

This English translation of the “Test Methods Pertaining to New Chemical Substances etc. (ready biodegradability test by microorganism for chemical substance and octanol-water partition coefficient test) “ has been translated by National Institute of Technology and Evaluation with the assistance of Japan Chemical Industry Association.

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この「新規化学物質等に係る試験の方法について（微生物等による化学物質の分解度試験及び1-オクタノールと水との間の分配係数測定試験）」の英文翻訳は、（独）製品評価技術基盤機構が、一般社団法人日本化学工業協会の支援を得て作成したものです。

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○ Test Methods Pertaining to New Chemical Substances etc.
(March 31, 2011 Pharmaceutical and Food Safety Bureau, MHLW 0331 No. 7,
March 29, 2011 Manufacturing Industries Bureau, METI No. 5,
Environmental Policy Bureau, MOE No. 110331009)

Last Revision July 1, 2019 Pharmaceutical Safety and Environmental Health
Bureau, MHLW0701 No. 1, 20190619 Manufacturing Industries Bureau, METI
No. 2, Environmental Policy Bureau, MOE No. 1907011
Enforcement date July 1, 2019

No. 1 Test Methods pertaining to New Chemical Substances etc.
Test methods for new chemical substances etc. shall be based on the methods
given in the Attachment, in principle.

No. 2 Handling of test methods pertaining to new chemical substances etc.

1. Transitional provision

1) With regards to handling the tests started on or before March 31, 2011, and
have been conducted based on the methods of each test provided for in 2003 joint
notice and "Test methods for study of hazardous properties of Type III Monitoring
Chemical Substance (March 25, 2004: March 19, 2004 Manufacturing Industries
Bureau, METI No. 6, Environmental Policy Bureau, MOE No. 040325004)", the
provisions then set in force remain applicable as privilege measures.

2) With regards to tests started on or before March 31, 2011, whose purposes meet
any of the objectives of combined repeated dose toxicity study with
reproduction/development toxicity screening test conducted with mammals
provided for in No. 1 above, and conducted based on the OECD test guidelines,
the tests started on and before March 31 2011 can be treated as the tests meeting
their objectives among them above.

2. Others

The tests whose purposes are consistent with the purpose of the chronic toxicity
study, studies for effects on reproductive ability and subsequent generations,
teratogenesis study, mutagenicity study, carcinogenicity study, study on
metabolic fate or pharmacological studies defined in No. 1 above, and
conducted based on the OECD test guidelines, can be treated as the tests that
meet their objectives among them above, in principle.

< Ready biodegradability test by microorganism for chemical substance >

I: Ready biodegradability test by microorganism for chemical substance (equivalent to OECD 301C)

I-I Scope of application

This section provides the method that should be the standard for the degradation test by microorganisms, etc. for chemical substances.

I-II Terms

The terms used in the test method have the same manner as the terms used in the Japanese Industrial Standards (hereinafter "JIS").

I-III Preparation of activated sludge

1 Sludge collection place

Considering the regional distribution throughout the country, at least 10 places all over Japan around the places where various types of chemical substances are expected to be consumed and discharged of.

2 Number of times of sludge collection

Four to six times in a year.

3 Sludge collection method

3-1 Municipal Waste water Return sludge at sewage treatment plant 1 L

3-2 River, lake or sea The surface water 1 L and the surface soil at the beach in contact with the atmosphere 1 L

4 Preparation

The sludge collected from various places is mixed and stirred in a single container, left to stand, and the floating foreign matter is removed. The supernatant is filtered using No. 2 filter paper. Adjust the pH of the filtrate to 7.0 ± 1.0 with sodium hydroxide or phosphoric acid, transfer to an incubation tank and perform aeration.

5 Culture

After stopping the aeration of the liquid obtained in step 4 for about 30 minutes, remove supernatant about 1/3 of the whole, add the same amount of 0.1% synthetic sewage^(Note 1), and aerate once again. Repeat this operation once a day. Culture temperature should be $25 \pm 2^\circ\text{C}$.

