

表二 環境衛生用藥新有效成分毒性測試項目

| 測試項目   | 必須檢具                            | 選擇性檢具       |
|--|---------------------------------|-------------|
| 急性毒性試驗(Acute toxicity testing)<br>口服急性毒(Acute oral toxicity)<br>皮膚急性毒(Acute dermal toxicity)<br>呼吸急性毒(Acute inhalation toxicity)<br>初發眼刺激(Primary eye irritation)<br>初發皮膚刺激(Primary dermal irritation)<br>皮膚過敏性(Dermal sensitization)<br>遲發神經毒性(Acute delayed neurotoxicity) | ○<br>○<br>○<br>○<br>○<br>○<br>○ | △           |
| 亞慢性毒性試驗 (Subchronic testing)<br>90 日餵食毒性(90-day feeding studies)<br>21 日皮膚毒性(21-day dermal studies)<br>90 日呼吸毒性(90-day inhalation)<br>90 日神經毒性(90-day neurotoxicity)   | ○                               | △<br>△<br>△ |
| 慢性毒性試驗(Chronic testing)<br>慢性餵食毒性(Chronic feeding)<br>致腫瘤性(Oncogenicity study)<br>後代繁殖 (至少二代) (Reproduction-2 generation)<br>致畸胎性(Teratogenicity)  | ○<br>○<br>○<br>○                |             |
| 致變異性試驗(Mutagenicity)<br>染色體變異(Chromosomal aberration)<br>基因變異性(Gene mutation)<br>其它遺傳毒性 (Other genotoxic effects)  | ○<br>○<br>○                     |             |
| 代謝試驗(Metabolism)<br>動物代謝測試(Metabolism in animal)<br>植物代謝測試(Metabolism in plant)  | ○<br>○                          |             |
| 環境影響試驗(Environmental fate studies)<br>水解(Hydrolysis)<br>光解性(Photodegradation)<br>土壤代謝(Metabolism in soil)<br>水域代謝(Metabolism in Aquatic)<br>累積性(Accumulation studies)  | ○<br>○<br>○                     | △<br>△      |
| 非目標生物毒性試驗(Nontarget organism toxicity)<br>水生生物毒(Aquatic organism toxicity)<br>鳥類毒性(Avian toxicity)<br>蜜蜂接觸毒性(Honey bee acute contact toxicity)   | ○                               | △<br>△      |

△選擇性檢具：原製造廠具有毒性測試資料者，應提供。