and Drugs Act / Food and Drugs Regulations</i>	<input type="checkbox"/>	<input type="checkbox"/>	
5. A) Compendium of Pharmaceuticals and Specialties	<input type="checkbox"/>	<input type="checkbox"/>	
5. B) Martindale - The Complete Drug Reference	<input type="checkbox"/>	<input type="checkbox"/>	
6. TPD's Drug Products Database	<input type="checkbox"/>	<input type="checkbox"/>	
OCS' List of Controlled/Non-Controlled Substances	<input type="checkbox"/>	<input type="checkbox"/>	
If yes: Decision: _____ Date of Decision: _____ File #: _____			
Information from "Compendium of Pharmaceuticals and Specialties and Martindale - The Complete Drug Reference":			
2. RECOMMENDATION			
<input type="checkbox"/> During the preliminary review of the above mentioned substance, it appears that it is NOT CONTROLLED under the CDSA, for the following reason(s): _____			
<input type="checkbox"/> During the preliminary review of the above mentioned substance, it appears that it is CONTROLLED under the _____. Therefore, a status decision <i>may not</i> be necessary.			
<input type="checkbox"/> During the preliminary review of the above mentioned substance, it appears that it MAY or MAY NOT be controlled under the CDSA. Therefore, a status decision is necessary.			
3. COMMENTS			

Prepared By:	Date:
	Forwarded to <input type="checkbox"/> YES <input type="checkbox"/> NO

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Health Canada / Santé Canada



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

Substance: Fluoromethcathinone

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):

- Fluoromethcathinone is included in item 1 of Schedule III to the CDSA and is a controlled substance.

Prepared by: Amira M. Sultan Date: 2009-10-16
AMIRA M. SULTAN

Verified by: See email Date: 2009-10-16
MICHAEL LEBELLE

Approved by: [Signature] Date: 2009/10/16
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by:
Nathalie Grondin
Spécialiste des laboratoires clandestins / Clan Lab Specialist
Service d'analyse des drogues / Drug Analysis Service

Drug Status Report

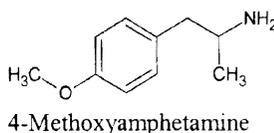
Drug: Fluoromethcathinone

Drug Name Status: Fluoromethcathinone is the common name.

There are three possible isomers - 2-, 3- and 4-fluoromethcathinone. The 4-fluoro isomer will be dealt with in detail. The other isomers have the same status as the 4 isomer.

Chemical Name: 2-Methylamino-1-(4-fluorophenyl)-1-propanone

Chemical structure:



Molecular Formula: C₁₀H₁₂FNO

Pharmacological class / Application: amphetamine

International status

US: The substance is not listed on the US Controlled Substances Act and is not mentioned on the DEA website. However, fluoromethcathinone may be controlled in the US due to the analogue provisions in the CSA.

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: Item 1 of Schedule III to the CDSA is, "Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues." Subitem 1(7) is 4-methoxyamphetamine which is also known as PMA (structure shown above). "Analogue" is defined in the Act as "a substance that, in relation to a controlled substance, has a substantially similar chemical structure." As the structure of 4-fluoromethcathinone is substantially similar to 4-methoxyamphetamine, it is an analogue of that substance and included in item 1 of Schedule III. As all isomers of substances in item 1 of Schedule III are also included in that item, the 2- and 3-positional isomers of 4-fluoromethcathinone are also included in item 1.

Recommendation: Fluoromethcathinone is included in item 1 of Schedule III to the CDSA and is a controlled substance.

October 16, 2009



2010-11-09 04:01 PM

To Status/HC-SC/GC/CA@HWC

cc

bcc

Subject classification request for Dinintel

History:

✉ This message has been replied to.

Good afternoon,

several hundred pills call **Dinintel**.

We believe they are Schedule 3 CDSA drugs :

Here is the web page that describes a bit Dinintel
<http://www.drugs.com/international/dinintel.html>

As you see, the chemical name is very similar to item number 18 of CDSA Schedule III
(Methamphetamine).

