

예시 1

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Dichlorodimethylstannane(CAS No. 753-73-1)

시험항목 : 육생무척추동물급성독성

등록제출자료 생략의 사유

(출처명) 본 생략사유 및 증명자료는 OECD SIDS 초기평가 보고서(SIAR: SIDS Initial Assessment Report for 23th SIAM, 2006)) 결과를 참고하였습니다.

(주요 종말점 및 결과값과 주요영향) Dichlorodimethylstannane(CAS No. 753-73-1)의 육생무척추동물급성독성 LC₅₀(14일) 값은 320 mg/kg(*Eisenia fetida*)(GLP), > 1000 mg/kg(*Eisenia fetida*)(GLP)로 기술되어 있으며, NOEC(14일) 값은 100 mg/kg(*Eisenia fetida*)(GLP), 100 mg/kg(*Eisenia fetida*)(GLP)로 기술되어 있습니다.

(생략 시험항목) 해당결과를 통해 육생무척추동물급성독성의 유해성을 판단할 수 있으므로 화학물질의 등록 및 평가 등에 관한 법률 시행령 제13조 제6호의2에 따라 Dichlorodimethylstannane(CAS No. 753-73-1)의 육생무척추동물급성독성 자료를 생략하고자 합니다.

증명자료

생략사유의 증명자료로 아래와 같이 해당자료의 국문요약을 참고로 제시합니다.

<표> 육생 무척추동물 급성독성 시험결과(요약)

출처: SIDS Initial Assessment Report for 23th SIAM(2006), 62~63쪽

No.	자료개요 및 시험방법	시험결과
1	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 2 (제한적인 신뢰도) - 근거(인용): OECD SIAR 보고서 급성독성 평가 자료 - 시험방법: OECD Guide-line 207 - 시험형태: 인공토양(artificial soil) - GLP 준수여부: GLP 준수 - 시험물질 정보: Dimethyltin Dichloride [CAS No. 753-73-1]; Methyltin Trichloride [CAS No. 993-16-8] (50:50% 혼합물); 투명액체, 45%를 methylt 	<ul style="list-style-type: none"> - 종말점 및 결과값: <ul style="list-style-type: none"> • LC₅₀ = 320 mg/kg • NOEC = 100 mg/kg - 주요영향: 사망개체 없음

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
	<p>in chlorides 혼합</p> <ul style="list-style-type: none"> - 시험종 정보: Eisenia fetida (지렁이 (Annelida), 토양 서식), 용량군당 10마리 - 노출기간: 14일 - 시험농도: 0, 0.10, 1.0, 10, 100, 1000 mg/kg (설정농도) 	
2	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 2 (제한적인 신뢰도) - 근거(인용): OECD SIAR 보고서 급성독성 평가 자료 - 시험방법: OECD Guide-line 207 - 시험형태: 인공토양(artificial soil) - GLP 준수여부: GLP 준수 - 시험물질 정보: Dimethyltin Dichloride [CAS No. 753-73-1]; Methyltin Trichloride [CAS No. 993-16-8] (75:25% 혼합물); 투명액체, 활성성분 100%로 간주 - 시험종 정보: Eisenia fetida (지렁이 (Annelida), 토양 서식), 용량군당 10마리 - 노출기간: 14일 - 시험농도: 0, 0.10, 1.0, 10, 100, 1000 mg/kg (설정농도) 	<ul style="list-style-type: none"> - 종말점 및 결과값: <ul style="list-style-type: none"> • LC50 > 1000 mg/kg • NOEC = 1000 mg/kg - 주요영향: 사망개체 없음

[별첨(원문 페이지 발췌)]

