

Other data and information to be attached to the application for Registration of an Agricultural Chemical

(The Notification, Ref.No.13-Seisan-3987, issued on 10 January 2002 by the Director General, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan)

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Partly revision: Ref.No.16-Shouan-9262, issued on 16 March, 2005

Partly revision: Ref.No.18-Shouan-14853, issued on 2 April, 2007

The latest revision: Ref.No.26-Shouan-535, issued on 15 May, 2014

I. Regarding data and documents on test of agricultural chemicals that are to be attached to the Agricultural Chemical Registration Application

1. Regarding data on test of agricultural chemicals that are to be attached to the Agricultural Chemical Registration Application
 - (1) According to Article 2, Paragraph 2 (and cases to which Article 15.2, Paragraph 6 apply) of the Agricultural Chemicals Regulation Law (Law No. 82, 1948; hereinafter referred to as “Law”), a party (hereinafter referred to as “the applicant”) applying for registration of agricultural chemicals (except for products that have natural enemies and/or microorganisms as their active ingredients; same below) must submit the following data as attachments to the Agricultural Chemical Registration Application.
 - 1) Data on the physical and chemical properties of the agricultural chemical
 - 2) Data on the storage stability of the agricultural chemical
 - 3) Data on the composition of and method of manufacturing the agricultural chemical (formulation) and its technical grade active ingredient (TGAI)
 - 4) Data on tests for dioxins in the agricultural chemical
 - 5) Data on tests for harmful contaminants other than dioxins in the agricultural chemical
 - 6) Data on concerning Predicted Environmental Concentration for short-term risk assessment on aquatic organisms
 - 7) Data on concerning Predicted Environmental Concentration for long-term risk assessment on human health
 - (2) The methods of implementing tests in regard to (1) 1) and 2) are to be as stipulated in the annex1 entitled “Guide to Implementation of tests in Regard to the Physical and Chemical Properties of Agricultural Chemicals, and their Storage Stability”.
 - (3) The analyses and/or tests in connection with preparation of the data referred to in (1) 3)-5)(limited to those related to analyses of the composition of components, in the case of 3)) are to be implemented in test facilities that comply with GLP standards for agricultural chemicals, in accordance with “Notification on the Good Laboratory Practice (GLP) Standards for Agricultural Chemicals” (notification issued by The Director-General, Agricultural Production Bureau, Ministry of Agriculture, Forestry, and Fisheries of Japan, 11-Nousan-No. 6283, dated October 1, 1999, hereinafter referred to as “GLP standards”). In such cases, the relevant analyses and tests

are to be regarded as analyses and tests within the scope of tests (the scope of tests concerning physical and chemical properties) referred to in section 2(3) of that document, as regards GLP standards.

(4) Regardless of (3), the analyses and tests concerning the data referred to in 4) may be implemented in the following test facilities, which have been approved for administration equivalent to that of test facilities that comply with GLP standards for agricultural chemicals.

- 1) Test facilities that comply with OECD GLP standards, or that comply with GLP standards equivalent to these.
- 2) Institutions that have been approved by their national governments as having sufficient capabilities as regards analysis of dioxins.

(5) The materials stated in Item 6) of (1) above shall be created by using a method specified in the annex2 entitled “Derivation of Predicted Environmental Concentration for short-term risk assessment on aquatic organisms”

(6) The materials stated in Item 7) of (1) above shall be created by using a method specified in the annex3 entitled “Derivation of Predicted Environmental Concentration for long-term risk assessment on human health”

2. Regarding documents on test of agricultural chemicals that are to be attached to the Agricultural Chemical Registration Application

The documents stipulated in the appendix table must be attached to applications or claims as stipulated in Article 1, Article 4.2, Article 5 Paragraph 1, Article 12, and Article 15 of the Enforcement Regulations of the Agricultural Chemicals Regulation Law (Ministry of Agriculture, Forestry, and Fisheries Ordinance No. 21, 1951; hereinafter referred to as “Enforcement Regulation”).

II. Regarding samples of agricultural chemicals

1. According to the stipulations in Article 2 Paragraph 2 of the Law (including cases to which Article 15.2 Paragraph 6 apply), the applicant must submit samples of the TGAI of the agricultural chemical, and samples of the active ingredients in their pure state, together with the sample of the agricultural chemical concerned in the application.

