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.

예시 1

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

대상물질 : Vanillin(121-33-5)

시험항목 : 이분해성

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 이분해성에 대한 주요 결과는 호기성 조건에서 6일후 62.5%가 분해되었으며, 혐기성 조건에서 28일후 72%가 분해된 결과를 근거로 빠르게 분해되는 물질로 판단한다고 기술되어 있습니다.

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

증명자료

생략사유의 증명자료로 아래와 같이 해당자료의 국문요약을 참고로 제시합니다.

<표> 이분해성 시험결과(요약)

출처: SIDS Initial Assessment Report for SIAM(1996), 5쪽, 43쪽

No.	자료개요 및 시험방법	시험결과
1	- **자료의 성격:** 주요자료, 요약서 - **신뢰도:** 신뢰도 기준 및 근거가 기술되지 않음 - **근거(인용):** OECD SIAR 생분해도 평가 자료 - **시험방법:** 국가·국제기구 등의 시험지침 기술되지 않음 - **시험조건:** 호기조건(Aerobic) - **GLP 준수여부:** 알 수 없음 - **시험물질 정보:** Vanillin(순도 미기재) - **접종원 정보:** Aspergillus sp.(Aspergillus terreus), Sewage treatment - **시험용량:** 기술되지 않음	- **종말점 및 결과값:** 빠르게 분해됨 - **분해율:** 62.5%/6일
2	- **자료의 성격:** 주요자료, 요약서 - **신뢰도:** 신뢰도 기준 및 근거가 기술되지 않음	- **종말점 및 결과값:** 빠르게 분해됨 - **분해율:** 0%/12일, 72%/28일

No.	자료개요 및 시험방법	시험결과
	- **근거(인용):** OECD SIAR 생분해도 평가 자료 - **시험방법:** 국가·국제기구 등의 시험지침 기술되지 않음 - **시험조건:** 혐기조건(Anaerobic) - **GLP 준수여부:** GLP 미준수 - **시험물질 정보:** Vanillin(순도 미기재) - **접종원 정보:** Anaerobic sludge, Water - **시험용량:** 300 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.

[별첨(원문 페이지 발췌)]

시험결과의 결론

3. ENVIRONMENT

3.1 Environmental Exposure

3.1.1 General Discussion

Level I fugacity calculation, using a six compartment global reference model shows that vanillin will be distributed mainly to water (98.5%), minor quantities will be distributed to soil solids (1.41%), while negligible quantities will be distributed to other compartments and there are no trends to bioaccumulation. This is in agreement with the Log P_{ow} value of 1.23. Compounds with a Log $P_{ow} < 3$ will not tend to bioaccumulate.

Abiotic degradation of vanillin has been studied as photodegradation and hydrolytic degradation in water. Vanillin has been estimated to be degraded by sunlight in air with a half-life of 4.7 hours. Meaurement of hydrolysis in water at different levels of pH, indicated slow rates and the hydrolyses did not reach 10 % in any of the pH systems investigated. The compound is thus considered stable in sterile water.

Biotic degradation of vanillin has been studied in soil, and in water after inoculation with *Aspergillus terrus*, anaerobic sludge or benthic microorganisms from an eutrophic lake.
In unamended garden soil, biodegradation was slow, with about 10 % degraded after 4 weeks, however after amending the soil with "active garden soil" a 41 %degradation was achieved after 21 days. Under aerobic conditions in water after inoculation with *Aspergillus terrus*, 62.5% was degraded after 6 days. Under anaerobic conditions in water after inoculation with anaerobic sludge, 72 % was degraded after 28 days. Benthic microorganisms, dependent on a carbon source in the growth medium, were able to grow on vanillin as the only carbon source after 6 days of incubation. It is concluded from these studies that vanillin is readily biodegradable.

The biochemical oxygen demand (BOD_5) and chemical oxygen demand (COD_{Cr}) of vanillin has been determined. Values of 1.26 mg/mg and 1.76 mg/mg respectively gives an aerobic degradation during 5 days incubation at 20 °C of BOD/COD = 72 %. This qualifies vanillin as a compound which is readily biodegradable.