(Note 1) 0.1% synthetic sewage

Prepared by dissolving 1 g each of glucose, peptone, and monopotassium dihydrogen phosphate in 1L water, after which the pH of the solution is adjusted to 7.0 ± 1.0 with sodium hydroxide

6 Management

For the management at the incubation stage, check the next items and make necessary preparations.

6-1 Appearance of the supernatant Supernatant of the activated sludge should be transparent.

6-2 Precipitability of activated sludge The sludge should be in large flocs and has excellent precipitability.

6-3 Conditions of activated sludge formation If no increase in flocs is observed, the additive amount or frequency of 0.1% synthetic sewage should be increased.

6-4 pH The pH of the supernatant should be 7.0 ± 1.0 .

- 6-5 Temperature Culture temperature of the activated sludge should be $25 \pm 2^\circ\text{C}$.
- 6-6 Volume of airflow Ensure sufficient airflow that the dissolved oxygen concentration in the incubation tank is more than at least 5 mg/L when the supernatant and synthetic sewage exchange.
- 6-7 Biota of activated sludge When the activated sludge is observed with a microscope (100-400 times), various types of many protozoans should be seen with cloudy flocks.

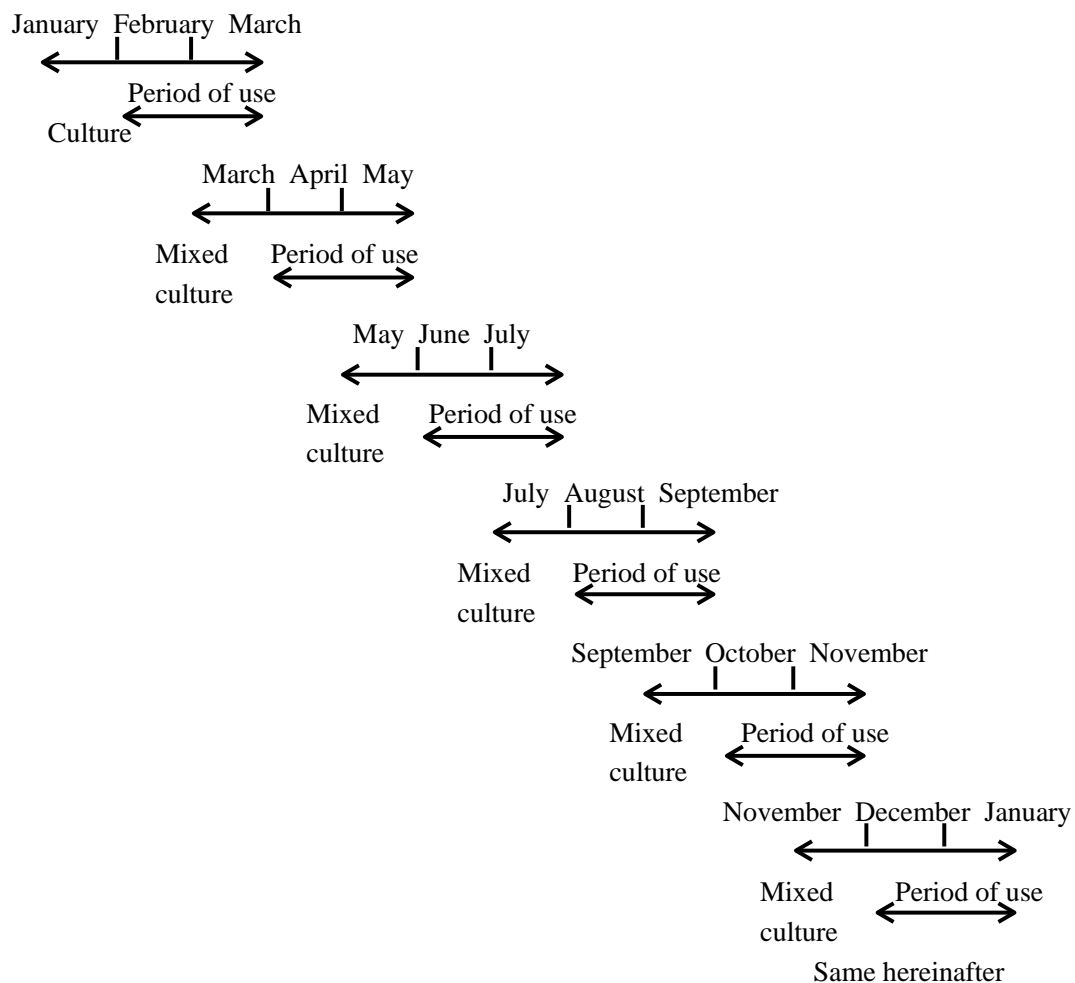
7 Mixing of fresh and old activated sludge