2. Data in regard to test of samples of the agricultural chemical must be attached to the Agricultural Chemical Registration Application Sample Test Report, in accordance with the Enforcement Regulation.

III. Regarding the submission of data and documents

Regarding the submission of data and documents listed in I and II.2, the applicant shall submit a list of the individual data and documents submitted, comprehensive summaries and assessments of individual data and documents, and a completed form for the checking of dossiers for completeness, together with the individual data and documents. Necessary matters for the submission of these data and documents shall be provided for separately by the Director of Plant Products Safety Division of the Food Safety and Consumer Affairs Bureau.

IV. Regarding exceptions from submission of data

In cases in which there is reasonable reason to regard as unnecessary the submission of data referred to in I. and II.2 above, the applicant may submit a document stating said reason instead of said data.

V. Regarding alternatives to data, etc. to be attached to the Agricultural Chemical Registration Application

In cases in which data referred to in I.1 have already been submitted in connection with another application for registration, and these data have been approved for use as agricultural chemical data in connection with said application, the applicant may submit a Data Alternative Document as a separate form instead of said data.

If the party who submitted the data which the applicant wishes to use is a different party from the applicant, the applicant must submit documents stating that it has been confirmed that the party who submitted the data that the applicant wishes to use has no objections to their use.

In cases in which documents, referred to in I.2, and/or samples of the TGAI of the agricultural chemical and samples of the active ingredients in their pure state, referred to in II.1 (referred to in IV as “documents, etc.”), have already been submitted in connection with another application for registration, and these data have been approved for use as agricultural chemical data in connection with said application, the applicant may omit submission of said documents, etc.

VI. Regarding requests for additional data, etc.

In cases in which it is deemed necessary, on the basis of registration inspections conducted in accordance with Article 2 Paragraph 3 of the Law, the Director-General of the Agricultural Production Bureau may request that the applicant submit necessary data, etc. regarding the agricultural chemical concerned in the application.

Supplementary Provisions

The stipulations in this notification apply to the following:

- (1) This notification applies to registration applications received beginning 10 February 2002.

However, this does apply to agricultural chemicals that are already registered, or to TGAI that are the same as agricultural chemicals that have been registered.

- (2) The stipulations in I.[1](3) apply to analyses and tests in connection with preparation of data commencing on or after 10 January 2003.
- (3) Data stated in Item 6) of I.1 apply to any application for registration of agricultural chemicals from 1 April 2005.
- (4) Data stated in Item 7) of I.1 apply to any application for registration of agricultural chemicals from 3 August 2006.

Supplementary Provisions (May 15, 2014)

1. The amendments in accordance with this notification shall apply to an application for registration of an agricultural chemical made on and after May 15, 2014.
2. Notwithstanding the provisions of the preceding paragraph, with regard to the data and documents pertaining to an application for registration of an agricultural chemical which is made before the day on which one year has elapsed from the effective date, or the data and documents pertaining to an application for registration of an agricultural chemical which contains the same active ingredient as the existing registered agricultural chemical for which the data and documents had been submitted pursuant to the provisions of the notification prior to the revision by this notification, the applicant may submit all or part of the data and documents in accordance with the provisions then in force, as specified separately by the Director of Plant Products Safety Division of the Food Safety and Consumer Affairs Bureau.

Appendix Table

| Type of claim or application | Grounds (Ministerial Ordinance) | Attached Documents |
|--|------------------------------------|--|
| Agricultural Chemical Registration Application | Article 1 (Form No. 1) | <ul style="list-style-type: none"> a. Certified copy of registry (for corporations) b. In the case of registration per Article 15.2 Paragraph 1 of the Law, documents, such as a business consignment contract, proving that [the applicant] has been appointed domestic manager by a registered overseas manufacturer |
| Claim for transfer of position due to inheritance, merger, severance, or transfer or business, and applications for renewal (issuance) of Agricultural Chemical Registration Certificate | Article 4.2 (Form No. 2.3) | <ul style="list-style-type: none"> a. Certified copy of registry (for corporations) b. Documents that can be used as proof that position has been transferred |
| Claim for change in items recorded in the Agricultural Chemical Registration Certificate | Article 5 Paragraph 1 (Form No. 4) | Certified copy of registry (limited to cases of changes in articles referred to in Article 2 Paragraph 2 No. 1 of the Law) |
| Claim for change in domestic management | Article 12 (Form No. 10) | Documents, such as a business consignment contract, proving that [the applicant] has been appointed domestic manager by a registered overseas manufacturer. |
| Claim for importation (change, discontinuation) of agricultural chemicals manufactured overseas | Article 15 (Form No. 12) | <ul style="list-style-type: none"> a. Certified copy of registry (for corporations) b. Copy of import contract, etc. |

