

예시 1

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Linalool(Cas No.78-70-6)

시험항목 : 육생식물급성독성

등록제출자료 생략의 사유

(출처명) 본 생략사유 및 증명자료는 OECD SIDS 초기평가 보고서(SIAR: SIDS Initial Assessment Report for 14th SIAM, 2002) 결과를 참고하였습니다.

(주요 종말점 및 결과값과 주요영향) Linalool(CAS No.78-70-6)의 육생식물독성에 대한 주요 결과는 *Lactuca sativa* (lettuce)와 *Lepidum sativum* (cress)를 사용한 발아영향 시험에서 NOEC \geq 100 mg/L으로, barley(*Hordeum vulgare*)를 사용한 발아영향 시험에서 NOEC \geq 50 mg/L이며, 육생식물에 대한 낮은 유해성을 가진다고 기술되어 있습니다.

(생략 시험항목) 해당결과를 통해 육생식물급성독성의 유해성을 판단할 수 있으므로 화학물질의 등록 및 평가 등에 관한 법률 시행령 제13조 제6호의2에 따라 Linalool(CAS No.78-70-6)의 육생식물급성독성 자료를 생략하고자 합니다.

증명자료

생략사유의 증명자료로 아래와 같이 해당 자료의 국문요약을 참고로 제시합니다.

<표> 육생식물 독성(급성) 시험결과(요약)

출처: SIDS Initial Assessment Report for 14th SIAM [2002], 90~91쪽

| No. | 자료개요 및 시험방법 | 시험결과 |
|-----|--|---|
| 1 | <ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도(결과도출방법 등): 신뢰도 4(not assignable) - 근거(인용): OECD SIAR 보고서 육생식물 독성(급성) 평가 자료 - 시험방법: 국가·국제기구 등의 시험지침 기술되지 않음 - 노출방법: 페트리 접시 위에 필터 2장과 함께 5ml의 물(대조군)과 솔루션(실험군), 3일, 25±2 °C 조건 - GLP 준수여부: GLP 미준수 - 시험물질 정보: Linalool(순도: 최소 90%) - 시험종 정보: <i>Lactuca sativa</i> (lettuce), <i>Lepidum sativum</i> (cress) - 시험용량: 100 mg linalool/L, 1g linalol/L | <ul style="list-style-type: none"> - 종말점 및 결과값: NOEC \geq 100 mg/L (발아, 초기 생장률) |

본 자료는 "화학물질등록평가법 시행령 제13조 및 같은법 시행규칙 제5조"에 따라 제출이 필요한 생략사유 및 증명자료의 예시로 추가검토·보완을 통해 수정·변경될 수 있으며 단순 참고자료로 활용하시기 바랍니다.

| No. | 자료개요 및 시험방법 | 시험결과 |
|-----|--|--|
| 2 | <ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 4(not assignable), - 근거(인용): OECD SIAR 보고서 육생식물 독성(급성) 평가 자료 - 시험방법: 국가·국제기구 등의 시험지침 기술되지 않음 - 노출방법: 페트리 접시 위에 필터 2장과 함께 5ml의 물(대조군)과 솔루션(실험군), 3일, 25±2 °C 조건 - GLP 준수여부: GLP 미준수 - 시험물질 정보: Linalool(순도: 최소 90%) - 시험종 정보: barley(<i>Hordeum vulgare</i>) - 시험용량: 0, 1, 10, 50 mg/L | <ul style="list-style-type: none"> - 종말점 및 결과값: NOEC ≥ 50 mg/L - 주요영향: 10mg/L에서 뿌리생장에 약간의 영향을 보임. 본 논문에서는 통계분석이 제공되지 않기 때문에 50mg/L에서 생장률이 약간 감소하는 것은 유의미한 영향이 아닌 것으로 보임(96%) |

시험결과의 결론

In conclusion, linalool shows moderate toxicity to aquatic organisms and low toxicity to micro-organisms, terrestrial plants and birds. It paralyses insects at higher concentrations but it is characterised as a moderate insect toxicant at the same time. Overall, linalool has a low to moderate toxicity towards environmental species. Due to its ready degradability, abiotic in the atmosphere and biological in water and soil, the low tendency for bioaccumulation and the well developed metabolic pathways from bacteria to mammals, no concentrations that might cause toxicity are expected.