In order to maintain the homogenization of fresh and old activated sludge, mix the same amount of the filtrate of the supernatant of activated sludge actually used in the test and the filtrate of the supernatant of freshly collected sludge, and culture it.

8 Inspection of the activity of the activated sludge

Periodically inspect the activity at least once in 3 months by using the reference substances. Test method is same as I-IV. In particular, when mixing fresh and old activated sludge, pay attention to the relationship with the old activated sludge.

[Example of activated sludge preparation and period of use (when collecting 6 times a year)]



I-IV Test method

1 Degradation test equipment

Closed system oxygen consumption measuring device

2 Base Culture Medium

Add 3 ml each of liquid A, liquid B, liquid C, and liquid D having the composition set forth in 21 of JIS K0102-2016 in water, and make it 1 L.

3 Adding test substance and preparing for the test

Prepare the following test vessels (300 ml each) and adjust them to the test temperature. If the test substance does not dissolve in water to the test concentration, use as finely pulverized substance as possible, and do not use a solvent or emulsifying agent.

3-1 Test vessel containing the liquid prepared by adding the test substance to water to make 100 mg/L, 1 nos.

3-2 Test vessels containing the liquid prepared by adding the test substance to Base Culture Medium to make 100 mg, 3 nos.

3-3 Test vessel containing the solution prepared by adding aniline to Base Culture Medium to make 100 mg/L, 1 nos.

3-4 Test vessel containing only Base Culture Medium, 1 nos.

4 Inoculation of activated sludge

In the test vessels described in 3-2, 3-3, and 3-4, inoculate the activated sludge to become the concentration of suspended solids set forth in 14.1 of JIS K0102-2016 to 30mg/L. However, regarding 3-2, when required, adjust the pH of the solution to 7.0 before inoculation. As for the activated sludge, use the sludge after 18 to 24 hours of adding the synthetic sewage.

5 Conducting the ready biodegradability test

Under the dark condition, while adequately stirring at $25\pm 1^{\circ}\text{C}$, culture for a certain period ^(Note 2), and measure the changes in the oxygen consumption over time.

After culturing for a certain period of time, analyze the residual test substance and the degradant for measuring their amount. If the test substance is soluble in water, measure the residual amount of dissolved organic carbon as well. In addition, measure the pH of the test solution.

(Note 2) Normally it is 28 days.

6 Method of calculating test Results

6-1 Validation of Test Conditions

The test is valid when the difference between the maximum and minimum values of the biodegradability of the test substance at the end of the test is less than 20%, and the biodegradability of aniline of 3-3 in I-IV calculated from the oxygen consumption is more than 40% after 7 days and more than 65% after 14 days.

6-2 Method of calculating biodegradability (%) from the oxygen consumption

$$\text{Biodegradability (\%)} = \frac{\text{BOD-B}}{\text{TOD}^{(\text{Note 3})}} \times 100$$

BOD: Biochemical oxygen demand of the test substance (measured value) (mg)

B : The oxygen consumption of the liquid prepared by the inoculation of the activated sludge in the Base Culture Medium (Measured value) (mg)

TOD: Theoretical oxygen demand required when test substance is completely oxidized (calculated value) (mg)

(Note 3) When the test substance containing nitrogen decomposes, calculate TOD according to the extent of nitrification.