(Separate form)

| |
|---|
| <p>Data Alternative Document</p> <p style="text-align: right;">Year Month Date</p> <p>To: The Minister of Agriculture, Forestry, and Fisheries of Japan</p> <p style="text-align: center;">Address: Name: (For corporations, corporate name and name of representative) Seal</p> <p>I am applying for an alternative to data to be provided in connection with an Agricultural Chemical Registration Application, in accordance with the Stipulation V in “Other data and information to be attached to the application for Registration of an Agricultural Chemical” (The Notification, Ref.No.13-Seisan-3987, issued on 10 January 2002 by the Director General, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan), as indicated below.</p> <p style="text-align: center;">To wit:</p> <ol style="list-style-type: none">1. Type and name of agricultural chemical (in the case of registered agricultural chemicals , enter the registration number)2. Description of the data to be used as an alternative, and the type and name of the agricultural chemical concerned in the data to be used (in the case of agricultural chemicals that are already registered, enter the registration number) |
|---|

(Japanese Industry Standard A4)

Note: If you sign your name (the name of a representative, in the case of a corporation), your personal seal may be omitted.

(Annex1)

Guide to Implementation of Tests in Regard to the Physical and Chemical Properties of Agricultural Chemicals, and their Storage Stability

| Item | Page |
|--|------|
| I. Basic matters..... | 8 |
| 1. Basic approach | |
| 2. Regarding tested substances | |
| 3. Objectives | |
| II. Tests in regard to the physical and chemical properties of agricultural chemicals..... | 8 |
| 1. Methods of measuring fineness, apparent specific gravity, suspensibility, wettability, pH, and stability of undiluted and diluted solution..... | 8 |
| 2. Methods of measuring particle size and angle of repose..... | 9 |
| 3. Method of determining color..... | 9 |
| 4. Method of determining drift index..... | 10 |
| 5. Methods of measuring average particle diameter and content of particles ≤ 0.01 mm (Andreasen pipette method)..... | 13 |
| 6. Method of measuring flowability..... | 15 |
| 7. Method of measuring moisture content..... | 16 |
| 8. Method of measuring friability..... | 16 |
| 9. Method of measuring friability in water..... | 16 |
| 10. Method of measuring dispersibility in water..... | 17 |
| 11. Method of measuring flame extension..... | 17 |
| 12. Methods of determining other test items..... | 17 |
| III. Tests in regard to storage stability of agricultural chemicals..... | 17 |
| ○ Appended Table 1 : General color names of agricultural chemical formulations, and indicators based on three attributes..... | 19 |
| ○ Appended Table 2 : Chemical composition, etc. of standard powder..... | 20 |
| ○ Appended Table 3 : Specifications of working standard powder..... | 20 |
| ○ Appended Figure 1 : Device for determining drift index..... | 21 |
| ○ Appended Figure 2 : Device for measuring internal pressure..... | 22 |
| ○ Appended Figure 3 : Graph showing the relationship between powder concentration and drift index..... | 22 |
| ○ Appended Figure 4 : Schematic diagram of a device for measuring flowability..... | 23 |

< I. Basic matters >

1. Basic approach

- (1) This guide is to be used as a yardstick when conducting tests as to the physical and chemical properties of formulations, and the storage stability of agricultural chemicals, for submission in connection with registration applications for agricultural chemicals.
- (2) We are not asking that persons conducting tests strictly adhere to this guide. Moreover, this guide need not preclude persons conducting tests from making changes in test methods for the purpose of more accurately achieving test objectives in accordance with the properties of the substances to be tested.
- (3) Results obtained by lawful methods (CIPAC method, JIS method) other than those described herein may also be used if they are equivalent or superior to those obtained using the following guidelines.

2. Regarding tested substances

The test substances are formulations. The formulations used must be the equivalent of agricultural chemical samples.

3. Objectives

The objectives of the tests described below are to confirm the effectiveness, uniformity, distribution performance, etc. of products by obtaining data on their physical and chemical properties, as well as on the temporal changes, etc. in the physical and chemical properties of their active ingredients.

