



Standard Operating Procedure

DEA Exempt Chemical Preparation Use

Department:	Chemistry
Date SOP was approved by PI/lab supervisor:	25 October 2021
Principal Investigator:	Vincent Remcho
Lab Safety Coordinator/Lab Manager:	Saichon Sumantakul
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Emergency Contact:	Vincent Remcho 541-737-8181
Location(s) covered by this SOP:	Linus Pauling Science Center 296

Type of SOP: Process Hazardous Chemical Equipment

1. Purpose

Propofol will be used for research purposes in the study high performance liquid chromatography (HPLC) separations for quantifying propofol in blood plasma for clinical research in anesthesiology.

2. Procedure/Scope:

Synthetic blood plasma is spiked with propofol to emulate propofol in human blood plasma. This sample will undergo ultrafiltration via centrifugation then liquid-liquid extraction where propofol will partition into an organic layer of cyclohexane. The organic layer will be injected into a HPLC coupled with mass spectrometry for quantification.

Physical & Chemical Properties/Definition of Chemical Group

CAS#: [2078-54-8]

The GHS classifies propofol as an irritant that has the potential to cause skin, eye, and respiratory tract irritation/damage. Propofol is also noted to be acutely toxic if ingested orally and has specific organ toxicity to the respiratory tract upon single exposure.

3. Safety Data Sheet (SDS) Location



Online SDS can be accessed at (<http://oregonstate.edu/ehs/sds>). A hard copy can be found at Oak Creek Building with Environmental Health & Safety.

4. Personal Protective Equipment (PPE)

Laboratory personnel must always wear a lab coat when working in a lab. Closed-toed shoes are also required at all times.

Hand Protection: Protective nitrile gloves are to be always used when handling

Eye Protection: Safety glasses or chemical splash goggles must be worn

Skin and Body Protection: Lab coat, pants that fully cover the skin, and close toed shoes must be worn

Respiratory Protection: To reduce the exposure, preparation must be completed in a fume hood or a well-ventilated area

Hygiene Measures: Thoroughly wash hands and skin used after handling

5. Security and Access Control

Only Authorized users shall have access to DEA Exempted chemical preparations. Authorized User Form available upon request.

Authorized users needing to use the propofol must request and sign out the key to the lock box and locked refrigerator from the principal investigator. The user will retrieve the propofol, then lock the box and freezer prior to performing the experiment. Upon completion of the experiment, the authorized user will request the keys from the principal investigator, return the stock propofol to the lock box and refrigerator, return keys to the principal investigator, sign the usage log, and indicate how much propofol was used.

6. Lost or Stolen Controlled Substances

Procedures for reporting lost or stolen DEA exempt chemical preparations (all thefts or losses of controlled substances must be reported to Public Safety and EH&S immediately upon discovery):

Significant losses or theft must be reported immediately to OSU Public Safety and Controlled Substance Program Coordinator must be contacted.

- Use online DEA Form 106: Report of Loss or Theft to follow up with the faxed report.

Minor discrepancies in inventory **that are not attributed to theft or loss** can be reconciled on the inventory report with proper notation. A DEA Form 106 does not need to be submitted for this purpose.



7. Record Keeping

Authorized user will note their name and date when obtaining the propofol from secured storage. Upon completion of an experiment and return of the stock bottle to secure storage, they will note the volume of drug used.

A Controlled Substance Usage Log will be used to log the physical balance of the CSs at all times, and all discrepancies will be documented with explanation. This form will be kept for the duration of the project plus an additional 3 years. An up-to-date inventory will be kept through OSU's EHS Assistance inventory log online.

A dilution log will be used to log a dilution, and each dilution will have its individual dilution log. These forms will be kept for the duration of the project plus an additional 3 years.

Only authorized users on the "Authorized Users Signature Log" will be able to conduct research with the CSs. The user(s) will be trained on the proper procedures on handling, storage, and the "CS Usage Log."

- **Other Record Keeping requirements:**

- All records must be kept on hand for at least 2 years from the date of record (the date on which you received the substance).
- All completed order forms
 - A copy of the invoice
 - A copy of the purchase order
 - A copy of the shipping document
 - A copy of the packing slip
 - The name, address, and DEA number of the company from which the Controlled Substance was purchased
 - The name of the Controlled Substance purchased
 - The size and strength of the Controlled Substance purchased
 - The amount purchased (which should match the amount received)
- Inventory forms: (All inventory forms must be kept on file in the lab where the substance is used)
- Controlled Substance Use Log - Every container of controlled substance in your possession must have an associated use log that is kept in the same locked and secure place.
- Containers of concentrated or solid - A controlled substances must each have a log sheet to record the amount removed to make dilutions or solutions.
- Dilutions and solutions - if the staff has diluted a product for use, and uses it all during one application, there is no need to create an inventory for that dilution. If any diluted material remains for intended use at a later date, a new inventory page must be created, as it is considered a "new product" and dilution.



- Transfer Log - To track the transfer of controlled substances from one authorized person or location to another.
- Biennial Inventory Form - A full inventory of all DEA controlled substances must be completed every two years. Any product that is in the lab at that time must be inventoried, even if it has not been in the lab's possession for the full two years.
 - Entries are made when the substance is dispensed and are hand-written in ink.
 - Waste bottles: If the lab makes a dilution of the product and does not use all of it in their work, the remaining portion is now considered waste. A new inventory form for the dilution must be initiated and kept for any amounts of that same dilution. Lab staff cannot add different dilutions to this waste bottle.
- Record of destruction of a lab's DEA materials will be recorded by the DEA program manager on the DEA Form 41. This form will be sent to the DEA regional manager and a copy sent to the individual PI.
- A Lab Specific **SOP for DEA Controlled Substance Use** and record of training completions must be on file.
- **Authorized User**
- Screening Form, if a Registrant wishes to grant a lab member access to the CS storage area as an Authorized User Screening must be completed.
- Authorized User Form, if a Registrant wishes to grant a lab member access to the CS storage area as an Authorized User Form must be completed.

8. Spills

The breakage, spillage, or other witnessed controlled substance losses do not require the immediate notification of DEA if the breakage or spillage is not recoverable. The PI must document the circumstances of the breakage in the inventory records and the Controlled Substance Use Log. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed.

9. Disposal Procedure

DEA Exempt Chemical Preparations will be properly disposed of prior to chemical expiration, or is no longer needed, and prior to the lab closing (if applicable).

DEA Exempt chemical preparations will be disposed so that it is non retrievable. The destruction will be documented and witnessed by EH&S Hazardous Waste Safety Officer.

10. References

DEA List of Controlled Substances & Exemption List:

<https://www.deadiversion.usdoj.gov/schedules/>

DEA Forms and Applications: https://www.deadiversion.usdoj.gov/online_forms_apps.html

11. Training Requirements