6-3 Method of calculating biodegradability (%) from direct quantification ^(Note 4)

$$\text{Biodegradability (\%)} = \frac{S_B - S_A}{S_B} \times 100$$

S_A: Residual amount of the test substance after the completion of the ready biodegradability test (measured value) (mg)

S_B: Residual amount of the test substance in blank test with only test substance added to water (measured value) (mg)

(Note 4) Chemical analysis by direct quantification

(i) When using Total Organic Carbon Analyzer

Take the appropriate amount of test solution from the test vessels, centrifuge it at about 40,000 m/s² for 15 minutes and filter (0.45 μm) it. Take an appropriate amount from the supernatant or the filtrate, and quantify the remaining dissolved organic carbon with the Total Organic Carbon Analyzer.

(ii) When using other analyzers

Extract the contents in the test vessels with a solvent suitable for the test substance etc., and after performing appropriate pretreatment such as concentration, conduct quantitative analysis with an analyzer. In this case, in principle, conduct analysis in accordance with the general rules of the analysis specified in JIS (gas chromatography, high performance liquid chromatography, absorption spectrophotometry, mass spectrometry, atomic absorption, etc.).

I-V Summary of results

Summarize the test results in form 1 and attach the final report.

II: Ready biodegradability test by microorganism for chemical substance (equivalent to OECD 301F)

II-I Scope of application

This section provides the method that should be the standard for the degradation test by microorganisms, etc. for chemical substances.

II-II Terms

The terms used in this test method have the same manner as the terms used in the Japanese Industrial Standards (hereinafter "JIS").

II-III Inoculum source (microbial source)

Use activated sludge or return sludge from an aerobic reaction tank (near the outlet) of a sewage treatment plant that mainly handles domestic wastewater, which is administered by the local government. After sampling sludge from the sewage treatment plant, remove large particles using a sieve, etc. if necessary, and maintain aerobic conditions until use for testing. If sludge is not used on the day of collection, maintain an aerobic condition at approximately 22°C and it may be used for 7 days after collection. Do not use test substance, standard substance (aniline, sodium acetate or sodium benzoate) and other chemical substances for acclimation.

II-IV Test method

1 Degradation test equipment

Oxygen consumption measuring device

2 Base Culture Medium

Prepare liquid A, liquid B, liquid C and liquid D shown below. Add water to liquid A 10 mL, liquid B 1 mL, liquid C 1 mL and liquid D 1 mL, to make it 1 L, and use it as Base Culture Medium.

Liquid A:

Potassium dihydrogen phosphate (KH_2PO_4)	8.50 g
Dipotassium hydrogen phosphate (K_2HPO_4)	21.75 g
Disodium hydrogen phosphate dihydrate ($\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$)	33.40 g
or Disodium hydrogen phosphate 12 hydrate ($\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$)	67.21 g
Ammonium chloride (NH_4Cl)	0.50 g

Dissolve the above in water and make it 1 L. Moreover, adjust the pH to 7.4

Liquid B:

Calcium chloride (CaCl_2)	27.50 g
or Calcium chloride dihydrate ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$)	36.40 g

Dissolve the above in water and make it 1 L.

Liquid C:

Magnesium sulphate heptahydrate ($\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$)	22.50 g
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Dissolve the above in water and make it 1 L.

Liquid D:

Iron (III) chloride hexahydrate ($\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$)	0.25 g
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Dissolve the above in water and make it 1 L. This solution is prepared immediately before use.

3 Adding test substance and preparing for the test

Prepare the test vessels given in 3-1 to 3-3 (Example 300 ml each), and adjust them to the test temperature. If the test substance is solid and does not dissolve in water to the test concentration, use as a finely pulverized substance, etc. as possible.

You may add test vessels given in 3-4 to 3-9 as needed. For test substances that have an inhibitory effect on microorganisms, 3-5 may be added to evaluate the degradability at a low concentration for the purpose of reducing the inhibition of microorganisms. The validity (test substance has inhibitory effect on microorganisms, etc.) shall be indicated by test vessels given in 3-6. For poorly water-soluble substances, add 3-7 to 3-9 using auxiliary substances (solvents, emulsifying agents or carriers) for the purpose of improving the contact between test substances and microorganisms in the test solution. However, the validity (the auxiliary substance has no biodegradability or inhibitory effect on microorganisms) of this shall be indicated.