< II. Tests in regard to the physical and chemical properties of agricultural chemicals >

1. Methods of measuring fineness, apparent specific gravity, suspensibility, wettability, pH, and stability of undiluted and diluted solution

- (1) Measurements are to be made according to the methods stipulated in “Physical Test Methods” (Notification No. 71 of the Ministry of Agriculture, Forestry, and Fisheries, February 3, 1960).
- (2) The amount of sample fine dust formulation in measurement of fineness will be 10 g.
- (3) The test methods concerned in Section 6, “Stability of Emulsion Undiluted Solution” in “Physical Test Methods” also apply to measurements of the stability of undiluted

solutions with respect to liquid formulations such as water-dispersible powder, soluble concentrate, oil solutions, ultra low volume liquid, machine oils, and spreaders.

2. Methods of measuring particle size and angle of repose

Measurements are to be made according to the methods stipulated in “Method of Inspecting Agricultural Chemicals on the basis of Article 14 Paragraph 2 of the Agricultural Chemicals Regulation Law” (Notification No. 750 of the Ministry of Agriculture, Forestry, and Fisheries, July 25, 1975).

3. Method of determining color

(1) Objective

The objective is to determine the color of agricultural chemical formulations.

(2) Method of determination

As a rule, determinations are to be made as follows, based on JIS-Z-8723-1975, “Method of Comparing Surface Color”.

1) Standard plane

Use “Standard Color Chart Conforming with JIS-Z-8721”, issued by the Japanese Standards Association, as a standard color chart for display symbols based on three attributes in Appended Table 1, “General color names of agricultural chemical formulations, and display symbols based on three attributes” when performing tests.

2) Natural illumination

Natural lighting (from 3 hours after sunrise until 3 hours prior to sunset), while avoiding direct sunlight.

3) Method of collecting samples

Collect 1 g of solid sample on white paper or a watch glass that is on white paper. Collect liquid sample in a colorless test tube with an inside diameter of 15 mm, so that the solution layer is 30 mm.

4) Observation

Observations should be made under natural illumination per 2). Make a sample plane with solid sample by making it level. Make comparative observations and determinations by placing the sample plane and the standard plane side-by-side, so that comparison is as easy as possible, and looking from left to right and right to left repeatedly. When using a mask (achromatic color, with apertures, placed over the surface of the sample plane and test plane) its brightness of color should be close to, but lower than, that of the sample plane.

Determinations in regard to liquid samples should be made by visually comparing them to the standard plane against white paper as a background.

(3) Method of indication

Colors are to be displayed as follows. Products to which provisions for color

labeling stipulated in Article 13 of the Law for Control of Poisonous and Powerful Agents (Law No. 303, 1950) apply are to be handled in accordance with those provisions.

1) In general, the color of an agricultural chemical preparation is to be determined in accordance with “Names of Colors” in JIS-Z-8102-1967. The basic color names are red, yellow-red, yellow, yellow-green, green, blue-green, blue, purple-blue, purple, and red-purple. The achromatic colors are white, gray, and black. Nearly white, comprising chromatic and achromatic colors, and brown, comprising chromatic colors, may also be used.

The modifiers to be used in reference to brightness and saturation are light and dark.

General color names and representative indicators based on three attributes are as shown in the appended table.

2) Color indicators that are specific to agricultural chemical formulations are nearly white and brown. Nearly white is a color that closely resembles white, and all hues have brightness 9, saturation 1 or 2 and brightness 8, saturation 1. Brown resembles yellow-red, but on the whole it is a color of low brightness and saturation. Expressions such as yellow-brown and red-brown that are not shown in the appended table are not to be used. Light gray, gray, and dark gray have a brightness of 7 or 6, 5 or 4, and 3 or 2, respectively, and saturation of 0 or 1. There are no colors such as white and nearly white that derive from reflected light for solution-like agricultural chemical preparations, such as emulsifiable concentrate and actual soluble concentrate, but such terms are used for suspensions of particles, such as sols.

4. Method of determining drift index

(1) Objective

The objective of these tests is to determine drift index, which is a yardstick of how readily powdered material drifts.

