

US EPA ARCHIVE DOCUMENT

Questions for the Scientific Advisory Panel

Applicability of the Up-and-Down Procedure Methodology for Acute Oral Toxicity Testing

1. Does the SAP agree that the Up-and-Down Procedure (UDP) test guideline generates usable point estimates of the LD50 and confidence intervals that aid in interpreting the significance of LD50 estimates for hazard classification and risk assessment purposes? If not, how might materials be modified to make the method better?
2. Is the conduct of the UDP practical for laboratories to perform in fulfillment of EPA uses? Are there suggestions for improvement?
3. Is the revised UDP method applicable to the regulatory uses for hazard classification for human health and the environment and certain hazard and risk assessment applications under FIFRA? Under TSCA?
4. The OPPTS Harmonized Test Guideline 870.1100 for Acute Oral Toxicity is intended to be used with the AOT425StatPgm software, accompanied by information included in the document titled *Additional Guidance, Toxicology Summary: Performance of the Up-and-Down Procedure*. This guidance describes the strengths and limitations of the UDP regarding estimation of LD50 and confidence intervals. In addition, a software manual for use with the AOT425StatPgm has been provided. Does the 870.1100 guideline and the accompanying manual and other guidance provide sufficient information for study performers and data reviewers? If not, make suggestions for improvement.