

예시 1

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Linalool(Cas No.78-70-6)

시험항목 : 활성슬러지 호흡저해

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 활성슬러지 호흡저해에 대한 EC₅₀(30분) 값은 > 100 mg/L(활성슬러지)(GLP)로 기술되어 있습니다.

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

증명자료

생략사유의 증명자료로 아래와 같이 해당 자료의 국문요약을 참고로 제시합니다.

<표> 활성슬러지 호흡저해 시험결과(요약)

출처: SIDS Initial Assessment Report for 14th SIAM [2002], 84~86쪽

No.	자료개요 및 시험방법	시험결과
1	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도(결과도출방법 등): 신뢰도 1(valid without restriction) - 근거(인용): OECD SIAR 보고서 활성슬러지 호흡저해 평가 자료로 인용 - 시험방법: OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test" - 노출방법: 30분 시험 - GLP 준수여부: GLP 준수 - 시험물질 정보: Linalool(CAS No.78-70-6) - 시험종 정보: 활성 슬러지 - 시험용량: 100.7, 32.22, 10.07, 3.22, 1.01 mg/L 	<ul style="list-style-type: none"> - 종말점 및 결과값: EC₅₀ > 100 mg/L
2	<ul style="list-style-type: none"> - 자료의 성격: 보조자료, 요약서 	<ul style="list-style-type: none"> - 종말점 및 결과값: EC₅₀ > 100 mg/L

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
	<ul style="list-style-type: none"> - 신뢰도(결과도출방법 등): 신뢰도 4(not assignable, Reliability is probably better than 4 but available test report is incomplete) - 근거(인용): OECD SIAR 보고서 활성슬러지 호흡저해 평가 자료로 인용 - 시험방법: OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test" - 노출방법: 30분 시험 - GLP 준수여부: GLP 준수 - 시험물질 정보: Linalool(CAS No.78-70-6) - 시험종 정보: 활성 슬러지 - 시험용량: 0, 96, 304, 912 mg/L 	(measured/nominal)

[별첨(원문 페이지 발췌)]

시험결과 표(또는 내용)

4.4 Toxicity to Microorganisms e.g. Bacteria	
Type:	aquatic
Species:	activated sludge, domestic
Exposure period:	30 minute(s)
Unit:	mg/l
NOEC:	= 100 -
EC50:	> 100 -
EC20 :	> 100 -
EC80 :	> 100 -
Method:	OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year:	1991
GLP:	yes
Test substance:	as prescribed by 1.1 - 1.4
Method:	Activated sludge
	Activated sludge was collected from the mainly domestic sewage treatment plant of CH-4152 Reinach, Switzerland, on Sept 29th, 1991; the pH at collection was 7.3. Preparation of the sludge was carried out according to OECD Guideline
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209 of April 1984. However, as a deviation from the Guideline, the sludge was separated from the aqueous layer only by settling instead of centrifugation.

Procedure
250-ml BOD flasks with gas inlet were used as test vessels, dechlorinated drinking water was used to make up the test solutions with the following dissolved nutrients: 16 g peptone, 11 g meat extract, 3.0 g urea, 0.7 g NaCl, 0.4 g (CaCl₂ * 2 H₂O), 0.2 g (MgSO₄ * 7 H₂O) and 2.8 g K₂HPO₄ per litre.

Temperature
The test was performed at room temperature (20 +/- 2 °C).

Duration
30 min and 3 hours.

Substances tested
Test substance: dl-Linalool as described under Test substance.
Reference substance: 3,5-dichlorophenol, source not stated.
Blank: None (2 vessels, sludge only).

Remark
The test substance was found to be volatile on pre-tests, with a reduction to 75% after 30 min with bubbling and to 42% after 3 h with bubbling compared to 100% without bubbling in both cases, measured by TOC. To compensate for this volatility, higher test substance concentrations were added to ensure concentrations above 100 mg/l at the end of the respective test.

Test concentrations
Test substance: 100.7, 32.22, 10.07, 3.22 and 1.01 mg/l.
Reference substance: 32, 10 and 3.2 mg/l.
The final sludge concentration in the test vessels was adjusted to 1.6 g dry weight per litre.

Measurements
Oxygen consumption per hour in mg/l was determined with an ORION Electrode Type 97-08 on an ORION Microprocessor Ionalyzer 901 and plotted on a recorder.

