



VCU

Environmental Health
and Safety

Safety and Risk Management

GUIDE FOR DEVELOPING IACUC PROTOCOLS INVOLVING HAZARDOUS CHEMICALS

1. Purpose: This guide was developed by the Institutional Biosafety Committee (IBC) to assist PIs in determining reporting requirements for *in vivo* chemical hazards during the preparation of protocols for submission to the Institutional Animal Use and Care Committee (IACUC). This reference should be used in conjunction with the regularly updated IACUC Hazardous Chemical Index spreadsheet, if agents are not listed on the IACUC Hazardous Chemical Index, PIs should refer to criteria outlined below to determine if IBC registration (reporting) is required via completion of the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form.

2. Scope / Applicability: The IBC criteria for determining “reportable chemicals” are consistent with the following sources:

a. The Occupational Safety and Hazard Administration (OSHA): "[Laboratory Safety Standard](#)" (29 CFR 1910.1450).

b. "Prudent Practices in the Laboratory: Handling and Disposal of Chemicals:" National Research Council, 1995.

c. *Sax's Dangerous Properties of Industrial Materials, 11th Edition*, edited by Richard J. Lewis, Sr.

d. Safety Data Sheets (product-specific) provided by various chemical vendors.

e. Physicians Desk Reference 71st Edition (Physicians' Desk Reference (PDR) by PDR Staff (December 13, 2016).

3. Procedure / Process / Guidelines / Steps:

a. All *in vivo* use of chemicals meeting the following criteria must be reported on the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form (unless exempted under 3j).

- Agents identified as reportable (“Y”) on most recent version of the IACUC Hazardous Chemical Index

b. Carcinogens:

- Identified on product Safety Data Sheet (SDS) as having known or suspected human carcinogenicity.
- [OSHA "Select Carcinogens"](#) Note: if protocol involves *in vivo* use of formaldehyde refer to section "3.h." for special considerations.
- National Toxicology Program (NTP) – “14th Annual Report on Carcinogens” chemicals identified in most recent revision as:
 - ["Known to be Human Carcinogens"](#)
 - ["Reasonably Anticipated to be Human Carcinogens"](#)
- International Agency for Research on Cancer (IARC)
 - Group 1 ("Carcinogenic to Humans") agents
 - Group 2A ("Probably Carcinogenic to Humans") agents
 - Group 2B ("Possibly Carcinogenic to Humans") agents

c. Hazardous Drugs:

- All agents listed on the NIOSH publication: “Preventing Occupational Exposure to Antineoplastic and other Hazardous Drugs in Health Care Settings
[Appendix A: "Drugs Considered Hazardous."](#)
- All agents listed on the OSHA Technical Manual: “Controlling Exposure to Hazardous Drugs, [Appendix VI, 2-1 "Some Common Drugs that are Considered to be Hazardous"](#)

d. Reproductive Toxins:

- All agents with SDS and/or other product information indicating that human reproductive toxin properties have been confirmed or are suspected (unless exempted under 3j).
- Agents listed on Sax’s Guide and/or product specific SDS with human test data available indicative of known or suspected human reproductive toxicity (unless exempted under Section IV or [“Guide to Chemical Classifications”](#)).

e. Acute Toxins:

- The National Research Council’s “Prudent Practices” manual identifies acute toxicants as chemicals with the capability of inducing harmful effects (local and/or systemic) after a single exposure. Determination of acute toxicity can be made by comparing the LD₅₀ of a compound (provided on product SDS) to the values listed in the tables below:

▪ *High-Hazard Acute Toxicants*: Any chemical that falls within the “HIGH” hazard level on Table 1 (below) is considered an acute toxicant and must be reported via hazardous chemical form (unless exempted under Section IV or “Guide to Chemical Classifications”).

TABLE 1. Acute Toxicity Hazard Level

Hazard Level	Toxicity Rating	Oral (Rats, kg)	LD ₅₀ Skin Contact (Rabbits, per kg)	LD ₅₀ Inhalation (Rats, ppm for 1 h)	LC ₅₀ Inhalation (Rats, mg/m ³ for 1 h)	LC ₅₀
High	Highly toxic	<50 mg	<200 mg	<200	<2,000	
Medium	Moderately toxic	50 to 500 mg	200 mg to 1 g	200 to 2,000	2,000 to 20,000	
Low	Slightly toxic	500 mg to 5 g	5 to 5 g	2,000 to 20,000	20,000 to 200,000	

▪ *Extremely Toxic Chemicals*: Chemicals falling within the “EXTREMELY and HIGHLY TOXIC” toxicity ratings on Table 2 (below) are acute toxicants and must be reported via hazardous chemical form (unless exempted under Section IV or “Guide to Chemical Classifications”).