4.2 Terrestrial Effects

Three germination tests with terrestrial plants, performed in aqueous solutions, were located. In the test with barley, germinating root length was measured: at 10 mg linalool/l, a slight elongation (112%) compared to controls was observed while there was a slight reduction (96%) at 50 mg/l, the highest concentration tested. As both deviations seem rather small, as the concentration range is limited and as no statistics are given, this test cannot be interpreted quantitatively. A germination and initial growth test with lettuce and cress spanned a concentration range up to 1000 mg/l. In lettuce, 1000 mg/l completely inhibited germination and had some undescribed effect on growth (presumably of plants pre-germinated in the absence of linalool, not stated) while the NOEC was 100 mg/l. For cress the NOEC for both germination and growth was 1000 mg/l. In a nonstandard phytotoxicity test, no effect of an unstated concentration of linalool, probably as an aerosol or vapour, on the closure of leaf stomata was found. In conclusion, linalool did not show any particular phytotoxic potential and the NOEC for germination and growth is 100 mg/l. These tests were performed in aqueous medium, therefore the derivation of a terrestrial plant PNEC is not possible.

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[별첨(원문 페이지 발췌)]

시험결과 표(또는 내용)

4.6.2 Toxicity to Terrestrial Plants

Species: other terrestrial plant: *Hordeum vulgare* (barley)
 Endpoint: other: root growth of germinating barley
 Expos. period: 3 day(s)
 Unit: mg/l
 NOEC: ≥ 50 - measured/nominal

Method: other
 Year: 1982
 GLP: no data
 Test substance: as prescribed by 1.1 - 1.4

Method: All plants were grown in 9-cm-diameter Petri dishes on two filter papers (Whatman 1) with 5 ml of water (controls) or test solution. [Barley grains were probably pre-soaked in water for 3 days, based on cross-reading with a parallel test and transferred to the experimental Petri dishes.] The dishes were incubated in the dark at 25 ± 2 °C for 3 days. Root length was measured as the endpoint. All treatments consisted of 5 replicate Petri dishes.

Result: Germinating barley root lengths

| Linalool concentration, mg/l | Relative root length, % |
|------------------------------|-------------------------|
| 0 (control) | 100 |
| 1 | 106 |
| 10 | 112 |
| 50 | 96 |

Test substance: Linalool was obtained from Sigma, London; all isoprenoid alcohols used in this study, including linalool, are stated to have a minimum purity of 90%.
 Test solutions (emulsions) were prepared by dissolving the test substance in a small quantity of acetone, adding water containing a few drops of teepol and shaking vigorously prior to making up to volume with water.

Conclusion: At 10 mg/l there was a slight stimulatory effect on root growth. As no statistical analysis is provided in the paper, the slight decrease at 50 mg/l cannot be characterised as to significance.

Reliability: (4) not assignable

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Species: other terrestrial plant: Lactuca sativa (lettuce) and Lepidum sativum (cress)
 Endpoint: other: germination and initial growth
 Expos. period: 3 day(s)
 Unit: mg/l
 NOEC: >= 100 - measured/nominal
 Method: other
 Year: 1982
 GLP: no data
 Test substance: as prescribed by 1.1 - 1.4
 Method: All plants were grown in 9-cm-diameter Petri dishes on two filter papers (Whatman 1) with 5 ml of water (controls) or

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test solution. 100 seeds (lettuce or cress) were spread on one Petri dish. The dishes were incubated in the dark at 25 +/- 2 °C for 3 days. Germination and growth [probably size, not stated] were measured as the endpoints. All treatments consisted of 3 replicate Petri dishes.
 Result: Treatment with 1 g linalool/l resulted in full inhibition of germination and "an effect" (unspecified) on the growth of lettuce, but in no adverse effect on germination or growth of cress.
 In the discussion, the authors write that "although it prevented lettuce germination at 1 g/l, lower concentrations [100 mg/l, table 3 in paper] were without effect even on growth and no effect was observed on the growth of cress."
 Test substance: Linalool was obtained from Sigma, London; all isoprenoid alcohols used in this study, including linalool, are stated to have a minimum purity of 90%. Test solutions (emulsions) were prepared by dissolving the test substance in a small quantity of acetone, adding water containing a few drops of teepol and shaking vigorously prior to making up to volume with water.
 Conclusion: No adverse effect was observed on germination and initial growth of lettuce and cress at or above 100 mg linalool/l.
 Reliability: (4) not assignable
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