(2) Device

1) Device for determining drift index

The structure of the device for determining drift index is in Appended Figure 1, and includes the following:

a. Dust tester

The model NDT-3 dust tester, manufactured by Kioritz Corporation, or a model with equivalent performance.

b. Impinger dust counter

The model IP-62 impinger manufactured by Shibata Chemical and Machinery Co., Ltd., or a model with equivalent performance.

c. Dust box

Adjust the internal pressure ^(Note 1) applied to the dust box so that it gives a water column of 2 ± 1 mm as measured at the impinger’s dust collection tube

opening. Adjusting the internal pressure involves increasing or decreasing, as appropriate, the area (Note 2) of the opening of the exhaust outlet, to which gauze (8 layers of Japanese Pharmacopoeia gauze (Type I)) is affixed.

2) Spectrophotometer

(3) Methods of operation and computation

1) Operation

a. Preparation

Assemble the device, put 75 ml of water in the impinger dust collection tube (Note 3), and mount it on the dust collection box as shown in Appended Figure 1.

b. Dusting

Open the open/close valve lever on the hopper, start idling the dust tester, and after 10 seconds temporarily add 10.0 g (Note 4) of the sample, which has been gathered in wrapping paper, and close the valve. Continue to run the dust tester for 30 seconds after adding the sample, and perform dusting. After dusting, let the apparatus stand as it is for 5 minutes.

c. Uptake

Using the impinger dust counter, uptake power particles that are suspended in the water in the dust box's impinger dust collection tube by implementing suction for 1 minute at a flow rate of 30 L per minute.

d. Absorbency Measurement

Shake well (Note 5) the suspension in the impinger dust collection tube, and remove it to a 100 ml ground stoppered Erlenmeyer flask. Add 1 ml of 6% sodium dodecyl benzene sulfonate solution (Note 6), and disperse the particles sufficiently by shaking well. Measure the absorbency of the suspension with a phase length of 1 cm and a wavelength of 610 nm. Measurements should be taken within a range of 30-120 minutes after completion of uptake.

2) Computing the drift index

a. Convert the drift index (A) of the working standard powder into absorbency (B), using the following formula.

$$\text{Absorbency (B)} = -\log \left(\frac{100 - \text{drift index (A)}}{100} \right)$$

b. Using samples of the working standard powder, repeat operation 1) 3 times, computing absorbency each time; obtain the average absorbency (C), and compute the correction factor (D) for the measuring device by means of the following formula.

$$\text{Correction factor (D)} = \frac{\text{Absorbency (B)}}{\text{Average value (C)}}$$

c. In the same way, measure the absorbency (E) of the test powder, and compute the corrected absorbency of said test powder by means of the following

formula.

$$\text{Corrected absorbency} = \text{Test powder absorbency (E)} \times \text{correction factor}$$

- d. Convert the corrected absorbency from c above into transmissivity (%), and compute the suspension index of the test powder by means of the following formula.

$$\text{Suspension index} = 100 - \text{transmissivity (\%)}$$

NOTES1: Use the device shown in Appended Figure 2 for measuring the internal pressure applied to the dust box. Tightly plug the impinger's dust collection tube opening with a rubber stopper, as shown in the diagram, and idle the dust tester. Measure the internal pressure applied to the dust box, using a U-shaped glass tube as a container.

- 2: The gauze is applied from the inside of the dust box, with 10 cm x 10 cm as a yardstick for the area of the opening of the exhaust outlet.
- 3: Set the spray strip inside the impinger dust collection tube at 175.
- 4: Prepare samples by measuring out 100 g each of working standard powder and test powder into 250 ml wide-mouth polyethylene bottles and placing them overnight in a desiccator at a constant temperature of 25° C. Place the samples carefully in the hopper so that they do not blow away.
- 5: Wash the particles that adhere to the upper opening of the impinger's dust collection tube back into the tube by stoppering the upper opening with a finger and shaking the tube by turning it upside-down several times.
- 6: 6% sodium dodecyl benzene sulfonate solution: Dissolve 6.0 g of sodium dodecyl benzene sulfonate (first class reagent) in water, for a total volume of 100 ml.
- 7: 0.08% sodium dodecyl benzene sulfonate solution: Add 1 ml of 6% sodium dodecyl benzene sulfonate solution in 75 ml of distilled water.

(4) Determining the suspension index of the fine dust formulation

Determine the suspension index of the fine dust formulation according to the following directions, in addition to the method described above.