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시험결과 내용

3.5 BIODEGRADATION

(a)

Type:	Aerobic (x); Anaerobic ( )
Inoculum:	Adapted (x); Non-adapted ( ) Aspergillus sp. (Aspergillus terreus)
Concentration of the chemical:	Related to COD ( ); DOC ( ); Test substance ( )
Medium:	Water ( ); Water-sediment ( ); Soil ( ); Sewage treatment (x)
Degradation:	62.5% after 6 days
Results:	Readily biodeg. (x); Inherently biodeg. ( ); Under test condition no biodegradation observed ( ); Other ( )
Method:	Assays in 5 litre batch reactor, steady flow of air 720 ml/min, stirring rate 200 rpm. Incubation at 28 °C for 6 days.
GLP:	Yes ( ) No ( ) ? (x)
Test substance:	Vanillin in the waste produced by the olive-oil extraction industry.
Remarks:	Biodegradation of Vanillin in the waste produced by the olive-oil extraction industry.
Reference:	Martinez et al, 1993.

(b)

Type:	Aerobic ( ); Anaerobic (x)
Inoculum:	Adapted (x); Non-adapted ( ) Anaerobic sludge
Concentration of the chemical:	300 mg/l related to COD ( ); DOC ( ); Test substance (x)
Medium:	Water (x); Water-sediment ( ); Soil ( ); Sewage treatment ( ) Containing $(NH_4)_2PO_4$, NH_4Cl, $MgCl_2$-$6H_2O$, KCl, $MnCl_2$-$4H_2O$, $CoCl_2$-$6H_2O$, H_3BO_3, $CaCl_2$-$2H_2O$, Na_2MoO_4-$2H_2O$, $ZnCl_2$, $FeCl_2$-$4H_2O$, $NaHCO_3$, Na_2S-$9H_2O$ and 1% (v/v) vitamin solution.
Degradation:	0% after 12 days 72% after 28 days
Results:	Readily biodeg. (x); Inherently biodeg. ( ); Under test condition no biodegradation observed ( ); Other ( )
Method:	A serum-bottle variation of the Hungate technique for growing anaerobic bacteria was adapted from Miller and Wolin (1974). The cultures were incubated in the dark at 35°C.
GLP:	Yes ( ) No (x) ? ( )
Test substance:	Vanillin. No further data.
Remarks:	10 methanogenic enrichment cultures were found to degrade Vanillin after a lag phase of 12 +/- 1.2 days; period of gas production (CO_2 and CH_4) 16 +/- 1.1 days; conversion of substrate carbon to gas 72 +/- 1.4 days. Vanillin is biodegradable to methane and carbon dioxide under strict anaerobic conditions.
Reference:	Healy et al, 1979.

예시 2

국가·국제기구 평가보고서를 통한 시험항목의 자료제출 생략사유 및 증명자료

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

시험항목 : 이분해성

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 이분해성에 대한 OECD TG 301(GLP) 시험 결과는 호기성 조건에서 28일 후 3%가 분해된 결과를 근거로 이분해성이 아닌 물질로 판단한다고 기술되어 있습니다.

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

증명자료

생략사유의 증명자료로 아래와 같이 해당자료의 국문요약을 참고로 제시합니다.

<표> 이분해성 시험결과(요약)

출처: SIDS Initial Assessment Report for 23th SIAM(2006), 20쪽, 39~41쪽

No.	자료개요 및 시험방법	시험결과
1	- **자료의 성격:** 주요자료, 요약서 - **신뢰도:** 신뢰도 1 (제한없는 신뢰도) - **근거(인용):** OECD SIAR 보고서 급성독성 평가 자료 - **시험방법:** OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test" - **시험형태:** • 호기조건(aerobiotic) • 시험기간: 28일 • 표준물질: Acetic acid, sodium salt - **접종원:** 국내 활성슬러지 (Municipality of Hazerswoude, The Netherlands) - **GLP 준수여부:** GLP 준수 - **시험물질 정보:** Dichlorodimethylstannane(순도:	- **종말점 및 결과값:** 이분해성 아님 - **분해율:** 3%(14/28/35일)

No.	자료개요 및 시험방법	시험결과
	99.66%) - **시험용량:** 111 mg/l	

[별첨(원문 페이지 발췌)]

시험결과의 결론

2.2.5 Biodegradation

Biodegradation studies of DMTC and DMT(EHTG) are summarized in Table 7.

