

Management of controlled substances and controlled plants

IMPLEMENTATION

Aim

To prescribe the responsibilities and actions required for the possession, use, storage and disposal of controlled substances and controlled plants on University premises and/or during University-related activities to ensure the University meets the requirements of the <u>Health, Safety and Wellbeing (HSW) Policy</u> and the relevant sections of the <u>Controlled</u> <u>Substances Act 1984</u> (SA), <u>Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2014</u> (SA), <u>Controlled Substances (Poisons) Regulations 2011</u> (SA), <u>Work Health and Safety (WHS) Act 2012</u> (SA) and <u>WHS</u> <u>Regulations 2012</u> (SA).

This Chapter should be read in conjunction with the <u>Chemical Safety Management Handbook</u> where the substance is also a <u>hazardous chemical</u> and/or a <u>dangerous goods</u> (see definitions).

1 Objectives

- **1.1** To ensure that the hazards associated with controlled substances and plants are identified, assessed and the appropriate control measures are in place to prevent an injury and/or minimise the risk of exposure.
- **1.2** To ensure that all incidents/injuries which include controlled substances and controlled plants have:
 - been investigated;
 - control measures reviewed before the activity is recommenced; and
 - corrective action(s) implemented where required to prevent a recurrence.
- **1.3** To ensure that all controlled substances and controlled plants' possession, use, storage, and disposal comply with legislative requirements.
- **1.4** To ensure the risk of unauthorised access to or loss of controlled substances and controlled plants is minimised.

2 Scope

2.1 Inclusions

This process applies to all workers (e.g. staff, titleholders, volunteers, contractors) and students who undertake University of Adelaide related activities.

2.2 Exclusions

This process does not include:

- prescribed equipment as described in the <u>Controlled Substances (Controlled Drugs, Precursors</u> and Plants) <u>Regulations 2014</u>. Please refer to the HSW Handbook Chapter <u>Plant/Equipment</u> <u>Safety Management</u>.
- Students on placement outside of the University.

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2 Scope (Continued)

2.3 Application

In addition to the requirements of this HSW Handbook chapter:

- If you are manufacturing therapeutic goods
 Refer and apply the <u>Therapeutic Goods Act 1989 (Cth)</u> and section 39 of the <u>Controlled Substances (Poisons) Regulations</u> 2011 (SA).
- If you are growing poppies
 Refer and apply the <u>Controlled Substances (Poppy Cultivation) Regulations 2016 (SA)</u>.
- If you are using hemp products Refer and apply Industrial Hemp Act 2017 and Regulations 2017 (SA).

3 Process: Permits, Checks and End User Declarations

Person Respo	onsible	Actions
3.1 Superviso control of area/activi		 Schedule 2 (S2) – Schedule 7 (S7) Ensure that all staff and students understand the conditions of the University's Research Instruction or Training Permit for controlled substances S2-S7 (refer to Appendix A). Ensure that when purchasing Regulation 25 substances they are listed on the University's permit. (Contact the HSW Team if required.) Schedule 8 (S8), Schedule 9 (S9), Schedule 17A Precursor (17A) Schedule 17B Precursor (17B) Schedule 17C Precursor (17C) and Controlled Plants Ensure workers purchasing, using and holding these substances or plants hold the relevant permit (refer to Appendix B). Ensure records are held and maintained in accordance with: Appendix B: S8 – S9 controlled substances Appendix D: Prescribed controlled plants. Ensure that if supplying a 17B or 17C controlled precursor to another work location that an "End User declaration/statement" is completed and held on file (refer to Appendix F). Ensure if you are importing or exporting any of the drugs listed in Appendix E that you have a permit from the Office of Drug Control.
•		 Ensure that no stocks of S8, S9 controlled substances, 17A precursors and controlled plants are held as stock within the chemical store/receiving area. Ensure that if supplying 17B and 17C controlled precursor from the chemical store/receiving area that an End User declaration/statement is completed and held (refer to Appendix F).
3.3 Director H (or <u>HSW Te</u> delegate)	-	Manage the Controlled substances Permit (S2- S7) on behalf of the University.

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4 Process: Hazard Management

	Person Responsible	Actions
4.1	Supervisor/Person in control of the area/activity	 Ensure that risk assessments are conducted in accordance with the HSW Handbook Chapter <u>Hazard Management.</u> Note: The risk assessment should consider: the risk of a needlestick, inhalation, absorption, or ingestion of a controlled substance and how best to mitigate the risk; the level of information, instruction, and training to be provided; access and storage requirements; and antidotes (where available).

5 Process: Provision of information, instruction, and training

Person Responsible	Actions
5.1 Supervisor/Person in control of the area/activity	 Ensure that all workers: using or working in the area have been provided with a local induction; using, storing or disposing of controlled substances and/or controlled plants are provided with the appropriate level of Information, Instruction and Training in accordance with the risk assessment for the activity and the <u>HSW Handbook Chapter "Provision of HSW Information, Instruction and Training";</u> are aware of all permit conditions for controlled substances and/or controlled plants that are held in the laboratory; and are provided with the appropriate level of supervision. Ensure that all records, including Level 2 chemical induction, are maintained in accordance with the <u>HSW Handbook Chapter</u> Provision of HSW Information, Instruction and Training in SSO.

6 Process: Registers

	Person Responsible	Actions
6.1	Supervisor/Person in control of the area/activity	S2 - S7, S8, S9 controlled substances, 17A, 17B, 17C precursors and controlled plants □ Ensure that all controlled substances and plants are entered onto the School/Branch Chemical register in accordance with: □ Appendix A: S2 - S7 controlled substances □ Appendix B: S8 - S9 controlled substances □ Appendix C: Controlled precursors; and □ Appendix D: Prescribed controlled plants.

