

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 persons as well as scientists.

1. Registration Number: 51-F-0019
2. Number 106 (rabbits) / 280 (guinea pigs) of animals used in this study.
3. Species (common name) rabbits/guinea pigs of animals used in the study.
4. Explain the procedure producing pain and/or distress.

One hundred six (106) rabbits and two hundred eighty (280) guinea pigs were used to test militarily unique compounds via the inhalation route to establish relative importance of exposure concentration and duration on the probability of toxic and lethal responses. Historically, in studies designed to generate lethal dose-response curves, it has been assumed that approximately half of the exposed animals would be expected to die and that this level of response may potentially be associated with pain, discomfort, and/or distress.

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)

For these studies, the use of anesthetic/analgesic drugs during exposure may compromise the results of the proposed studies due to the fact that this class of compound may alter the respiratory minute volume and thus the dose of test compound that the animal receives. In addition, the expression of toxic signs may be altered by such treatment. Clement and Coperman (1984) suggest that chemical agent-induced convulsion and death are not necessarily associated with pain.

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
2. Number 308 (rabbits) / 131 (swine) of animals used in this study.
3. Species (common name) rabbits/swine of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Three hundred eight (308) rabbits and one hundred thirty-one (131) swine were tested with previously untested chemicals of military interest. The materials were tested by dermal route.

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)

Animals that either died or suffered convulsive seizures during the test – these severe toxic signs could not be alleviated so that accurate test data could be collected. The data collected were important for several reasons: 1) to establish the toxicological profile of the chemical; 2) to establish data to be used for human estimates; 3) to establish data from which therapy/prophylaxis could be established; and 4) data would be included in material safety data sheets as a warning to potential users or in support to chemical staff in case of accidental exposures.

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1. Registration Number: 51-F-0019
2. Number 71 rabbits of animals used in this study.
3. Species (common name) rabbits of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Seventy-one (71) rabbits were tested with previously untested chemicals of military interest. The materials were tested by intravenous route.

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 animals will be exposed to procedures, which can potentially cause them distress. At doses that result in toxic effects (gasping, bronchoconstriction), pain may develop during or after exposure resulting from an injury or stress/irritation of tissues. Toxic signs are expected to be relatively mild. While these should not be painful, they could cause some degree of distress. Pre-treating the animals with analgesics is not an option because it could potentially affect the BAL, or pathology results.

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