Please note that I will be out of the office tomorrow Wednesday, November 10, therefore would you please

Best regards,



2010-11-10 09:57 AM

To Status <status@hc-sc.gc.ca>, Permit-Permis <permitpermis@phac-aspc.gc.ca>, ImportZoopath <ImportZoopath@inspection.gc.ca>

cc

bcc

Subject FW: REGULATORY ISSUE?

History:

This message has been replied to.

Dear OCS, PRD, OBCS,

Our Customer Service manager has brought the product below to my attention. Do any of your respective offices regulate this item. I took a quick look through the HPTA and did not find this toxin listed under the Toxins section, nor did I find this on any of the scheduled of Controlled Substances. I did not check whether this could be pathogenic in animals.

Pasted below is information about the product, as well as the link to this company's website:

<http://www.latoxan.com/PHP/00000007.php>

Page [Alphabetical Index](#) - ACONITINE

ACONITINE Prod. No L6001 - CAS # **302-27-2**

< [First](#) < [Previous](#) - [Next](#) > [Last](#) >

Product Name ACONITINE

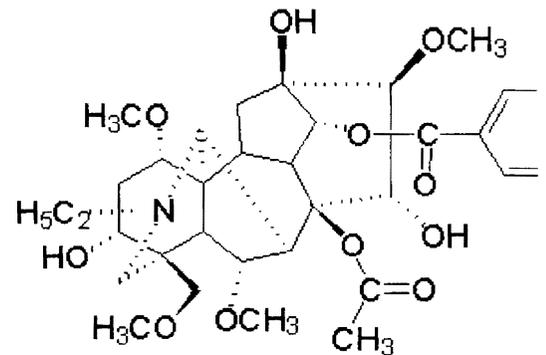
(Syn.: Aconitin, Aconitinum, Aconitysat, Akonitin)

Product Code L6001

Molecular Formula $C_{34}H_{47}NO_{11}$

Description Neurotoxic; opens the TTX-sensitive Na^+ channel in the heart and other tissues; used for creating models of cardiac arrhythmia.

Alkaloid $C_{34}H_{47}NO_{11}$, from the plant *Aconitum karacolicum*, Ranunculaceae.



Please advise about any questions or concerns.

Many thanks for your assistance with this item.

Have a nice day.

Kind regards,

Not Relevant as agreed by requester

This communication, including any attachments, is intended solely for the use of the addressee and may contain information which is privileged, confidential, exempt from disclosure under applicable law or subject to copyright. If you are not an intended recipient, any use, disclosure, distribution, reproduction, review or copying is unauthorized and may be unlawful. If you have received this transmission in error, please notify the sender immediately. Thank you.



Status request for ω -Hydroxy Fentanyl [83708-11-6]

to:
Evelyn Soo
2010-11-10 11:53 AM
[Show Details](#)

History: This message has been replied to.

Dear Evelyn,

I just want to confirm with you if ω -Hydroxy Fentanyl [83708-11-6] is **controlled** in Canada.

Thank you for your time and consideration,

Not Relevant as agreed by requester

000015

Status request for 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (cis/trans mixture) [30223-73-5]

to:

Evelyn Soo

2010-11-10 03:33 PM

Show Details

History: This message has been replied to.

Dear Evelyn,

Please check status if 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (cis/trans mixture) [30223-73-5] is controlled. It's a metabolite of methadone [76-99-3].

Thank you for your time and consideration,

Not Relevant as agreed by requester



Status request for 1-[1-(2-Thienyl)cyclohexyl]pyrrolidine Hydrochloride [22912-14-7]

to:

Evelyn Soo

2010-11-10 03:39 PM

Show Details

Not Relevant as agreed by requester

History: This message has been replied to.

Dear Evelyn,

1-[1-(2-Thienyl)cyclohexyl]pyrrolidine Hydrochloride [22912-14-7] is an analog of phencyclidine hydrochloride [956-90-1]. It's ought to be controlled.

Thank you for your time and consideration,