1) Plotting calibration curves

a. Calibration curves for test samples

Accurately measure out 10, 20, 30, 40, and 50 mg of test sample, and add them to ground stoppered 100 ml Erlenmeyer flasks with 75 ml of distilled water each. Add 1 ml of 6% sodium dodecyl benzene sulfonate solution with a whole pipette, and separate the particles by shaking lightly. Measure the absorbency of these suspensions with a phase length of 1 cm and a wavelength of 610 nm, with 0.08% sodium dodecyl benzene sulfonate solution as the contrast solution. Plot the calibration curves with sample density (mg/76 ml) on the x-axis, and absorbency on the y-axis.

b. Calibration curves for standard powder

Accurately measure out 5, 10, 15, 20, 25, 50, and 100 mg of test sample, and add them to separate stoppered 100 ml Erlenmeyer flasks with 75 ml of distilled water each. Add 1 ml of 6% sodium dodecyl benzene sulfonate solution with a whole pipette, and separate the particles by shaking lightly. Compute the drift indices (100 - transmissivity) of these suspensions with a phase length of 1 cm and a wavelength of 610 nm, with 0.08% sodium dodecyl benzene sulfonate solution as the contrast solution. Plot the calibration curves with sample density (mg/76 ml) on the x-axis, and suspension index on the y-axis (Appended Figure 3).

2) Method of determining suspension index: (3) 1)b. Dusting

Open the open/close valve lever on the hopper, start idling the dust tester, and after 10 seconds add 5.0 g of the sample, which has been gathered in wrapping paper, for 20 seconds, and close the valve. Continue to run the dust tester for 10 seconds after adding the sample, and perform dusting. After dusting, let the apparatus stand as it is for 5 minutes.

3) Method of computing drift index

Obtain the uptake sample concentration, using the calibration curves for the tests samples, based on the values obtained by the method of determining suspension index in (3) 1)d. Multiply this value by 2, and obtain the suspension index, using calibration curves for the standard powder.

4) Standard powder

Use finely powdered kaoline composed of grains with an average diameter of approximately 0.002 mm, for which a curve has been obtained that is the same as the calibration curve shown in Appended Figure 3, plotted according to 1) above.

(5) Definitions

1) Drift index: Determined on the basis of the suspension index for the standard powder, this is a unit of measure expressing the degree of drifting and scattering of powdered material.

2) Standard powder: A standard for Type 2 dust stipulated in Japanese Industrial Standard No. Z8901, used to stipulate the suspension index of working standard powder. The chemical composition, etc. of the standard powder are shown in Appended Table 2.

3) Working standard powder: This is pyrophyllite that has been specified by the Ministry of Agriculture, Forestry, and Fisheries of Japan as the standard for use in determining the suspension index of powdered material. Standard powdered materials are to be sealed in containers and stored in a desiccator.

5. Methods of measuring average particle diameter and content of particles ≤ 0.01 mm (Andreasen pipette method)

(1) Objective

The objective of this test is to measure average particle diameter and content of particles ≤ 0.01 mm.

(2) Operational and computational methods

- 1) Approximately 5 g of the sample is weighed out, and placed in a 500 ml beaker. Approximately 300 ml of dispersion medium is added, and secondary cohesion is completely dispersed by agitation with a stirrer. Next, wash the suspension in the beaker into a tube settler, add dispersion medium to 2 mm below the reference line, insert a pipette, and add dispersion medium up to the reference line.

Remove Andreasen pipettes that have been completely prepared from the thermostat set at 20° C, and disperse the material within them by shaking them vigorously from right to left while they are in a horizontal position, occasionally turning them upside-down. Finally, shake them repeatedly while they are upside-down (shaking time, approximately 2-3 minutes). After shaking is completed, place the pipettes in the thermostat immediately. At the same time, start running the stopwatch, and take fractions in evaporating dishes at fixed time intervals.

After the fractions of the suspension have been dried over a water bath, they are further dried for 2 hours in an incubator at 105° C. After drying is complete, they are left to cool in a desiccator for 30 minutes, and then weighed.

The true specific gravity of the samples is also determined, using the pycnometer method.

2) Method of computing average particle diameter

Multiply the central particle diameter in each fraction by the particle distribution (%), and divide by 100 to obtain the cumulative average particle diameter as the average particle diameter.

When using a particle size distribution measuring device, etc. confirm the correlation with the present method before proceeding.

Use Formula 1 to obtain the central particle diameter for each fraction, Formula 2 to obtain the particle distribution (%), and Formula 3 to obtain the average particle diameter.