- 3-1 Test vessels containing the liquid prepared by adding the test substance to Base Culture Medium to make 100 mg/L, At least 2 nos.
- 3-2 Test vessel containing the liquid prepared by adding reference substance (aniline, sodium acetate or sodium benzoate) to Base Culture Medium to make 100 mg/L, 1 nos.
- 3-3 Test vessels containing only Base Culture Medium, 2 nos.

<When confirming the effect on no organisms>

- 3-4 Test vessels containing the liquid prepared by adding the test substance to pure water to make 100 mg/L, Any random number of vessels

<When confirming degradability at low concentrations for test substances that inhibit microorganisms>

- 3-5 Test vessels containing the liquid prepared by adding the test substance to Base Culture Medium to make 30 mg/L, At least 2 nos.
- 3-6 Test vessels containing the liquid prepared by adding the test substance (quantity to be 100 mg/L) and the reference substance (quantity to be 100 mg/L) to the Base Culture Medium, Any random number of vessels

<When using auxiliary substances for poorly water-soluble substances>

- 3-7 Test vessels containing the liquid prepared by adding the test substance (quantity to be 100 mg/L) and the auxiliary substance (appropriate quantity) to the Base Culture Medium, At least 2 nos.
- 3-8 Test vessel containing the liquid prepared by adding the reference substance (quantity to be 100 mg/L) and the auxiliary substance (appropriate quantity) to the Base Culture Medium, 1 nos.
- 3-9 Test vessels containing the liquid prepared by adding the auxiliary substance (appropriate quantity) to the Base Culture Medium, 2 nos.

4 Inoculation of inoculum sources

In the test vessels given in 3-1 to 3-3, inoculate the inoculum sources to become the concentration of suspended solid set forth in 14.1 of JIS K0102-2016 to 30 mg/L. However, regarding 3-1, when required, adjust the pH of the solution to 7.4 ± 0.2 before inoculation.

When adding test vessels, inoculate the inoculum sources in 3-5 through 3-9 in the same manner. However, regarding 3-5 through 3-9, when required, adjust the pH of the solution to 7.4 ± 0.2 before inoculation.

5 Conducting degree of degradation test

Under the dark condition, while adequately stirring at $22 \pm 1^\circ\text{C}$, culture it for a certain period ^(Note 5), and measure the changes in the oxygen consumption over time.

After culturing for a certain period of time, analyze the residual test substance and the degradant for measuring their amount.

If the test substance is soluble in water, measure the remaining amount of dissolved organic carbon as well. However, regarding the test vessels mentioned in 3-6, it is not necessary to measure the residual test substance, the degradant and residual amount of dissolved organic carbon. In addition, measure the pH of the test solution.

(Note 5) Normally it is 28 days.

6 Method of calculating test Results

6-1 Validation of Test Conditions

The test is valid when at the time of completion of test, the difference between the maximum value and the minimum value of degree of degradation in 3-1 of II-IV is less than 20%, the oxygen consumption in 3-3 of II-IV is 60 mg/L or less, and the degree of degradation of the reference substance in 3-2 of II-IV reaches 60% before 14 days.

6-2 Method of calculating biodegradability (%) from the oxygen consumption

Biodegradability (%) = $(\text{BOD}-\text{B}) / \text{TOD} \times 100$ ^(Note 6)

BOD: Biochemical oxygen demand of the test substance (measured value) (mg)

B: The oxygen consumption of the liquid prepared by the inoculation of the activated sludge in the Base Culture Medium (Measured value) (mg)

TOD: Theoretical oxygen demand required when test substance is completely oxidized (calculated value) (mg)

(Note 6) When the test substance containing nitrogen decomposes, calculate TOD according to the extent of nitrification.