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6 Process: Registers (Continued)

	Person Responsible	Actions
6.1	Supervisor/Person in control of the area/activity (Continued)	 S8, S9, 17A, 17B and 17C □ Ensure that controlled substance purchase/usage/disposal is recorded in an auditable format e.g., in a logbook or on a computer system that is backed up. (Refer to <u>Appendix B</u> and <u>Appendix C</u>)
		Controlled plants □ Ensure that controlled plant purchase/usage/disposal is recorded in an auditable format e.g. in a log book or on a computer system that is backed up. (Refer to <u>Appendix D</u>)

7 Process: Storage

Person Responsib	Actions
7.1 Supervisor/ in control o area/activity	

8 Process: Labelling

Pe	rson Responsible	Actions		
8.1	Supervisor/Person in control of the area/activity	 S2-S7 □ Ensure that if the controlled substance is placed into another container, that it is labelled in accordance with <u>Appendix A</u> S8 and S9 □ Ensure that if the substance is placed into another container, that it is labelled in accordance with <u>Appendix B</u> <u>17A, 17B and 17C</u> □ Ensure that precursors are labelled in accordance with <u>Appendix C</u>. <u>Controlled Plants</u> □ Ensure that controlled plants are labelled in accordance with <u>Appendix D</u>. 		

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9 Process: Transportation

Person Responsible		Actions
9.1	Supervisor/Person in control of the area/activity	 S2-S7 □ Ensure workers, who transport controlled substances, pack them to avoid leakage and separate from food. S8 and S9 □ Ensure that substances which are transported outside the University, are transported in accordance with your permit and <u>The Code of Practice for the Storage and Transport of Drugs of Dependence Nov 2012 (SA).</u> <u>17A,17B and 17C</u> □ Ensure precursors are transported in accordance with <u>Appendix C. Controlled Plants</u> □ Ensure that controlled plants are transported in accordance with <u>Appendix D</u>.

10 Process: Reporting and investigating a safety issue or incident

Person Responsible		Actions	
10.1	Supervisor/Person in control of the area/activity	Ensure that all instances involving controlled substances, precursors and/or controlled plants including misuse loss breaches are reported and investigated in accordance with HSW Handbook Chapter Incident, Near miss Reporting an Investigation; and	n the
		□ Ensure that in the circumstances of a loss or theft of a S8 substance, 17A or controlled plant, the permit holder under reasonable lines of enquiry to determine the facts and the to the <u>HSW Team</u> as soon as possible. The HSW Team the facts and if required, report the incident together with the holder, to SA Health and SAPOL in accordance with the <u>Suspected Theft or Loss of Drugs from licence or permit he</u> policy.	rtakes n reports will gather he permit <u>A Health</u>

11 Process: Emergency contingency

area/activity risk assessment (section 6.1). □ Ensure you are aware of the relevant emergency contingency arrangements, including the location and use of spill kits,	Person Responsible	Actions
 Participate in any testing of emergency contingency arrangements where required. 	in control of the	 in the Provision of information and instruction (section 4) and on the risk assessment (section 6.1). Ensure you are aware of the relevant emergency contingency arrangements, including the location and use of spill kits, emergency showers/eyewash stations and first aid provisions in your area. Participate in any testing of emergency contingency arrangements

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12 Process: Disposal

Person Responsible	Actions
12.1 Supervisor/Person in control of the area/activity	 S2 - S7, 17B and 17C Ensure that if you are leaving the University permanently that all substances are either disposed of or the substances are transferred to another worker. Ensure that at least once a year all substances are checked against the Chemical register and have an assigned current owner to avoid legacy substances being stock piled and that all substances without an owner are disposed of. Dispose of substances in accordance with Chemical Disposal Requirements (see <u>Appendix A</u>). S8 and S9 Ensure permit holders dispose of substances in accordance with the Disposal Requirements (see <u>Appendix B</u>) Ensure that if you are leaving the University permanently that all substances are either disposed of by the person on the permit or that you contact SA Health for permission to transfer the permit and substance to another worker. Return the key or keypad code to the drug safe to the Head of School. 17A and Controlled Plants Ensure17A and Controlled Plants are disposed of in accordance with the permit requirements. Note: It is illegal to supply (without permission) any part of a controlled plant to another person, including waste and/or non-active parts of the plant. If the permit holder wishes to transfer any part of the plant material (including waste) the permit holder must inform <u>SA Health</u> before transfer so that their permit can be modified, to include the new people and the secondary location.

13 Process: Special circumstances and exemptions

Person Responsible	Actions
13.1 Managers and Supervisors of Laboratories, Workshops and Chemical Stores	 Ensure that all staff and students are aware of and apply the special circumstances and exemptions (where applicable) outlined in: Appendix A: <u>S2 – S7 controlled substances</u> Appendix B: <u>S8 – S9 controlled Substances</u> Appendix C: <u>Controlled precursors</u>; and Appendix D: <u>Prescribed controlled plants</u>.

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14 Definitions

17A substances: are precursors which cannot be sold or possessed without a permit from the Minister. These chemicals are listed in section 16 of the Controlled Substances (Poisons) Regulations 2011 (SA).

17B and 17C substances: are precursors which require photographic identification to be produced and for an End User Statement to be completed at purchase. These chemicals are listed in section 16 and 17 of the <u>Controlled Substances (Poisons) Regulations 2011</u> (SA).

Controlled substances (or scheduled drugs & poisons): are pharmaceuticals and poisons that require licensing. Under the licence conditions there are restrictions on access, labelling and use. The purpose of the classification is to restrict the accessibility by non-authorised people to particular groups of pharmaceutics and poisons.

Dangerous Goods: are solids, liquids or gases that have been classified as dangerous under the *Dangerous Substances Act* 1979, *Dangerous Substances (Dangerous Goods Transport) Regulations* 2008 and the *Australian Code for the Transport of Dangerous Goods by Road or Rail* (the ADG code). Substances in this classification must adhere to legislative requirements when being **transported** by road or rail.

· Packing Group I (PGI) indicates dangerous goods that are highly dangerous.

• Packing Group II (PGII) indicates dangerous goods that are moderately dangerous.

• Packing Group III (PGIII) indicates dangerous goods that are mildly dangerous.

Note the storage of dangerous goods is now included in the term hazardous chemicals. Dangerous goods requirements only are applicable to the transportation.

End User statement/ declaration: is a statement which is required by the supplier, on behalf of South Australian Police, to allow the supply of substances which have been classified as section 17B or 17C under the Controlled Substances Act 1984.