Determine the true specific gravity of the samples by means of the pycnometer method, and use Formula 1 to compute the relationship between particle diameter and fraction time.

$$t = \frac{h}{v} = 18 \frac{qh}{(p - p_0)g} \times \frac{1}{d^2} \quad \dots\dots \text{Formula 1}$$

q : Coefficient of viscosity of the dispersion medium (0.2% Neogen powder solution = 0.01031)

h : Distance from the liquid surface to the sampling position

p : True specific gravity of the sample

p₀ : True specific gravity of water

g : Acceleration of gravity

d : Diameter of sediment particles (cm) ... central diameter

t : fraction time (seconds)

<Example> Dispersing agent: 0.2% Neogen powder solution, 20° C

| | True Specific Gravity = 1.85 | | | True Specific Gravity = 2.64 | | | True Specific Gravity = 2.71 | | |
|-------|------------------------------|---------|---------|------------------------------|---------|---------|------------------------------|---------|---------|
| | Fraction Time | | | Fraction Time | | | Fraction Time | | |
| | Hours | Minutes | Seconds | Hours | Minutes | Seconds | Hours | Minutes | Seconds |
| 50 μm | | 2' | 58" | | 1' | 32" | | 1' | 28" |
| 40 | | 4' | 31" | | 2' | 20" | | 2' | 14" |
| 30 | | 7' | 50" | | 4' | 03" | | 3' | 53" |
| 20 | | 17' | 10" | | 8' | 53" | | 8' | 32" |
| 10 | 1: | 06' | 52" | | 34' | 36" | | 33' | 12" |
| 5 | 4: | 20' | 03" | 2: | 14' | 33" | 2: | 09' | 03" |

Particle distribution (%) of each fraction = $(W_1 - W_2) \times K \times 100$ Formula 2

$$K = \frac{550}{\text{amount sampled} \times 10}$$

550 : Content volume up to the reference line of the tube settler (ml)

10 : Suspension fraction amount (ml)

W_1 : Gross weight after fraction drying

W_2 : Weight after fraction dispersion medium drying (Neogen powder)

Average particle diameter = $\Sigma \left(\frac{\text{central particle diameter} \times \text{particle distribution} (\%)}{100} \right)$ Formula 3

3) Method of measuring content of particles ≤ 0.01 mm

Use the Andreasen pipette method to compute the content of particles ≤ 0.01 mm from the particle distribution obtained by the particle distribution measurement method.

When using a particle size distribution measuring device, etc. confirm the correlation with the present method before proceeding.

6. Method of measuring flowability

(1) Objective

The objective is to measure flowability, in order to obtain physical properties that coincide with the discharge characteristics of the duster. Vibration is applied to powdered material by means of a vibrator, and the material drops from the device's meshes. Flowability is measured according to the time it takes the material to drop.

(2) Device (See Appended Figure 4.)

(3) Operation

In order to standardize measurement conditions, put 50 grams of standard sample (talc, dispersion index 35, estimated specific gravity 0.44) into the mesh-equipped cylinder. After 10 g has dropped, adjust the vibration strength so that it takes 30 ± 1 seconds for 20 g to drop.

Under the same conditions, measure the amount of time that it takes 20 g of the sample to drop (stir gently 10-15 times with a spatula).

7. Method of measuring moisture

(1) Objective

The objective is to measure moisture content, as basic information concerning the formulation.

(2) Operational and computational methods

Accurately weigh out approximately 2 g of the sample into a flat type weighing bottle (JISR3625), equipped with a lid, and with a diameter of 40-50 mm, and spread the sample in a thin layer. Open the lid on a slant, and place the bottle in a desiccator from the inside of which moisture has been removed.

After the weighing bottle has cooled in the desiccator for 20 minutes with its lid open, weigh it, and compute the percentage loss on drying. Conditions: drying temperature $105 \pm 2^\circ \text{C}$, drying time 1 hour, or drying temperature $50 \pm 2^\circ \text{C}$, drying time 3 hours.

(NOTE) Use calcium chloride as the desiccant.

8. Method of measuring friability

(1) Objective

The objective is to measure the stability of granular particles.

(2) Operation

Perform sieving for 10 minutes and 20 minutes according to a method based on the particle size measurement method, and compare the difference in particle size distribution after 10 versus 20 minutes of sieving. Use 4 sieve types, with sieve openings of 1700 μm (10 mesh), 300 μm (48 mesh), 105 μm (150 mesh), and 45 μm (300 mesh).