Table 7 Results of Biodegradation Studies of the Dimethyltin Compounds and the Thioglycolate Esters

Compound	Test method	Percent degradation	Result	Reference
DMTC	OECD TG 301F	3% degradation after 28 days	Not readily biodegradable	Hanstveit 2003
DMT(EHTG)/ (IOTG)	Directive 92/69/EEC[1]	38–57 % degradation after 28 days	Not readily biodegradable	BASF 2000
IOTG/EHTG	OECD TG 301B	15% degradation after 29 days	Not readily biodegradable	Epona Associates, LLC 2006b

1 Comparable to OECD TG 301F

Most of this degradation, as measured by CO2 release, is from the breakdown of the EHTG ligands on the dimethyltin. However, it should also be noted that dimethyltins can be broken down through a de-methylation process by microorganisms (Maguire 1991), a process that would not lead to CO2 formation.

No biodegradation studies of DMT(IOTG) or the thioglycolate ester EHTG were found; however, DMT(EHTG) and DMT(IOTG) and IOTG and EHTG are isomers and data for these materials are used interchangeably.

Conclusion

DMTC, DMT(EHTG)/(IOTG) and IOTG/EHTG are not readily biodegradable.

시험결과 내용

3. Environmental Fate and Pathways

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precise, they do provide a reasonable estimation as to which compartments the commercial products will migrate until they are able to hydrolyze.

17.07.2006 (99)

3.3.2 DISTRIBUTION

Media	:	water - soil
Method	:	other (calculation): PCKOCWIN v1.66
Year	:	
Remark	:	Koc (calculated from structural features) = 48.64 L/kg (log Koc = 1.6870)
Source	:	Assessment Technologies, Inc.
Test substance	:	Dimethyltin Dichloride [CAS No. 753-73-1]; SMILES: C[Sn](C)(CL)CL
Reliability	:	(4) not assignable Value(s) derived using calculation method/software.

Current versions of EPIWIN, developed by Syracuse Research Corporation, have not been validated for estimating endpoints for chemicals that contain metals in their molecular structure; therefore, the estimated values derived from the EPIWIN models should be used with caution.

04.04.2005 (101)

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge, domestic
Concentration	:	111 mg/l related to Test substance related to
Contact time	:	28 day(s)
Degradation	:	= 3 (±) % after 28 day(s)
Result	:	other: under test conditions, not readily biodegradable
Kinetic of testsubst.	:	14 day(s) = 3 % 28 day(s) = 3 % 35 day(s) = 3 % % %
Control substance	:	Acetic acid, sodium salt
Kinetic	:	14 day(s) = 82 % 35 day(s) = 88 %
Deg. product	:	not measured
Method	:	OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"
Year	:	1992
GLP	:	yes
Test substance	:	other TS
Method	:	METHOD FOLLOWED: OECD Guideline 301F (1992) and EU Guideline C.4-D (1992). DEVIATIONS FROM GUIDELINE: 25g NaNO3 and 1g extra of NH4Cl were added as bacterial nitrogen sources to prevent inhibition of biodegradability due to nitrogen limitation. This deviation did not affect the results of the study. GLP: Yes. STATISTICAL METHODS: No statistical analysis was performed.

