

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (DEVCOM Chemical Biological Center)**
2. Number of animals used in this study: **3**
3. Species (common name) of animals used in the study: **guinea pigs**
4. Explain the procedure producing pain and/or distress.

Three (3) guinea pigs were intravenously exposed to a high dose of VX, which was expected to produce moderate toxic signs. The experiment was conducted to identify biomarkers of VX exposure using blood and interstitial fluid collected from hairless guinea pigs. The VX caused moderate toxic signs such as ataxia, tremors, splayed legs, lacrimation, and salivation in these guinea pigs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

Any attempt to alleviate the pain/distress associated with exposure to VX would have confounded the investigator's attempt to identify biomarkers of exposure.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

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1. Registration Number: **51-F-0019 (DEVCOM Chemical Biological Center)**
2. Number of animals used in this study: **16**
3. Species (common name) of animals used in the study: **minipigs**
4. Explain the procedure producing pain and/or distress.

Sixteen (16) minipigs were exposed to military grade compounds via whole-body inhalation to attain LC₅₀'s (lethal to 50% of the animals tested) and EC₅₀'s (concentration that causes an effect in 50% of the animals tested) for each exposure duration. The compounds caused toxic signs such as salivation, miosis, tremors, and convulsions in these minipigs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

The use of analgesics would have interfered with, or potentially blocked, clinical signs that the investigators were trying to acquire as endpoints. Additionally, administering analgesics may have resulted in respiratory depression which could have altered the respiratory minute volume during the aerosol exposure and exacerbate the expected signs, thereby confounding the outcomes of the exposure.

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Agency _____ CFR _____