시험결과의 결론

4.2 Terrestrial Effects⁴

Two acute toxicity studies of DMTC:MMTC mixtures with earthworms (*Eisenia fetida*) [OECD TG 207] were conducted in artificial soil. A 50:50 DMTC:MMTC mixture resulted in complete mortality at Day 14 at a nominal concentration of 1000 mg/kg. No mortality was observed at nominal concentrations of 0.10, 1.0, 10 and 100 mg/kg, and average weights were not significantly different from the control group. The 14-d LC50 was 140 (45-450 mg/kg) and the NOEC was 45 mg/kg, when calculated on an active ingredient basis. On a whole test substance basis, the 14-d LC50 was 320 (100-1000 mg/kg) and the NOEC was 100 mg/kg (Ward et al. 1995e). ⁴

The second study was conducted with a 75:25 DMTC:MMTC mixture. One earthworm died on Day 7 at a nominal concentration of 10 mg/kg; no deaths were reported at nominal concentrations of 0.1, 1.0, 100 or 1000 mg/kg. Relative to the control group, average weights were reduced 7 to 38% at all exposure levels. The 14-d LC50 was > 1000 mg/kg, and the NOEC (based on survival) was reported as 1000 mg/kg (Ward et al. 1996c). ⁴

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시험결과 내용

5. Toxicity

Id 753-73-1
Date 24.07.2006

Analytical monitoring : no data
Method : other: not reported
Year :
GLP : no data
Test substance : other TS

Remark : IC50 = 50% inhibition of function/growth.
Source : Cooney et al. 1989
Test substance : Dimethyltin Dichloride [CAS No. 753-73-1]
Reliability : (4) not assignable
Provided for information purposes only.

30.04.2002

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4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

Type : artificial soil
Species : Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint : other: survival and sublethal effects
Exposure period : 14 day(s)
Unit : other: mg/kg
NOEC : = 100
LC50 : = 320
Method : OECD Guide-line 207 "Earthworm, Acute Toxicity Test"
Year : 1984
GLP : yes
Test substance : other TS

Method : Earthworms, obtained from Carolina Biological Supply, were acclimated at the testing facility for 4 days. Worms were not fed during acclimation or testing. Prior to using in the test, worms were washed, dried, and weighed. Final weights of surviving worms were obtained on day 14.

Artificial soil containing 70% industrial sand, 20% kaolin clay, and 10% finely ground sphagnum peat was used to conduct the 14-day toxicity study. The test substance was added to deionized water and thoroughly mixed with the artificial soil.

Nominal concentrations tested were 0, 0.10, 1.0, 10, 100, and 1000 mg/kg. Ten worms per concentration were tested without replication. The test was performed in 3.8-L glass jars. The temperature range was 19.3-20.7 deg. C, and a 24-h light photoperiod was maintained. Light intensity was 800 lux. Mortality and sublethal effects (lethargy, color change, physical abnormalities, and inability to burrow) were visually assessed on days 7 and 14.