6-3 Method of calculating biodegradability (%) from direct quantification ^(Note 7)

Biodegradability (%) = $(\text{B}-\text{A}) / \text{B} \times 100$

A: Residual amount of the test substance after the completion of the ready biodegradability test (measured value) (mg)

B: Test substance addition amount (theoretical value) (mg)

(Note 7) Chemical analysis by direct quantification

(i) When using Total Organic Carbon Analyzer

Take the appropriate amount of test solution from the test vessels, centrifuge it at about 40,000m/s² for 15 minutes and filter (0.45 μm) it. Take an appropriate amount from the supernatant or the filtrate, and quantify the remaining dissolved organic carbon with the Total Organic Carbon Analyzer.

(ii) When using other analyzers

Extract the contents in the test vessels with a solvent suitable for the test substance etc., and after performing appropriate pretreatment such as concentration, conduct quantitative analysis with an analyzer. In this case, in principle, conduct analysis as per the general rules of analysis provided for in JIS (gas chromatography, high performance liquid chromatography, absorption spectrophotometry, mass spectrometry, atomic absorption, etc.).

6-4 Remarks

When calculating the biodegradability from the oxygen consumption in 6-2 of II-IV, if required, you may check whether it reaches 60% or not within 10 days (10-d window) of reaching 10%.

II-V Summary of results

Summarize the test results in form 1 and attach the final report.

<The octanol-water partition coefficient test >

I Scope of application and test method

In principle, measure the partition coefficient between 1-octanol and water of chemical substances (excluding organometallic compounds) that are soluble in water and have no surface activity in the same manner as the method defined in OECD Test Guideline 107 or OECD Test Guideline 117.

II Summary of results

Summarize the test results in form 3 and attach the final report.

[Form 1]

Ready Biodegradability Test Report

1. General matters

Name of the new chemical substances (In accordance with IUPAC nomenclature)			
Synonym			
CAS Number			
Structural formula or rational formula (When both are not known, outline of the production method)			
Molecular weight			
Purity of the new chemical substance used in the test (%)			
Lot number of the new chemical substance used in the test			
Name and percentage content impurity			
Vapor pressure			
Solubility in water			
1-octanol/water partition coefficient			
Melting point			
Boiling point			
Properties at normal temperature			
Stability			
Solubility etc. in solvent	Solvent	Solubility	Stability in solvent

[Remarks] Write down the physical and chemical properties as much as possible.

1. In the "Vapor pressure" column, write down the vapor pressure of the test substance.
2. In the "Stability" column, write down stability with respect to temperature, light, etc.
3. In the "Solubility etc. in solvent" column, write down the solubility of the test substance in the solvent and its stability in the solvent.

2. Test method

Test method	
Exposure period (days)	
Type of Sludge	
Test substance concentration	
Suspended matter concentration of sludge	
Reference substance	
pH adjustment	Yes / No

3. Test results

(1) BOD chart

* Can also be provided as an attachment.

(2) BOD measurement results

Measurement date Test vessels	BOD (mg)				
		7th day	14th day	21st day	28th day
(Water + test substance)		*1	*1	*1	*1
(Sludge + test substance)	No.1				
	No.2				
	No.3	*2	*2	*2	*2
(Sludge + reference substance)					
Sludge blank	No.1				
	No.2	*3	*3	*3	*3

*1: Need not be described when this is not conducted in the test equivalent to 301F

*2: Need not be described when this is conducted with 2 test vessels in the test equivalent to 301F

*3: Need not be described in the case of the test equivalent to 301C

<In the test equivalent to 301F, when confirming degradability at low concentrations for test substances that inhibit microorganisms>

Measurement date Test vessels	BOD (mg)				
		7th day	14th day	21st day	28th day
(Sludge + test substance)	No.1				
	No.2				
(Sludge + test substance + reference substance)					

<In the test equivalent to 301F, when using auxiliary substances for poorly water-soluble substances>

Measurement date Test vessels	BOD (mg)				
		7th day	14th day	21st day	28th day
(Sludge + test substance + auxiliary substance) Auxiliary substance () Auxiliary substance concentration ()	No.1				
	No.2				
(Sludge + reference substance + auxiliary substance) Auxiliary substance () Auxiliary substance concentration ()					
(Sludge + auxiliary substance) Auxiliary substance () Auxiliary substance concentration ()	No.1				
	No.2				