GHS: means the Globally Harmonised System of classification and labelling of chemicals (7th edition)

Hazardous chemical: is a substance, mixture or article that satisfies the criteria for a hazard class in the GHS. This term replaces hazardous substances and the storage of dangerous goods.

Hazard Statement (H-Statements) are part of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Hazard statements provide standardised wording to indicate the hazards of a product including, when appropriate the degree of the hazard.

Proficiency (for the purposes of University Training)

Achievement of a level of demonstrable knowledge, ability or skill acquired through training, which enables the operator to complete a high-risk activity safely and without supervision.

Research chemical: means a substance or a mixture that is manufactured in a laboratory for genuine research and is not for use or supply for a purpose other than analysis or genuine research.

Safety Data Sheet (an **SDS**): is a document prepared by the manufacturer or importer of all chemicals that describes uses, chemical and physical properties, health hazard information, precautions for use, safe handling information and emergency information.

Supervisor/Person in control of the area/activity

In the context of this chapter the supervisor has two meanings:

1. the line manager of a staff member or the principal supervisor of a higher degree research student. The responsibility of this type of supervisor is captured in section 3.2 and should be read in relation to all activity other than where the worker's activity is supervised by someone as described in the second meaning below.

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14	Definitions	(Continued)
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Supervisor/Person in control of the area/activity (continued0

In the context of this chapter the supervisor has two meanings:

- 2. Any other individual who (separate to the line manager/manager/principal supervisor) has control of a laboratory, clinic, workshop, field activity or other activity in which the worker is participating or working. For example, a workshop manager who has control of what is undertaken and/or who determines which workers may/may not work within the workshop they control. These supervisors also have the responsibility captured in section 3.2 for the activities under their control. (Note: Control means that these individuals have the right to deny access to or stop any activity until they are satisfied that the activity can occur safely.)
- (NOTE: A student is not to be the Supervisor/person in control of the area/activity.)

Worker means according to the WHS Act 2012 (SA) a person who carries out work in any capacity for a person conducting a business or undertaking, including work as -

- an employee; or a)
- b) a contractor or subcontractor; or
- an employee of a contractor or subcontractor; or c)
- an employee of a labour hire company who has d) been assigned to work in the person's business or undertaking; or
- an outworker; or e)
- f) an apprentice or trainee; or
- a student gaining work experience; or g)
- h) a volunteer; or
- a person of a prescribed class. i)

The person conducting the business or undertaking is also a worker if the person is an individual who carries out work in that business or undertaking. Note -Higher Degree Research and Honours (Research) students and Academic Visitors are likely to be workers under the WHS Act 2012 (SA).

15 **Performance Measures**

The HSW Team will use performance measures to assist in identifying areas of success and/or where corrective action is required to meet the objectives and targets of this process.

The level of compliance with the chapter and effectiveness will be determined during the internal audit process.

16 Useful information and resources

16.1	University related documents and resources
	HSW Handbook Chapter <u>Hazard Management</u>
	HSW Handbook Chapter Report a safety issue or incident and Incident investigation
	HSW Handbook Chapter Provision of HSW Information, Instruction and Training
	• <u>Chemwatch</u>
16.2	Related Legislation
	Agricultural and Veterinary Chemicals Code Act 1994
	 Controlled Substances (SA) Act 1984 (v2019)
	Controlled Substances (Therapeutic Goods and Other Matters) Amendment Bill (SA) 2011
	Controlled Substances (Controlled Drugs, Precursors and Plants) (SA) Regulations 2014 (v2019)
	Controlled Substances (Poisons) (SA) Regulations 2011 (v2020)
	Globally Harmonized System of Classification and Labelling of Chemicals seventh edition 2017
	Therapeutic Goods Act 1989 (v 2020)
	Poisons Standard July 2020
	Code of Practice for the Storage and Transport of Drugs of Dependence
	 The Australian Code for the Transport of Dangerous Goods by Road or Rail (2020) ed.7.7
	AS/NZS 3809:1998 Safes and Strongrooms
16.3	Other Resources
	 Australian Government the Department of Health - <u>The Office of Drug Control</u>

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SCHEDULE 2 (S2) – SCHEDULE 7 (S7) CONTROLLED SUBSTANCES

S2 – S7 (including Regulation 25) General

How to identify if a substance is controlled

To identify if a substance is controlled refer to:

- the Safety Data Sheet (SDS) under 'Poisons schedule'.
- Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2014 (SA).
- Controlled Substances (Poisons) Regulations 2011 (SA).

S2 - S7 Drugs and Poisons

Drugs and poisons are classified according to the Schedules below

Schedule	Signal Words	Access and use requirements			
Schedule 1		[This Schedule is intentionally blank.]			
Schedule 2	Pharmacy Medicine	Substances, the safe use of which may require advice from a pharmacist, and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person. Covered by University Permit			
Schedule 3	Pharmacist Only Medicine	Substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist without a prescription. Covered by University Permit			
Schedule 4	Prescription Only Medicine, or Prescription Animal Remedy	ubstances, the use, or supply of which should be by or on the order of persons ermitted by State or Territory legislation to prescribe and should be available from a harmacist on prescription. overed by University Permit ubstances with a low potential for causing harm, the extent of which can be reduced			
Schedule 5	Caution	Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label. Permit is not required			
Schedule 6	Poison	Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label. Permit is not required			
Schedule 7	Dangerous Poison	Substances with a high potential for causing harm at low exposure and which requir special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage, or use may apply. Covered by University Permit			
Regulation 25 (section 22 of the Controlled Substances Act)	ection 22 of e Controlled ubstances Act)Regulations Section 25 and are required to have a permit by the Controlled Substances Act (1984).Specifically listed on the University Permit				
		Refer to <u>SA Health</u> for a listing of the specific poisons.			

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SCHEDULE 2 (S2) – SCHEDULE 7 (S7) CONTROLLED SUBSTANCES

2 <u>S2 – S7 (including Regulation 25) Permits</u>

University Controlled Substances Permit S2 – S7

The University of Adelaide has "Research Instruction or Training Permits" for each of the four campuses (Adelaide, Waite, Roseworthy, and Thebarton) which allows the University to manufacture, supply, possess and use Schedule 2, 3, 4, and 7 substances (Note: a permit is not required for S5 and S6 substances).

