Safety approval form for work with newly synthetized chemicals, biological active substances* or natural toxins** in the experimental animals

Before submitting an Animal Protocol or Animal Protocol Amendment to use chemicals with unknown properties (or not FDA approved) in the experimental animals, you must complete the questionnaire below.
This is required for proper risk assessment evaluation to protect human health and prevent exposure.

* Biological Active Substance (BAS): Substance that is produced by or extracted from a biological source, such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids of human or animal origin, and biotechnological cell constructs and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterization and the determination of its quality.
Examples of BAS: snake venom; antibodies

** Natural toxins are toxic compounds that are naturally produced by living organisms. These toxins are not harmful to the organisms themselves but they may be toxic to other creatures, including humans. These chemical compounds have diverse structures and differ in biological function and toxicity. Some toxins are produced by plants as a natural defense mechanism against predators, insects or microorganisms, or as consequence of infestation with microorganisms, such as mould, in response to climate stress (such as drought or extreme humidity).(WHO https://www.who.int/news-room/fact-sheets/detail/natural-toxins-in-food).
Examples of natural toxins: Muscimol from is one of the principal psychoactive constituents of *Amanita muscaria* mushroom, algal toxins.

Compared with Select agents, both BAS and Natural toxins do not have pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products.

References

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Harley, Alan L. "Natural products in drug discovery", Drug Discovery Today, Vol. 13, Numbers 19/20, 10/2008 https://pubs.acs.org/doi/pdf/10.1021/np068054v?rand=l98cntjm

Newman, David J. * and Cragg, Gordon M. "Natural Products as Sources of New Drugs over the Last 25 Years", J. Nat. Prod. 2007, 70,461-477
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Working with newly synthetized chemicals, biological active substances* or natural toxins** in experimental animals

Safety Approval Form

Name

_____

Title

_____

Section A. Physical and Chemical Properties

1. **Formula and Full name of the chemical (without abbreviation).**

2. **CAS number (if applicable).**
   If you supply CAS number you do not need to complete this form.

3. **List the name and address of the chemical supplier/source**

4. **Potentially primary hazard**
   Check all that apply.

- [ ] Flammable
- [ ] Oxidizer
- [ ] Corrosive
- [ ] Toxic
- [ ] Carcinogen
- [ ] Irritant

Other

5. **How will you receive this compound**

Check all that apply.

- [ ] Powder
- [ ] Solution (or Liquid)
- [ ] Gas
- [ ] Solid

Section B. Toxicity to Human

7. **What is the intended use of the chemical?**

Provide the proposed mechanism of action. (for e.g. BrdU (Bromodeoxyuridine / 5-bromo-2'-deoxyuridine) is an analog of the nucleoside thymidine used in the BrdU assay to identify proliferating cells. During the BrdU assay, BrdU is incorporated into replicating DNA and can be detected using anti-BrdU antibodies.). Are there any analogs or similar FDA approved drugs or chemical compounds already on market? If so, please provide references.

8. **What is the LD50 for the animal model and route of exposure?**

If it is unknown, is the material hazardous to human? If so, how was toxicity established (for example cell toxicity studies)? Was this compound tested on humans in clinical trials?

9. **What effect are you looking to cause in animals? Could the same effect occur in humans?**

10. **How many animals will be housed simultaneously in the animals facility? List animal species and approximate weight.**

11. **What is the administration dose, number of doses, amount used per procedure and delivery form (e.g. solution or food pellets)? Routes of delivery -including orally, gavage, topical and via injection**

12. **Will any hazardous metabolite or unmetabolized chemicals be excreted in the urine/feces?**

Section C. Exposure Prevention

13. **Describe PPE required for drug preparation.**
Check all that apply.

- [ ] Lab Coat
- [ ] Nitrile Gloves
- [ ] Mask
- [ ] Other:

14. **Describe PPE required for personnel administering drug to animals**
Check all that apply.

- [ ] Lab Coat
- [ ] Nitrile Gloves
- [ ] Mask
- [ ] Other: _____

15. **Does the preparation process require a chemical fume hood?**
Select one.

- ( ) Yes
- ( ) No

16. **Is a chemical fume hood/biosafety cabinet required for delivery to the animal?**
Select one.

- ( ) Yes
- ( ) No

17. **Specify possible kinds of exposure and what first aid measures will be taken if exposure occurs.**
e.g. Eye Contact, Dermal contact, Oral/ingestion, Inhalation
**Not required if manufacturer's SDS is available.