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		METHOD OF CALCULATION: The oxygen consumption (mg O2/L) was calculated based on the respiration rate (mg O2/flask/h) as measured by a Micro-Oxymax respirometer. The oxygen consumption due to test or control substance was calculated by subtracting the mean cumulative oxygen consumption in the blanks from that of the flask under consideration. These values were then converted to the Biological Oxygen Demand (BOD) which is expressed in mg O2/mg test substance. The percentage biodegradation of the test substance was calculated as BOD/ThOD x 100 (ThOD: Theoretical Oxygen Demand). ANALYTICAL METHODS: None.
Result	:	RESULTS: EXPOSED TEST SUBSTANCE: - ThOD(NH3): 0.51 mg O2/mg test substance. - BOD (mg O2/mg test substance): 0.02 (14d), 0.01 (28d) and 0.02 (35d). - Biodegradation: 3% (14d), 3% (28d), 3% (35d). CONTROLS: - Cumulative oxygen consumption (inoculum blank): 2.4 mg O2/flask (14d), 3.2 mg O2/flask (28d), 3.5 mg O2/flask (35d). - Cumulative oxygen consumption (inoculum activity control): 19.0 mg O2/flask (14d), 21.0 mg O2/flask (28d), 21.4 mg O2/flask (35d). - Biodegradation (inoculum activity control): 82% (14d), 87% (28d), 88% (35d). - Cumulative oxygen consumption (toxicity control): 21.0 mg O2/flask (14d), 23.8 mg O2/flask (28d), 24.3 mg O2/flask (35d). - Biodegradation (toxicity control): 50% (14d), 55% (28d), 56% (35d). OTHER: The cumulative oxygen consumption in the toxicity control (sodium acetate and test substance) after 14 days was slightly higher than that of the inoculum activity control (sodium acetate) alone. This indicated that the test substance did not inhibit the degradation of sodium acetate at the concentration tested. Based on the combined ThOD of both substances a biodegradation of >25% was reached which, according to the guidelines, means that the test substance is considered not toxic to the inoculum. The test substance was only slightly biodegraded (3%) after 28 days at a test concentration of 111 mg/L and is therefore considered to be not readily biodegradable.
Source	:	Hanstveit. 2003
Test condition	:	INOCULUM/TEST ORGANISM: - Type of sludge: Activated sludge from an oxidation ditch, which is used to treat domestic waste water. - Species/strain: Not specified. - Source: Not applicable. - Sampling site: Municipality of Hazerswoude, The Netherlands. - Feeding: Mineral medium. - Method of cultivation: The activated sludge was kept in a plastic flask and aerated until use. - Preparation of inoculum: Not applicable. - Pretreatment: Diluted in mineral medium. - Initial concentration: 30 mg sludge (dry weight)/L mineral medium TEST SYSTEM: - Culturing apparatus: 500 ml glass flasks. - Number of culture flasks per concentration: 3 replicate flasks for test substance, 2 replicate flasks (blanks) for inoculum activity control and 2 replicate flasks for toxicity control. - Aeration device: None; the test media were saturated with oxygen at the start of the test. - Measuring equipment: Columbus Instruments Micro-Oxymax Respirometer. - Closed vessels used: The incubator of the Manometric Respirator. INITIAL TEST SUBSTANCE CONCENTRATION: 111 mg/L, corresponding to a ThOD(NH3) of 56.6 mgO2/L or 17.0 mg O2/flask.

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시험결과 내용

METHOD OF PREPARATION OF TEST SOLUTION: 0.8325 g of the test substance was dissolved in 25 ml ultrapure water (Stock I). An aliquot of 1 ml of Stock I was added in the test flasks that were filled with 300 ml mineral medium.
DURATION OF THE TEST: 35 days.
ANALYTICAL PARAMETER: Oxygen consumption.
SAMPLING: Every 4 h during 35 days.
TEST CONDITIONS:
- Composition of medium: As specified in OECD Guideline 301.
- Additional substrate: $NaNO_3$ was added to prevent nitrogen limitation.
- Test temperature: 23°C (range 19.6-24.0°C).
- pH value: 6.7-7.3 at the start of the test. At the end of the test the pH was 7.3-7.4 in the test substance medium and 8.0-8.2 in the reference substance and toxicity test medium.
- Aeration of dilution water: None.
- Concentration of suspended solids: Ca. 30 mg/L.
INTERMEDIATES / DEGRADATION PRODUCTS: Not measured.
NITRATE/NITRITE MEASUREMENT: Not confirmed by analysis.
CONTROLS: Toxicity control (111 mg/L test substance and 100 mg/L reference substance).
REFERENCE SUBSTANCE: 100 mg/L Sodium acetate, anhydrous.

Test substance : SOURCE: ORTEP Association Stabilizer Task Force.
PURITY: 99.66% dimethyltin dichloride.
IMPURITY/ADDITIVE/ETC.: 0.25% methyltin trichloride and 0.09% trimethyltin chloride.
OTHER: The substance is soluble in water.

Reliability : (1) valid without restriction
Guideline study conducted under GLP.

Flag : Critical study for SIDS endpoint

24.07.2006 (44)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

BCF : = 3.16
Elimination :
Method : other: (calculated) BCFWIN v2.15
Year :
GLP : no
Test substance : other TS

Remark : BCF value of 3.162 L/kg (log BCF = 0.5) was estimated based on a measured log Kow of -2.18.
Source : Assessment Technologies, Inc.
Test substance : Dimethyltin Dichloride [CAS No. 753-73-1]; SMILES: C[Sn](C)(CL)CL
Reliability : (4) not assignable
Value(s) derived using calculation method/software.

Current versions of EPIWIN, developed by Syracuse Research Corporation, have not been validated for estimating endpoints for chemicals that contain metals in their molecular structure; therefore, the estimated values derived from the EPIWIN models should be used with caution.

24.07.2006 (96)

BCF : = 50