The permit requires the University to abide by the following conditions:

- The poisons must not be re-sold or supplied to any other person.
- The permit holder shall store scheduled poisons in suitable containers, appropriately labelled and shall store schedule 2, 3, 4 & 7 poisons, when not in use in a locked receptacle or enclosure.
- The poisons shall not be kept elsewhere than at the premises specified, except when in accordance with written guidelines or protocols prepared by or on behalf of the permit holder.
- Access to the poisons shall be restricted to persons under the direction of the permit holder, or in accordance with written guidelines or protocols prepared by or on behalf of the permit holder.
- A record indicating the quantity of each schedule 2, 3, 4 and 7 poison manufactured, produced, received, used or destroyed during the currency of this permit must be kept by the permit holder.
- The permit holder must comply with the requirements of the <u>SA Health Suspected Theft of Loss of Drugs or</u> <u>Substances</u> from licence or permit holder policy dated March 2011

To breach the conditions of the University's permit is an **unlawful act**, which could result in a loss of the University's permit and hence ability to purchase and hold these types of substances. Any breach of these conditions must be reported to the <u>HSW Team</u>.

3 <u>S7 Prohibition on use</u>

Prohibition on use of certain poisons

Section 31 of the <u>Controlled Substances (Poisons) Regulations 2011</u> calls out S7 poisons which require a higher authorisation to use

- amygdalin for human therapeutic use.
- chloramphenicol for the treatment of stock bred, raised, or used for the purpose of providing a product for human consumption.
- Any poison produced for the treatment of animals if that poison is intended for human use.

If you are intending to use these substances in the manner outlined above, contact the HSW Team.

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SCHEDULE 2 (S2) – SCHEDULE 7 (S7) CONTROLLED SUBSTANCES

4 <u>S2 – S7 (including Regulation 25) Storage and access</u>

Permit condition - The permit holder shall store scheduled poisons in suitable containers, appropriately labelled, and shall store schedule 2, 3, 4 and 7 poisons, when not in use, in a locked receptacle or enclosure.

Meaning in the University context

- Keep the substance in the original container, however if you need to decant the substance then refer to labelling requirements below.
- Schedule 2, 3, 4 and 7 poisons must be stored in a locked cabinet when the substances are not in use, or the laboratory/workshop/building must be locked, or access restricted by some means when not in use.
- Poisons must be stored in the original container or is placed into another container normally associated with substance. Solutions placed into another container should not be put into a container used for (or look similar to) one used for food or beverages.

Permit condition - The poisons shall not be kept elsewhere than the premises specified, except when in accordance with written guidelines or protocols prepared by or on behalf of the permit holder.

Meaning in the University context

 The four permits the University holds covers each of the four main campuses of the University: Adelaide, Waite, Roseworthy, and Thebarton campus. The Adelaide campus permit covers North Terrace and additionally covers staff and students working in the hospitals and field/offsite locations (including permanent locations such as the farms and non-permanent locations such as sites visited on School field trips). When transporting controlled substances to a field trip location a Risk Assessment and Safe Operating Procedure must be written detailing the safe transport and security of the substances (contact the <u>HSW Team</u> for assistance with this requirement).

Permit condition - Access to the poisons shall be restricted to persons under the direction of the permit holder, or in accordance with written guidelines or protocols prepared by or on behalf of the permit holder.

Meaning in the University context

 Only staff and students given permission to access individual laboratories and workshops are allowed access to the controlled substances in those individual laboratories and workshops. Any person who is not authorised to use substances in a laboratory or workshop must be supervised (or not permitted to enter) where controlled substances are not in locked receptacles.

5 S2 – S7 (including Regulation 25) Labelling

Labelling of S2 - S7 substance placed into another container

All substances are required to be labelled in accordance with GHS and WHS Regulations 2012 (SA) Part 2 Schedule 9.

Whilst the manufacturer or supplier of substances are required to have extensive labelling the label for a **substance** placed into another container, or **research substance**, or **sample for analysis** shall at a minimum:

- □ be legible and in English,
- have the product identifier (name or number found on the suppliers' label or in the SDS),
- have a pictogram or hazard statement consistent with the chemical,
- the full name (or staff/student number) of the worker who made or placed the chemical into another container, and
- □ the controlled substance signal words as per the original container (refer to signal words table 1 above).

Note- decanting into a syringe only requires the name of the substance on the syringe. However, the substance must be used, and syringe disposed of within one working day.

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SCHEDULE 2 (S2) – SCHEDULE 7 (S7) CONTROLLED SUBSTANCES

6 <u>S2 – S7 (including Regulation 25) Registers</u>

All substances are required to be on a University authorised chemical register (contact the <u>HSW Team</u> for assistance) which is updated at least once a year with the following information:

- **Chemical/Material Name** Use the common name if it exists, and please put the name of the chemical/substance before the concentration if applicable,
- **GHS Class and Category** (This is the Class and the Category under the Globally Harmonized system of classification and labelling of chemicals seventh edition 2017 e.g., Flammable Liquid Category 2);
- Primary Dangerous Goods (DG) Class (These are solids, liquids or gases that have been classified as dangerous under Dangerous Substances Act 1979, Dangerous Substances (Dangerous Goods Transport) Regulations 2008 and the Australian Code for the Transport of Dangerous Goods by Road or Rail [the ADG code]).
- Building
- Room
- Controlled substance classification Use the appropriate S number such as S4, S8 etc.
- Unit of measurement (e.g., grams, millilitres, kilograms, litres)
- Maximum volume/weight this is the max holdings in the location.

7 <u>S2 – S7 (including Regulation 25) Transport</u>

- Transportation by hand by using carriers, baskets, or trolleys to carry chemicals, where possible.
- Outside the University the load is to be bunded, segregated and transported in a way, which discourages breakage of containers.
- All loads are to be secured (large amounts must also be transported behind a cargo barrier)
- Transportation of large quantities of chemicals may require placarding (refer to Chemical Storage and Transportation Handbook Chapter).
- If chemicals are to be transported by air refer to CASA guidelines
- If chemicals are being transported by post, refer to <u>Australia Post guidelines</u>.
- All S2 S7 controlled substances must be secure from unauthorised access during transport.

