

예시 1

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Tris(1,3-dichloro-2-propyl) phosphate (CAS No.13674-87-8)

시험항목 : 흡착 및 탈착

등록제출자료 생략의 사유

(출처명) 본 생략사유 및 증명자료는 유럽연합 위해성 평가보고서(EU RAR: European Union Risk Assessment Report, 2008) 결과를 참고하였습니다.

(주요 종말점 및 결과값과 주요영향) Tris(1,3-dichloro-2-propyl) phosphate(CAS No.13674-87-8)의 흡착 및 탈착에 대한 log Koc 값은 3.25(GLP) 및 4.09(GLP)로 기술되어 있습니다.

(생략 시험항목) 해당결과를 통해 토양 이동성에 대한 유해성을 판단할 수 있으므로 화학물질의 등록 및 평가 등에 관한 법률 시행령 제13조 제6호의2에 따라 Tris(1,3-dichloro-2-propyl) phosphate(CAS No.13674-87-8)의 흡착 및 탈착 자료를 생략하고자 합니다.

증명자료

생략사유의 증명자료로 아래와 같이 해당 자료의 국문요약을 참고로 제시합니다.

<표> 활성슬러지 호흡저해 시험결과(요약)

출처: European Union Risk Assessment Report [May 2008], 33~38쪽

No.	자료개요 및 시험방법	시험결과
1	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 1(valid without restriction) - 근거(인용): 유럽연합 위해성 평가보고서(EU RAR) 흡착 및 탈착 평가 자료로 인용 - 시험방법: OECD Guideline 106 - GLP 준수여부: GLP 준수 - 시험물질 정보: Tris(1,3-dichloro-2-propyl) phosphate(순도 미기재) - 시료정보: 3 soils, sediment and sludge 	<ul style="list-style-type: none"> - 종말점 및 결과값: Koc = 1780 (1540~2010) L/kg, log Koc = 3.25
2	<ul style="list-style-type: none"> - 자료의 성격: 주요자료, 요약서 - 신뢰도: 신뢰도 1(valid without restriction) - 근거(인용): 유럽연합 위해성 평가보고서(EU RAR) 흡착 및 탈착 평가 자료로 인용 	<ul style="list-style-type: none"> - 종말점 및 결과값: Koc = 12300 L/kg, log Koc = 4.09±0.29

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"> - 시험방법: EU Method C.19 - GLP 준수여부: GLP 준수 - 시험물질 정보: Tris(1,3-dichloro-2-propyl) phosphate(순도 미기재) - 시료정보: soil 	

[별첨(원문 페이지 발췌)]

시험결과 표(또는 내용)

Endpoint	Year test completed	Protocol cited	Results	Reliability	Study reference
Adsorption to 3 soils, sediment and sludge ¹	2006	OECD 106	$K_{oc} = 1780$ (range 1540 – 2010), $\log K_{oc} = 3.25$	(1) valid without restriction. GLP study	Schaefer and Ponizovsky, 2006
Adsorption to soil ²	2002	Method C.19 of 2001/59/EC	$\log K_{oc} = 4.09 \pm 0.29$	(1) valid without restrictions ³ . GLP study	Cuthbert, J.E. and D.M. Mullee, 2002a

The study was conducted to a high standard, in full compliance with all three tiers of the OECD 106 method and in accordance with the principles of GLP. TDCP in 0.01 M calcium chloride was equilibrated with each of three soils (a clay loam, a loamy sand and a clay), one sediment and one activated sludge solid. Study of the kinetics of adsorption was made which showed that the equilibration time was adequate. The solids and aqueous phase were separated by centrifugation. Method checks on the adsorption to glassware were made and this was found to be insignificant. The stability of the substance was checked.

Both adsorption and desorption were studied, and the equilibrium constants (K_d) were sufficiently similar to show that there was reversibility. Kinetic studies showed that the processes were rapid. The determination of Freundlich isotherms was made which showed that the processes were not highly concentration-dependent (results not reported herein).

The data are presented in Table 3.4.

Table 3.4 TDCP OECD 106 study: partition data

Substrate	% organic carbon	K_d (adsorption phase)	K_d (desorption phase)
Clay loam (TB-PF)	5	56	82
Loamy sand (Roger Myron)	1.3	18	26
Clay (Montana clay)	0.7	11	16
Sediment (Turkey Creek)	5.9	193	227
Sludge solids	34.46	590	606

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Review of the other K_{oc} data

A reliable modern measurement of the soil adsorption coefficient K_{oc} obtained by the HPLC estimation method is available (Cuthbert and Mullee, 2002a). The result is $K_{oc} = 1.23 \times 10^4$, $\log K_{oc} = 4.09 \pm 0.29$. The \pm value is the 95% confidence interval. It should be noted that the calibration substances were general substances, not related structurally to TDCP, there being insufficient reliable calibration substances containing the phosphate group. For this reason, estimates of K_{oc} from the EPIWIN program are not considered to be reliable enough for phosphates and are not included here.

시험결과의 결론

Conclusions

For TDCP, good agreement is found between the QSAR predictions of K_{oc} from K_{ow} ($K_{oc} = 950.8$ (range 633.4 – 1427.2) and the value measured in the OECD 106 study ($K_{oc} = 1780$ (range 1540 – 2010)). The HPLC screening estimates of K_{oc} appear to consistently overestimate this value for the chloroalkylphosphates. For TDCP, the K_{oc} measured in the OECD 106 study will be used for the risk assessment, $K_{oc} = 1780$ $\log K_{oc} = 3.25$. The regression equation derived from this study will be used to derive K_{oc} values for TCPP and V6 based on their measured $\log K_{ow}$ values.

The measured value of $K_{oc} = 1780$ is used in the risk assessment of TDCP. The range of the value does not have a significant impact on the conclusions.