시험결과 내용

4. Ecotoxicity		Id 753-73-1 Date 24.07.2006	
Result	:	<p>The 14-day LC50 was determined using standard statistical methods (Stephan 1983) and the NOEC was defined as the highest concentration tested that allowed at least 90% survival and did not cause sublethal effects.</p> <p>There was no mortality or sublethal effects observed in the control and in nominal concentrations up to 1000 mg/kg. At 1000 mg/kg, there was no mortality on day 7, but all worms died by day 14. Relative to the control group, there were no apparent effects on the average weights of surviving worms at any test concentration. Worms exposed to the control and all test substance concentrations burrowed into the soil within 10 minutes on days 0 and 7.</p> <p>The 7-day LC50 was reported as >450 mg/kg on an active ingredient basis or >1000 mg/kg on a whole test substance basis.</p> <p>The 14-day LC50 (95% c.i.) was reported as 140 (45-450) mg/kg on an active ingredient basis or 320 mg/kg (100-1000) mg/kg on a whole test substance basis.</p> <p>The 14-day NOEC was 45 mg/kg on an active ingredient basis or 100 mg/kg on a whole test substance basis.</p>	
Source	:	Rohm and Haas	
Test substance	:	Dimethyltin Dichloride [CAS No. 753-73-1];Methyltin Trichloride [CAS No. 993-16-8] (50:50% mixture); clear liquid, 45% mixed methyltin chlorides, source: Morton International, Inc. (Cincinnati, OH).	
Reliability	:	(2) valid restriction GLP guideline study without replication. No analytical confirmation of exposure concentrations.	
26.09.2003			(104)
Type	:	artificial soil	
Species	:	Eisenia fetida (Worm (Annelida), soil dwelling)	
Endpoint	:	other: survival and sublethal effects	
Exposure period	:	14 day(s)	
Unit	:	other: mg/kg	
NOEC	:	= 1000	
LC50	:	> 1000	
Method	:	OECD Guide-line 207 "Earthworm, Acute Toxicity Test"	
Year	:	1984	
GLP	:	yes	
Test substance	:	other TS	
Method	:	<p>Earthworms, obtained from Carolina Biological Supply, were acclimated at the testing facility for 4 days. Worms were not fed during acclimation or testing. Prior to using in the test, worms were washed, dried, and weighed. Final average weights of surviving worms were obtained on day 14.</p> <p>Artificial soil containing 70% industrial sand, 20% kaolin clay, and 10% finely ground sphagnum peat was used to conduct the 14-day toxicity study. The test substance was added to deionized water and thoroughly mixed with the artificial soil.</p> <p>Nominal concentrations tested were 0, 0.10, 1.0, 10, 100, and 1000 mg/kg. Ten worms per concentration were tested without replication. The test was performed in 3.8-L glass jars. The temperature range was 19.0 to 21.5 deg. C, and a 24-h light photoperiod was maintained. Light intensity was 800 lux. Mortality and sublethal effects (lethargy, color change, physical abnormalities, and inability to burrow) were visually assessed on days 7 and 14.</p> <p>The 14-day LC50 was determined using standard statistical methods (Stephan 1983) and the NOEC was defined as the highest concentration</p>	

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시험결과 내용

5. Toxicity

Id 753-73-1

Date 24.07.2006

Result	: tested that allowed at least 90% survival and did not cause sublethal effects. There was no mortality observed in the control and in the 0.10, 1.0, 100, and 1000 mg/kg test concentrations. One worm died by day 7 in the 10 mg/kg test concentration. Worms exposed to the control and all test substance concentrations burrowed into the soil within 10 minutes on days 0 and 7. Relative to the control group, there were apparent decreases in the average weights of surviving worms at all test concentrations.
Source	: The 7- and 14-day LC50s were reported as >1000 mg/kg. The 14-day NOEC (based on survival) was 1000 mg/kg.
Test substance	: Rohm and Haas : Dimethyltin Dichloride [CAS No. 753-73-1]; Methyltin Trichloride [CAS No. 993-16-8] (75:25% mixture); clear liquid, assumed to be 100% active ingredients, source: Morton International, Inc. (Cincinnati, OH).
Reliability	: (2) valid with restriction GLP guideline study without replication. No analytical confirmation of exposure concentrations.

26.09.2003

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4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

예시 2

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Vanillin(cas no. 121-33-5)

시험항목 : 육생무척추동물급성독성

등록제출자료 생략의 사유

(출처명) 본 생략사유 및 증명자료는 OECD SIDS 초기평가 보고서(SIAR: SIDS Initial Assessment Report for SIAM, 1996) 결과를 참고하였습니다.

(주요 종말점 및 결과값과 주요영향) Vanillin(cas no. 121-33-5)의 지렁이(*Eisenia foetida*)를 이용한 육생무척추동물급성독성 시험에서 토양 중 농도 0~8% 범위에서 4%로 42시간 노출 시 성장률을 현저히 감소시키고 시험동물의 80%에서 사망을 유발하였고, NOEC가 10,000 mg/kg soil dw로 기술되어 있습니다.