8 S2 – S7 (including Regulation 25) Incident Reporting

The permit holder shall comply with the requirements of the <u>SA Health "Suspected Theft or Loss of Drugs or Substances</u> from Licence or Permit Holders" policy dated March 2011.

- All Controlled substance incidents, including suspected theft, injury and hazards are to be reported via the <u>University's</u> <u>on-line incident reporting system.</u>
- The <u>HSW Team</u> must be contacted where there are reasonable grounds to suspect the occurrence of:
 - a theft or loss of a drug, prohibited substance, Schedule 7 poison or prescribed laboratory equipment (refer to the HSW Handbook chapter <u>Plant/Equipment safety management</u>); or
 - a quantity of drugs or prohibited substances that cannot be reasonably accounted for; or
 - worker or student who has access to such drugs or prohibited substances exhibits such behaviour that you or others may reasonably suspect that they have a drug problem or are diverting drugs or substances.

9 S2 – S7 (including Regulation 25) Disposal

Disposal of S2 – S7 drugs/poisons can be collected by waste disposal companies as these companies hold the appropriate permits to undertake destruction/disposal. However, it is a breach of the University's Controlled Substances Licences to leave controlled substances unattended in loading bays whilst waiting for collection.

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SCHEDULE 2 (S2) – SCHEDULE 7 (S7) CONTROLLED SUBSTANCES

10 S2 – S7 (including Regulation 25) Disposal (Continued)

Do not discharge to the sewer:

- any concentrated acids or bases;
- highly toxic, malodorous (bad odour), or lachrymatory (produces tears) substances;
- any substances which might interfere with the biological activity of wastewater treatment plants;
- any controlled substance which could create fire or explosion hazards;
- any controlled substance which could cause structural damage or obstruct flow.

In University buildings

All requests for waste disposal should be submitted on the <u>Waste Collection Request</u> Form from Infrastructure website. If delays occur, contact <u>Infrastructure</u> to resolve the issue.

Commercial buildings

The first point of contact for requests is the Building Facilities Manager. The Building Facilities Manager will submit the request to the chemical waste service provider. The chemical waste service provider receives the request, and they will contact the person requesting waste collection to obtain a copy of the waste manifest. If the requester does not have a manifest the chemical waste service provider will provide a blank manifest for them to complete.

11 S2 – S7 (including Regulation 25) Records

Permit condition - A record indicating the quantity of each schedule 2, 3, 4 and 7 poison manufactured, produced, received, used or destroyed during the currency of this permit must be kept by the permit holder.

Meaning in the University context

- By ensuring the local chemical register is kept up to date a comparison between current and previous years can be made to determine substances used, destroyed, or disposed of. Information on chemicals received should be obtainable through purchasing staff.
- S2 S6 records must be kept in an auditable format.
- S7 records must be kept in an auditable format.

12 <u>S2 – S7 (including Regulation 25) Special Circumstances and Exemptions</u>

1. Permit condition - The poisons must not be re-sold or supplied to any other person.

Meaning in the University context

- Within the University it is acceptable to transfer S2 S7 controlled substances and Regulation 25 substances between Schools/Branches as each School/Branch is part of the organisation. Please ensure that your chemical register is updated if transferred. However, if the Regulation 25 is not on the campus permit, then you must contact the <u>HSW</u> team to seek an amendment to the campus permit.
- Where transfer is occurring between institutions this cannot be done unless the University has permission from SA Health, contact the <u>HSW team</u>.
- Where a researcher is moving to another research organisation and is intending to transfer substances to that
 organisation, there are a number of things that must be considered i.e., permits held by the other organisation,
 transport, and security arrangements. Contact the <u>HSW team</u> if you wish to transfer any controlled substances with
 you when moving organisations.
- Disposal: Poisons/chemicals (not controlled drugs or prohibited substances S8 & S9 see Appendix B) can be collected by waste disposal companies as they are doing so for the purpose of destruction/disposal, and they hold the appropriate permits to undertake this type of activity.

2. Pentobarbitone (Lethabarb)

Pentobarbitone is classified as an S4 drug however for the purposes of storage within the University of Adelaide it will be treated as an S8.

- Anyone using pentobarbitone (who is not a veterinary surgeon) must ensure that they get approval <u>University Veterinarian and Animal Welfare Officer</u> and receive training from a South Australian registered veterinarian.
- This drug is to be kept secure at all times (when in use) as to prevent unauthorised access and is stored (when not in use) in a drug safe.

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SCHEDULE 8 (S8) AND SCHEDULE 9 (S9) CONTROLLED SUBSTANCES

1 S8 and S9 - General

Schedule	Signal Words	Access and use requirements
Schedule 8	Controlled Drug/Drug of dependence/Drug of addiction	Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. Individual Permits are required
Schedule 9	Prohibited Substance	Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities. Individual Permits are required

1 The list of S8 and S9 substances can be found in <u>Controlled Substances (Controlled Drugs, Precursors and Plants)</u> <u>Regulations 2014</u>.

Controlled drugs (S8) include:

- □ the natural or synthetic form, or
- any salt, derivative, or isomer (or salt of the derivative or isomer) of the natural or synthetic form, or
- any analogue (or salt of the analogue) of the natural or synthetic form, or
- any homologue of the natural or synthetic form of the substances listed in <u>schedule 1</u> of the Regulations.

2 <u>S8 and S9 Permits</u>

Use Permit

Any person intending to obtain and use substances classified as S8 or S9 is required to obtain an individual permit from SA Health. Please use the SA Health form to obtain the permit.

The primary responsibility is retained by the permit holder. The permit holder must ensure that the following conditions are met and understand that they are personally responsible for all inactions or actions which breach the Act and the conditions within this handbook.

To breach the conditions of an individual's permit is an **unlawful act**. Any breach (including loss) of these conditions must be reported to the <u>HSW Team</u>.