GC Analysis
The content in water of linalool was determined by gas chromatography. For the sample solution, at least 2 samples of ideally 100 ml each were taken into a 250-ml separation funnel. The empty original sample bottle is rinsed with 10 ml n-hexane (all n-hexane to be of analytical grade); the funnel is extracted 3 times with 10 ml n-hexane; the collected organic phases are made up to 50.0 ml with n-hexane.
For the reference solution, at least 80 mg linalool are accurately weighed, then dissolved in and made up to 100.0 ml with n-hexane; from this stock solution at least two reference solutions are diluted to the range of test concentrations using n-hexane.

The GC apparatus and conditions were as follows:

Chromatograph:	HP 5890 Series II
Injector:	splitless, 100 °C
Injection volume:	5 µl (manual injection)
Oven program:	initial temperature 50 °C
	initial time 3 min
	temperature rise rate 32 °C/min
	final temperature 175 °C
	final time 1 min
Detector:	FID, 300 °C
	air: 400 ml/min
	H ₂ : 30 ml/min

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	He make-up: 30 ml/min
Integrator:	HP workstation
Column:	HP 5 (5% Ph-Me-Silicone, 10 m x 0.53 mm, 2.65 um film)
Mobile phase:	He, 30 ml/min
Retention time:	approx. 5 min
Analysis time:	approx. 8 min
Inhibition calculations	
	Inhibitions were calculated on the basis of the measured time-dependent oxygen consumption of blank, test solutions and reference substance.
Result:	Linalool did not inhibit during 30 min nor during 3h the oxygen consumption of activated sludge at any of the concentrations tested and analytically confirmed at the end of the test. The reference substance did inhibit oxygen consumption with a graphically determined EC 50 of 24 mg/l (30 min) respectively 19.9 mg/l (3 h).
Test substance:	Test substance: dl-Linalool from F. Hoffmann-La Roche Ltd, batch no. 08071, purity 97.8%, retest date June 30th 1992 (testing date was July 30th, 1991).
Reliability:	(1) valid without restriction
Flag:	Critical study for SIDS endpoint
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Type:	aquatic																																								
Species:	activated sludge, domestic																																								
Exposure period:	30 minute(s)																																								
Unit:	mg/l Analytical monitoring: yes																																								
EC10:	ca. 110 - calculated																																								
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Year:	1989																																								
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Method:	According to the guideline, 2 blank controls (sludge plus nutrients); 3 times 2 linalool concentrations (96, 304, 912 mg/l) plus sludge plus nutrient; and 1 inhibitory/negative control (sludge plus nutrient plus 272 mg 2,5-dichlorophenol/l) were tested in parallel.																																								
Result:	<table><tr><td>Vessel</td><td>Linalool, mg/l</td><td>Respiration rate</td><td>Inhibition, %</td></tr><tr><td>Control1</td><td>0</td><td>1.053</td><td>-</td></tr><tr><td>Control2</td><td>0</td><td>1.111</td><td>-</td></tr><tr><td>Substance1</td><td>96</td><td>1.081</td><td>7</td></tr><tr><td>Substance2</td><td>96</td><td>1.081</td><td>7</td></tr><tr><td>Substance3</td><td>304</td><td>0.727</td><td>37</td></tr><tr><td>Substance4</td><td>304</td><td>0.741</td><td>36</td></tr><tr><td>Substance5</td><td>912</td><td>0.260</td><td>78</td></tr><tr><td>Substance6</td><td>912</td><td>0.267</td><td>77</td></tr><tr><td>Inhibition (272 dichlorophenol)</td><td></td><td>0.367</td><td>68</td></tr></table>	Vessel	Linalool, mg/l	Respiration rate	Inhibition, %	Control1	0	1.053	-	Control2	0	1.111	-	Substance1	96	1.081	7	Substance2	96	1.081	7	Substance3	304	0.727	37	Substance4	304	0.741	36	Substance5	912	0.260	78	Substance6	912	0.267	77	Inhibition (272 dichlorophenol)		0.367	68
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시험결과의 결론

Linalool is of low toxicity to activated sludge bacteria, with the exception of one, contested, result from a non-standard activated sludge inhibition test. In all other, including OECD, tests, the NOEC was 100 mg/l or higher. This is confirmed by minimal inhibition concentration (MIC) tests with eight common bacteria and five common fungi, where in 2/13 cases the lowest MIC was 200 mg/l. Low toxicity is also inferred from biodegradation tests. Some published data on relatively high toxicity of linalool to 18 species of bacteria and 12 species of fungi cannot be assessed due to lack

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of quantitative data. The NOEC of linalool for micro-organisms is set at 100 mg/l, the PNEC at 10 mg/l using an assessment factor of 10.