(3) Measurement results (value after 28 days)

Measurement item		(Sludge + test substance)			(Water + test substance)	Theoretical feed amount
		No.1	No.2	No.3		
BOD*1	mg			*3	*4	
DOC*1	mg			*3	*4	
Test substance residual amount and residual rate (Analytical instruments)	mg			*3	*4	
	%(i)			*3	*4	
Degradant amount and its formation rate*2 (Analytical instruments name)	mg	*2	*2	*2, *3	*2, *4	*2
	%(ii)	*2	*2	*2, *3	*2, *4	*2
Material balance ((i)+(ii))	%			*3	*4	

*1: (Sludge + test substance) value is calculated by subtracting the Sludge blank value.

*2: Fill in when any degradant is generated

*3: Need not be described when this is conducted with 2 test vessels in the test equivalent to 301F

*4: Need not be described when this is not conducted in the test equivalent to 301F

<In the test equivalent to 301F, when confirming degradability at low concentrations for test substances that inhibit microorganisms>

Measurement item		(Sludge + test substance)		(Sludge + test substance + reference substance)	Theoretical feed amount
		No.1	No.2		
BOD*1	mg				
DOC*1	mg				
Test substance residual amount and residual rate (Analytical instruments name)	mg				
	% (i)				
Degradant amount and its formation rate*2 (Analytical instruments name)	mg	*2	*2	*2	*2
	% (ii)	*2	*2	*2	
Material balance ((i)+(ii))	%				

*1: (Sludge + test substance) and (Sludge + test substance + reference substance) values are calculated by subtracting the Sludge blank value.

*2: Fill in when any degradant is generated

<In the test equivalent to 301F, when using auxiliary substances for poorly water-soluble substances>

Measurement item		(Sludge + test substance + auxiliary substance)		(Sludge + reference substance + auxiliary substance)	Theoretical feed amount
		No.1	No.2		
BOD*1	mg				
Test substance residual amount and residual rate (Analytical instruments name)	mg				
	% (i)				
Degradant amount and its formation rate*2 (Analytical instruments name)	mg	*2	*2	*2	*2
	% (ii)	*2	*2	*2	
Material balance ((i)+(ii))	%				

*1: (Sludge + test substance + auxiliary substance) and (Sludge + reference substance + auxiliary substance) values are calculated by subtracting the (Sludge + auxiliary substance) value.

*2: Fill in when any modified substance is generated

(4) Degree of Degradation

		(Sludge + test substance)			Average value
		No.1	No.2	No.3	
BOD degree of degradation	%			*1	
DOC degree of degradation	%			*1	
Test substance degree of degradation	%			*1	

*3: Need not be described when this is conducted with 2 test vessels in the test equivalent to 301F

<In the test equivalent to 301F, when confirming degradability at low concentrations for test substances that inhibit microorganisms>

		(Sludge + test substance)		Average value
		No.1	No.2	
BOD degree of degradation	%			
DOC degree of degradation	%			
Test substance degree of degradation	%			

<In the test equivalent to 301F, when using auxiliary substances for poorly water-soluble substances>

		(Sludge + test substance + auxiliary substance)		Average value
		No.1	No.2	
BOD degree of degradation	%			
Test substance degree of degradation	%			

4. Recovery rate (average values)

(Water + test substance) recovery rate	%	*1
(Sludge + test substance) recovery rate	%	

*1: Need not be described when this is not conducted in the test equivalent to 301F

<In the test equivalent to 301F, when confirming degradability at low concentrations for test substances that inhibit microorganisms>

(Sludge + test substance) recovery rate	%	
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<In the test equivalent to 301F, when using auxiliary substances for poorly water-soluble substances>

(Sludge + test substance + auxiliary substance) recovery rate	%	
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5. Considerations

<p>* To the extent possible, write down the considerations of the test results (degree of degradation of the test substance).</p> <p>* Describe the material balance etc., especially if any degradant is generated.</p> <p>* In the test equivalent to 301F, when checking the degradability at a low concentration for a test substance having an inhibitory effect on microorganisms, or when using an auxiliary substance for a poorly water-soluble substance, describe its validity and appropriateness.</p>

6. Others

Facility where the test was administered	Name	
	Location	TEL FAX
Study director	Title and name	
	Years of experience	
Test number		
Test period	From YYYY/MM/DD to YYYY/MM/DD	

[Remarks]

1. Fill in this form by copying from the final written report.
2. Fill in the same test number as the final written report.
3. The person responsible for preparing this form shall write down his department and name outside the column of this form.