Supply Permit

In rare circumstances a supply permit will be granted by SA Health. Where a supply permit exists the permit holder must ensure that all S8 substances that they will be supplying are listed on their permit and that recipient of the S8 substance has a permit of use.

3 S8 and S9 Prohibition on use

- No S8/S9 is to be held within the University unless there is a valid permit.
- The S8/S9 must not be re-sold or supplied to any other person (with the exception of supplying, when giving the
 substance to a prescribed person for the purposes of disposal; refer to section 9 or where there is valid supply permit).
- The permit holder must not give control of the S8/S9 to another person unless they are listed on the permit or the supplier have a supply permit and the receiver has a use permit for the substance.
- The primary permit holder must be an employee, titleholder or affiliate of the University.

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SCHEDULE 8 (S8) AND SCHEDULE 9 (S9) CONTROLLED SUBSTANCES

4 S8 and S9 storage and access

- The permit holder shall store S8/S9 in suitable containers, appropriately labelled (see below) and in a locked drug safe that meets or exceeds the requirements of **resistance grade 1** (Refer to <u>AS/NZ 3809: 1998 Safes and Strongrooms</u>).
- The permit holder must not allow a spare key to the drug safe to be held by anyone not listed on the permit. All keys to the drug safe will be the responsibility of the permit holder.
- The sharing of drug safes is not permitted unless all persons who are sharing are listed on the permit/s for all substances within the safe.
- All access to S8/S9 substances is strictly restricted to persons listed on the permit (this includes use and disposal; the only exception is for delivery and good receiving who should not unpack these substances).
- The quantity of the substance must not exceed the amounts listed on the permit. All holdings are counted towards the total amount regardless if the substance has expired. The permit holder must seek an amendment to the permit conditions or dispose of items if quantities are exceeding the permit listed amounts.
- Be aware that the permit is specific for substances and locations in which the substances can be held.
- For those s8/s9 substances that are temperature sensitive, the substance must be held in a lockable refrigerator or freezer (where applicable).
- The permit holder is required to comply with <u>The Code of Practice for the Storage and Transport of Drugs of</u> <u>Dependence Nov 2012.</u>

5 S8 and S9 labelling

Any drugs placed into another container are to be labelled with the safety information on the original container.

6 S8 and S9 registers

All substances are required to be on a University authorised chemical register (contact the <u>HSW Team</u> for assistance) which is updated at least once a year with the following information:

- Chemical/Material Name Use the common name if it exists, and please put the name of the substance before the concentration if applicable,
- GHS Class and Category (This is the Class and the Category under the Globally Harmonized system of classification and labelling of chemicals seventh edition 2017 e.g. Flammable Liquid Category 2); and/or
- Primary Dangerous Goods (DG) Class (These are solids, liquids or gases that have been classified as dangerous under the Australian Code for the Transport of Dangerous Goods by Road or Rail [the ADG code]).
- Building
- Room
- Controlled substance classification Use the appropriate S number such as S4, S8 etc.
- Unit of measurement (e.g. grams, millilitres, kilograms, litres)
- Maximum volume/weight this is the max holdings in the location.

In addition to an entry on the chemical register a second register of drugs of dependence indicating the quantity of each S8/S9 manufactured, produced, received, used, or destroyed during the currency of the permit must be kept by the permit holder. These records must be kept updated in real time and be kept in an auditable format.

As a minimum the following information must be recorded in the drug register (note that each drug has a separate drug register or be clear within the one drug register regarding which drug is being tracked):

- 1. Date
- 2. Patient ID or owner (where applicable)
- 3. Amount added to the safe (in mls/g)
- 4. Amount taken from the safe (in mls/g)
- 5. Balance of drug (in mls/g)
- 6. Name of veterinary surgeon or permit holder
- 7. Name of dispensing person
- 8. Broken or expired bottles are to be entered in the Register and disposed of via witnessed destruction (see disposal section below).

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SCHEDULE 8 (S8) AND SCHEDULE 9 (S9) CONTROLLED SUBSTANCES

6 S8 and S9 registers (continued)

The drug of dependence register must be audited/stocktake against holdings at least once a month for high use areas (e.g. Veterinary clinic) and every 6 months for low use areas (e.g. researchers) by a person named on the permit and these records (audit/stocktake and the register) held in an auditable format (e.g. in a log book or on a computer system that is backed up).

7 S8 and S9 transport

 The permit holder is required to comply with <u>The Code of Practice for the Storage and Transport of Drugs of</u> <u>Dependence Nov 2012</u> when transporting S8/S9 substances.

8 S8 and S9 Incident Reporting

- All chemical incidents including suspected theft, injury and hazards are to be reported via the <u>University's on-line</u> incident reporting system.
- Also, in the circumstances of a loss or theft of a S8/S9 substance, the permit holder must undertake reasonable lines
 of inquiry to determine the facts and then report the status of the S8/S9 to HSW Team who will gather facts and if
 required, report with the permit holder, the incident to SA Health and SAPOL. These are the requirements of the <u>SA</u>
 <u>Health Suspected Theft of Loss of Drugs or Substances from licence or permit holder policy dated March 2011</u> and
 <u>The Code of Practice for the Storage and Transport of Drugs of Dependence Nov 2012.</u>

9 S8 and S9 disposal

- The permit holder is responsible for disposal of the substance before the expiry date or before they leave the University.
- SA Health requires all S8 and S9 substances to undertake "witness destruction". The permit holder or a person who is
 listed on the permit must take the substance and the inventory to any pharmacy, veterinary, doctor or nurse (or other
 prescribed people). These professionals will sign receipt and dispose of them. The permit holder must keep a copy in
 an auditable format.
- The person destroying the drug ensures that the following information is recorded in respect of the drug immediately
 after its destruction:
 - (i) the full names and the signatures of the person and the witness to the destruction;

(ii) the trade name or approved name of the drug or, if it did not have either a trade or approved name, its ingredients;
 (iii) the amount and, if applicable, the strength of the drug;

- (iv) the date and time of the destruction;
- (v) the amount of the drug (if any) now remaining in stock on the premises at which the destroyed drug was stored.

10 S8 and S9 records

All S8 and S9 records must be kept in an auditable format.