TABLE 2. Probable Lethal Dose for Humans

Toxicity Rating	Animal LD ₅₀ (per kg)	Lethal Dose When Ingested by 70-kg (150-lb) Human
Extremely toxic	Less than 5 mg	A taste (less than 7 drops)
Highly toxic	5 to 50 mg	Between 7 drops and 1 teaspoonful
Moderately toxic	50 to 500 mg	Between 1 teaspoonful and 1 ounce
Slightly toxic	500 mg to 5 g	Between 1 ounce and 1 pint
Practically nontoxic	Above 5 g	Above 1 pint

SOURCE: Modified, by permission, from Gosselin et al. (1984). Copyright 1984 by Williams & Wilkins, Baltimore.

Obtained from “Prudent Practices in the Laboratory” (2011). National Academy of Science.

f. Mutagens and Teratogens:

- All agents with SDS and/or other product information indicating that human mutagenic and/or teratogenic properties have been confirmed or are suspected (unless exempted under 3j).

- Agents listed on Sax's Guide and/or product specific SDS with human test data available indicative of known or suspected human mutagenicity and or teratogenicity ((unless exempted under 3j).

g. Other Reportable Chemicals:

- Due to special health and safety concerns, a limited number of chemicals that may not otherwise fall within the reportable categories listed above must also be reported via hazardous chemical form. The current list of special chemicals includes:
 - 5-bromo-2-deoxyuridine (BrdU)
 - Complete Freund's Adjuvant (CFA)
 - Centers for Disease Control "Select Agents": Refer to the "[Select Agent Information Page](#)" for details regarding the special health and safety concerns and reporting requirements for select agents.

h. Formaldehyde and Glutaraldehyde, Special Conditions:

- When used in conjunction with perfusion procedures: (Glutaraldehyde and Formaldehyde with concentrations $\leq 37\%$): Formaldehyde solutions containing $\leq 37\%$ and all Glutaraldehyde solutions are exempt from IACUC reporting requirements, provided that the laboratory maintains an up-to-date Chemical Hygiene Plan, participates in applicable University Laboratory Safety Training Modules located on BioRaft and meets other general program requirements of the Environmental Health and Safety/Safety and Risk Management (EHS/SRM) - Laboratory Safety Section.
 - All other in vivo use of formaldehyde and Glutaraldehyde will be reported on the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form.

i. Novel Chemicals with Unknown or Limited Available Toxicological Data:

- Compounds with limited hazard information will be considered hazardous and reported on the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form until sufficient toxicological data becomes available for making a hazard assessment.
- Test compounds with unknown identities/toxicological properties (such as proprietary pharmaceutical compounds) will be considered as hazardous chemicals, reported on the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form as a "novel compound" or "unknown test compound."

j. Exemptions:

- Routinely Administered Pre/Post Operational Drugs: Analgesics, anesthetics, antibiotics, perfusates, and euthanasia agents do not require reporting on the Drug/Compound list

provided they are addressed in the laboratory chemical hygiene plan and meet the following criteria:

- Agents must be addressed in laboratory chemical hygiene plan.
- Agents are not listed IARC 1, 2A, or 2B or NTP “Known” or “Suspected” carcinogens, NIOSH and/or OSHA “hazardous drugs,” OSHA select carcinogens, and are not listed in section "3.g." (“Other Reportable Chemicals”) of this text.
- Euthanasia agents manufactured under the label “Euthasol®” (or similar preparations) do not require reporting.
- Formaldehyde and/or Glutaraldehyde used in perfusion procedures under conditions established in section "3.h." do not require reporting.
- New or novel pre/post operational drugs will be addressed on a case-by-case basis, contact the Biosafety Office to initiate a product review.
- USDEA Schedule I and II Controlled Substances: Drugs listed under **Schedule I and II of the U.S. Drug Enforcement Agency Controlled Substance Act** are not required to be reported on Appendix C provided the agents are addressed in laboratory chemical hygiene plan.