[Form 3]

The octanol-water partition coefficient test report

1. General matters

Name of the new chemical substances (In accordance with IUPAC nomenclature)			
Synonym			
CAS Number			
Structural formula or rational formula (When both are not known, outline of the production method)			
Molecular weight			
Purity of the new chemical substance used in the test (%)			
Lot number of the new chemical substance used in the test			
Name and percentage content impurity			
Vapor pressure			
Solubility in water			
1-octanol/water partition coefficient			
Melting point			
Boiling point			
Properties at normal temperature			
Stability			
Solubility etc. in solvent	Solvent	Solubility	Stability in solvent

[Remarks] Write down the physical and chemical properties as much as possible.

1. In the "Vapor pressure" column, write down the vapor pressure of the test substance.
2. In the "Stability" column, write down stability with respect to temperature, light, etc.
3. In the "Solubility etc. in solvent" column, write down the solubility of the test substance in the solvent and its stability in the solvent.

2. Test method etc.

Test method	Method provided for in OECD Test Guideline 107	Method provided for in OECD Test Guideline 117
Dissociation Constants in Water	pKa ₁ = pKa ₂ =	pKa ₁ = pKa ₂ =
Acid or base		
Temperature (°C)		
Name and composition of eluant		

[Remarks] In the "Name and composition of eluant" column, fill in the buffer type and pH if buffer is used.

3. Test results

3-1 Method provided for in the OECD Test Guideline 107

(1) Partition coefficient measurement results

		Pow=Co/Cw				log Pow				
		Measurement value	Average value	Average value	Standard deviation	Measurement value	Average value	Average value	Standard deviation	Maximum difference
Measurement condition-1	a									
	b									
Measurement condition-2	a									
	b									
Measurement condition-3	a									
	b									

(2) pH measurement result of water layer

		Measurement value	
			Average value
Water used			
Measurement condition-1	a		
	b		
Measurement condition-2	a		
	b		
Measurement condition-3	a		
	b		

3-2 Method provided for in OECD Test Guideline 117

(1) Measurement results

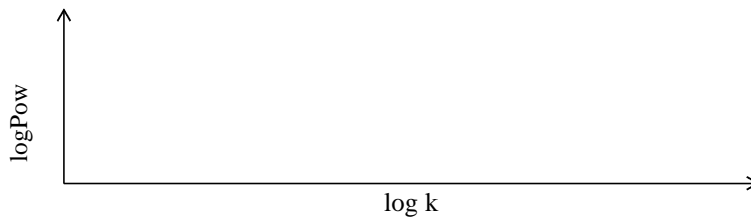
	Name of the measured substance	t _R	k	logk	logPow
Standard substance	(For dead time measurement: t ₀)		—	—	—
			—	—	
Test substance					

t₀: Dead time (min)

t_R: Retention time (min)

k (Retention coefficient) = (t_R-t₀) / t₀

(2) Correlation diagram and regression formula (including correlation coefficient)



[Remarks] Plot regarding standard substance and test substance.

(3) Partition coefficient of test substance

logPow	
Measured value	Average value

4. Considerations

5. Others

Facility where the test was administered	Name	
	Location	TEL FAX
Study director	Title and name	
	Years of experience	
Test number		
Test period	From YYYY/MM/DD to YYYY/MM/DD	

[Remarks]

1. Fill in this form by copying from the final written report.
2. Fill in the same test number as the final written report.
3. The person responsible for preparing this form shall write down his department and name outside the column of this form.