11 S8 and S9 Special circumstances and exemptions

11.1 Permit holder has left the organisation

In the event that the permit holder leaves the University (e.g. retirement, death, termination of contract) and there is nobody else listed on the permit then the University must get permission from SA Health to be able to have access to transfer to another person (not on the permit), or to make an inventory or to dispose.

11.2 Transfer between permit holders

- A substance cannot be transferred to another person not named on the permit unless (1) The supplier holds a supply permit or (2) there is clear approval from SA Health (regardless if the recipient has their own permit with the same substance listed).
- If the primary permit holder leaves the organisation, then SA Health must be notified as soon as possible so that the permit can be reissued.
- If a person is listed as a secondary person on the permit, then this person can take control of the substance from the primary permit holder, however SA Health must still be notified.

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SCHEDULE 8 (S8) AND SCHEDULE 9 (S9) CONTROLLED SUBSTANCES

11 S8 and S9 Special Circumstances and Exemptions (Continued)

11.3 Exemptions

11.3.1 Holding an S8 Permit

- Veterinary practices do not require a permit to hold a drug of dependence.
 - Veterinary surgeon undertaking veterinary activities do not require to hold a permit for a drug of dependence. However, if a veterinary surgeon is undertaking research, which involves the use of an S8 drug, then they must obtain a personal permit and cannot use the veterinary surgeons or practices exemption.

11.3.2 Access to drug of dependence

Veterinary nurses (according to SA Health) if working under the direction of a veterinary surgeon, can access S8 drugs as long as it is accordance with the normal veterinary duties and under the direct supervision of a veterinary surgeon.

11.3.3 Activities around Controlled drugs and poisons, equipment

If the activity is for veterinary surgeon's profession the following is not an offence for a veterinary surgeon to:

- manufacture, pack, sale, supply or administer a poison, or the sale or supply of equipment for use in connection with the consumption or administration of a poison; or
- prescribes a drug of dependence for an animal; or
- be in possession of controlled poison or equipment.

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CONTROLLED PRECURSORS

1 Precursors – General

Section 17A, 17B and 17C are substances that are regulated, in the <u>Controlled Substances Act</u>, as chemicals used in illicit drug manufacture.

A controlled precursor includes all substances listed in <u>schedule 2</u> of the Controlled Substances (Controlled drugs, precursors and plants) Regulations.

2 Precursor permits and requirements

17A substances

 These substances cannot be sold/used/held without a permit from the Minister. Please use the SA Health form to seek permission to hold and use 17A substances and inform the <u>HSW team</u> of your intention to hold and use these substances.

17B and 17C substances

- The 17B and 17C substances require an end user declaration (EUD) which the supplier will request before delivery of these goods.
- An end user declaration must be signed by the staff member who is associated with the area ordering the substance not a student.
- Where a goods receiving store purchases on behalf of the end user, the end user or supervisor (if it is a student) are required to sign off on the end user declaration and hold the copy for any future request from South Australian Police (SAPOL).

(Note: For external purchases the end user declaration will be provided by the supplier and a copy is required to be kept by the laboratory for 5 years.)

 Where the purchase is for stocking our store for later dispensing to unknown end users then the manager of the store is to sign off on the end user statement and provide it to the supplier. Then, when the chemical is provided by our chemical store to a staff member or student, the staff member or the academic supervisor of the student is to sign off on the End user Declaration form (see <u>Appendix F</u>).

3 Precursor storage and access

- 17A precursors will be stored in accordance with the permit.
- 17B and 17C precursors will be stored in suitable containers and when not in use in a locked receptacle or enclosure.

4 Precursor labelling

There are no special requirements for labelling beyond what is required for S2 – S7 controlled substances. (Please refer to <u>Appendix A S2-S7 labelling</u>.)

5 Precursor registers

- All controlled precursors are required to be on the chemical register (updated at least once a year) refer to <u>Appendix A</u> <u>S2 - S7 registers</u>. Records are to be held in an auditable format (e.g., in a logbook or on a computer system that is backed up).
- 17A precursors will be tracked in accordance with the permit.

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CONTROLLED PRECURSORS

6 Precursor Transport

 There are no special requirements beyond general chemical transportation principles. (Refer to <u>Chemical Management Handbook Chapter</u>).

7 Precursor Incident Reporting

- All incidents including suspected theft, injury and hazards are to be reported via the <u>University's on-line incident</u> reporting system.
- In addition, any incidents relating to 17A precursors will be reported in accordance with the permit requirements.
- If there is a suspicion that an order or a transfer of a controlled precursor may be connected to unlawful act; contact the HSW team.

8 Precursor Disposal

- 17A precursors will be disposed of in accordance with the permit requirements.
- 17B and 17C will be disposed of by the same method as S2-S7 substances (Refer to Appendix A).

9 Precursor Records

<u>17A precursor records</u>

Are to be kept in accordance with the permit requirements.

• <u>End user declaration</u> A copy is to be kept by the laboratory in a format which can be retrieved if SAPOL requests for the period of 5 years.

10 Precursor Special Circumstances and Exemptions 17B and 17C Substances

 There is no requirement for an End user declaration for a 17B or 17C precursor if the preparation is designed, packaged and labelled for human or animal therapeutic use and is made by a veterinary surgeon or registered health practitioner.

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PRESCRIBED CONTROLLED PLANTS

1 Prescribed Controlled Plants General

Section 12 (4b) of the Controlled Substances Act declares that some plants and classes of plants have the potential to lead to dependence in humans as listed in the table below.