(생략 시험항목) 해당결과를 통해 육생무척추동물급성독성의 유해성을 판단할 수 있으므로 화학물질의 등록 및 평가 등에 관한 법률 시행령 제13조 제6호의2에 따라 Vanillin(cas no. 121-33-5)의 육생무척추동물급성독성 자료를 생략하고자 합니다.

증명자료

생략사유의 증명자료로 아래와 같이 해당자료의 국문요약을 참고로 제시합니다.

<표> 육생무척추동물급성독성 시험결과(요약)

출처: SIDS Initial Assessment Report for SIAM(1996), 8쪽, 56~7쪽

No.	자료개요 및 시험방법	시험결과
1	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 기준 및 근거가 기술되지 않음 - 근거(인용): OECD SIAR 육생무척추동물독성 평가 자료로 인용 - 시험방법: 국가·국제기구 등의 시험지침 기술되지 않음 - 노출방법: 42일 노출 - GLP 준수여부: 알 수 없음 - 시험물질 정보: Vanillin(순도 미기재) - 시험종 정보: <i>Eisenia foetida</i> (Earthworm) - 시험용량: 0, 0.1, 1.0, 4, 8% (w/w) 	<ul style="list-style-type: none"> - 종말점 및 결과값: <ul style="list-style-type: none"> • NOEC = 약 10000 mg/kg soil dw • LOEC = 약 40000 mg/kg soil dw - 주요영향: LOEC 값의 사망률은 80%

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[별첨(원문 페이지 발췌)]

시험결과의 결론

3.2.2 Terrestrial effects

Plants

Toxicity of vanillin to plants has been tested with lettuce, wheat and cotton. Germination testing with lettuce using water with 650 \pm 30 mg/l produced a 50 % reduction in germination compared to controls. Using a Petri dish bioassay, the elongation of cotton radicles was visually observable inhibited (11 %) after addition of 30 mg vanillin/dish, while no effect was observed on the wheat.

Earthworm

The effect of vanillin has been tested on growth and survival of the earthworm *Eisenia foetida*. The tested concentrations in soil, were 0, 0.1, 1.0, 4 and 8 %, the exposure period was 42 days. Of these, 4% was the lowest concentration which significantly reduced growth rate and caused death (in 80 % of the worms), the NOEC value was 10 g/kg dw.

Conclusion

As plants seem more sensitive than earthworm the EC₅₀ value is multiplied with an application factor of 1000, giving a PNEC_{max} of 0.647mg/kg ww.

3.2.3 Other effects

The white root fungi, which are responsible for breakdown of most of the lignin in nature, are rather tolerant to vanillin, showing 0-33 % inhibition at 152 mg/l, 76-100% at 760 mg/l and no growth at 1520 mg/l.

시험결과 내용

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

Type:	Artificial Soil (<input type="checkbox"/>); Filter paper (<input type="checkbox"/>); Other (<input checked="" type="checkbox"/>)
Species:	<i>Eisenia foetida</i> (Earthworm)
End point:	Mortality (<input checked="" type="checkbox"/>); Weight (<input checked="" type="checkbox"/>); Other (<input type="checkbox"/>)
Exposure period:	42 days
Results:	EC ₅₀ (...d) = EC _{xx} (...d) = NOEC = approx. 10,000 mg/kg soil dw LOEC = approx. 40,000 mg/kg soil dw
Method:	Activated sludge (ca. 13% solids) with test substance were placed over a ca. 4 mm depth of silt loam in a Petri dish.
<hr/>	
	The amount of substance tested was mixed with the activated sludge. There were 2 hatchlings per concentration and 5 replicates per concentration. Concentrations: approx. 0, 0.1, 1.0, 4 and 8% (w/w). Stored at 24°C.
GLP:	Yes (<input type="checkbox"/>) No (<input type="checkbox"/>) ? (<input checked="" type="checkbox"/>)
Test substance:	Vanillin from Aldrich Chemical Co., Milwaukee, WI, USA. Purity: No data.
Remarks:	The mortality at LOEC was 80%.
Reference:	Hartenstein, 1982.