Controlled Plants including the growing plant or cutting of the plant	 Any plant of the genus Erythroxylum P. Browne including Erythroxylum coca Lam and Erythroxylum nova-granatense. Papaver bracteatum Lindley. Papaver somniferum L. All fungi that contain PSILOCIN. All fungi that contain PSILOCYBIN. Any plant containing MESCALINE including any plant of the genus Lophophora. Salvia divinorum EPL. & Jativa (Diviners Sage). Mitragyna speciesa Korth (Kratom). Catha edulis Forsk (Khat). Any plant of the genus Ephedra which contains ephedrine. Any plant of the genus Cannabis L including the plant, a cutting of the plant, the seeds, the oils and resins. (<i>Cannabis oils and resins mean substances which contain chemicals of the following classes cannabinoids; tetrahydrocannabinols; or alkyl homologues of tetrahydrocannabinols.</i>) Note 1 for poppy cultivation regulations refer to <u>Controlled Substances (Poppy Cultivation) Regulations 2016 (SA)</u>. Note 2 for research using hemp also refer to <u>Industrial Hemp Act 2017</u> and <u>Regulations 2017</u> (SA).
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2 Prescribed Controlled Plants Permits and requirements

- It is an offense to cultivate or sell commercial quantities of controlled plants however, if you intend to obtain and use, for research purposes, a controlled plant then you must ensure that you obtain an individual permit from SA Health. Please use the SA Health <u>form</u> for a S8 permit.
- Permits for controlled plants are for the whole plant (regardless of where the active ingredient resides), this includes any waste products and there must be a valid (in date) permit for all controlled plants being used or stored.
- If the research also involves the cultivation or production of <u>medicinal cannabis</u>, the <u>Office of Drug Control</u> permit is required.
- If the research requires importation of <u>hemp products</u> contact <u>Office of Drug Control</u> to determine if an import permit is required.

3 Prescribed Controlled Plants Storage and Access

- Controlled Plants must be stored and secured in a within a restricted location. This location is only allowed to be
 accessed by people who are listed on the permit. Where there are two different controlled plants (with different people
 on the permits) in the same location, then two different secured storage areas are required with access restricted to
 persons on the permit.
- The holdings of controlled plant on the permit must not exceed the permit amount.
- The permit is person and location specific. Only person/s on the permit are allowed access to the controlled plant and the location on the permit is the only place which the controlled substance is allowed to be held and worked on.

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PRESCRIBED CONTROLLED PLANTS

4 Prescribed Controlled Plants Labelling

All plant material must be clearly labelled with the name of the material the permit number and the licence holders name and contact details.

5 Registers

All amounts of plant material received, used, discarded, or not destroyed (i.e., samples held within the laboratory) must be recorded on a register held with the controlled plant. The records held are to be in an auditable format (e.g., in a logbook or on a computer system that is backed up.

6 Transport

Controlled plants must be only transported by a person listed on the permit and they must ensure that the material is secure at all times.

7 Incident reporting

Any losses or access breaches identified must be reported to SA Health and recorded in <u>University's on-line incident</u> reporting system. Contact the <u>HSW team if you require assistance</u>.

8 Disposal

- Any part of a controlled plant (including waste) no longer needed must be destroyed and this destruction must be recorded on the register.
- Only persons who are listed on the permit can access the plants for disposal.

9 Records

All controlled plants (including the waste) must be tracked via a register i.e., when it is received, stored, used, discharged, destroyed, and stored. This register must be kept in an auditable format.

10 Prescribed Controlled Plants Special Circumstances

Any Changes to the permit

- If anything changes (i.e. extra locations or change in location or access to other people) then <u>SA Health</u> must be notified (before it happens) so they can reissue your permit.
- If the permit holder is no longer at the University, <u>SA Health</u> must be notified so that the permit can be transferred to
 another person listed on the permit. If the permit holder is the only person listed, then contact the <u>HSW team</u> so they
 can assist in seeking permission for access/transfer/disposal of the controlled plant.

Transfer

It is illegal to supply (without permission) any part of a controlled plant to another person, including waste and/or non-active parts of the plant. If the permit holder wishes to transfer any part of the plant material (including waste) the permit holder must inform <u>SA Health</u> before transfer so that their permit can be modified, to include the new people and the secondary location.

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Appendix E

IMPORTATION AND EXPORTATION

<u>Drugs</u>

There are many substances require a licence and permit, issued by the Office of Drug Control, in accordance with Regulation 5 of the *Customs (Prohibited Imports) Regulations 1956* and Regulation 10 of the *Customs (Prohibited Exports) Regulations 1958*. Contact the Office of Drug Control.

Agricultural or veterinary chemicals

Only registered products and approved active constituents can be imported without the need for further approval. The Australian Pesticides and Veterinary Medicines Authority (APVMA) are to be contact to authorise the importation of unregistered and unapproved agricultural and veterinary chemicals. Contact <u>APVMA</u>

Therapeutic goods

For these activities refer to Australian Government Department of Health Therapeutic Administration.

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Appendix F

INTERNAL TRANSFER - END USER DECLARATION FORM

This form is for **internal purposes only** i.e., when a 17B or 17C substance is provided by the supplier to a staff member or student or if transferred between research groups. This form is required to be signed off by a staff member or the academic supervisor of the student and the original must be kept by the supplier and a copy kept by the receiver in a form which can be retrieved if requested by SAPOL for a period of 5 years. For external purchases, this form will be provided by the external supplier and a copy is required to be kept by the receiver for 5 years.

Name and University number of supplier	
Location and research group	

Name of person and university	
number of the receiver	
Location and research group	

END USER STATEMENT

The controlled substance product I wish to purchase is classified as a possible illicit drug precursor or auxiliary reagent. I understand that to be supplied this product a signed end user declaration must be provided together with the order.

CAS Number	Product Name			Quantity/ Pa	ck Size	Order No.
Intended Use						
Analytical	Research	and Design	Manufactu	ring	D 01	ther (please specify)
Please specit	fy the details of intended use					
RECEIVERS	USER DECLARATION					
		1				
I,	Full Name	being	Desition			
	Fuil Name		Position			
I declare that	the apparatus/chemical listed	above will not be used	l for the m	anufacture of	illicit drug	ns
	the apparatus/onemical instea				intent ana	yo.
Signature				Date		
THE RECEIV	ER'S SUPERVISOR AUTHORIS	ATION				
l.		. beina				
	Full Name					,
approve that	the purchase/transfer of the ap	oparatus/chemicals is	for resear	ch use.		
Signature				Date		
	ed by the internal supplier					
	noto identification					
	tion card type of the receiver			er		
Current Photo Identification NumberExpiry Date						
Signature of supplierDate						
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