9. Method of measuring friability in water

(1) Objective

The objective is to measure the collapsibility of particles in water, in order to obtain information on the performance and quality of granules used in rice paddies.

(2) Operation

Place 50 ml of water (with water hardness of 3*) in a glass petri dish with a diameter of 9 cm, and allow it to stand. Add 5 roughly uniform grains of the test granules. Measure the time, beginning immediately after addition of the granules,

until the test granules no longer maintain their original shape.

* Method of preparing water of with a water hardness of 3 degrees: After dissolving 0.3077 g of calcium carbonate and 0.092 g of magnesium oxide in a small amount of diluted hydrochloric acid, remove the hydrochloric acid by evaporating to dryness over a sand bath, and dilute in 1 L of water. Dilute this water 10 times when using, since it has a hardness of 30 degrees.

10. Method of measuring dispersibility in water

(1) Objective

The objective is to measure the formulation's dispersibility in water, in order to obtain information on its performance and quality.

(2) Operational and computational methods

Mix and disperse the sample by stirring well with a spoon, etc. Place 20 g of the sample in a 200 ml beaker with 200 ml of water (Note). After it is completely hydrated, stir it counterclockwise 10 times with a stick. After the water has nearly stopped moving, stir it clockwise 10 times, and then pour out the contents immediately into a 355 μm sieve. If there is any remnant in the beaker, flush it out into the sieve with a small amount of water, using a wash bottle. If the water stops running out of the bottom of the sieve, transfer the contents to a beaker with a small amount of water, and weigh after exsiccating over a water bath until most of the water has been removed, and then drying at 105° C.

$$\text{Dispersion ratio} = (20 - \text{residue}) / 20 \times 100$$

(Note) Use water with a hardness of 3 degrees.

11. Method of measuring flame extension

Use the method stipulated in the High Pressure Gas Control Law.

12. Methods of determining other test items

Select and implement methods that are appropriate for achieving the objectives of the tests. Include summaries of these methods in the report on test results.

< III. Tests in regard to storage stability of agricultural chemicals >

1. Objective

The objective of this test is to obtain information regarding such matters as temporal attenuation in active ingredient content and changes in the physical and chemical properties of agricultural chemicals.

2. Test Method

(1) Temperature

As a rule, test at room temperature. However, formulations regarding which it is deemed possible, on the basis of past test data and reference literature, to obtain results by means of severe tests that are the same as those of tests performed at room temperature, may be tested according to said severe tests. Severe tests at a constant temperature of 40° C are among the tests that may be substituted for tests at room temperature.

(2) Test period

This should be a period that, at the very least, falls between the manufacture date of the agricultural chemical, and the final effective month and date as displayed on the label. Note that severe tests conducted for 1 month at a constant temperature of 40° C shall be considered the same as tests conducted at room temperature for 1 year.

(3) Test containers

These should be made of materials of the quality that is used when said agricultural chemicals are sold. However, when various kinds of containers and packaging are used for said agricultural chemical, select those that are thought to be greatly affected by temporal changes in agricultural chemicals.

3. Observations, etc.

Implement the following observations, etc. temporally.

- (1) Quantitative analysis of active ingredients
- (2) Computation of the decomposition rate of active ingredients
- (3) Observation of physical and chemical properties of a formulation, such as its outer appearance (color, outer appearance, state, re-dispersibility)
- (4) Observation of the condition of the container

(Appendix Table 1) General color names of agricultural chemical formulations, and indicators based on 3 color parameters

| Hue name | General color name | Indicators based on 3 color parameters | Hue name | General color name | Indicators based on 3 color parameters |
|---------------------|--------------------|--|--------------------|--------------------|--|
| Red, 5R | Light red | 5R 6/7 | Purple-blue, 10PB | Light Purple-blue | 10PB 6.5/7 |
| | Red | " 4/12 | | Purple-blue | " 3/11 |
| | Dark red | " 2.5/6 | | Purple-blue | " 2.5/5 |
| Yellow-red, 5YR | Light yellow-red | 5YR 8/7 | Violet, 5P | Light purple | 5P 7/7 |
| | Yellow-red | " 6/12 | | Purple | " 3/12 |
| | Dark yellow-red | " 4/7 | | Dark purple | " 2/6 |
| Yellow, 5Y | Light yellow | 5Y 9/7 | Red-purple, 2.5 RP | Light red-purple | 2.5RP 7/7 |
| | Yellow | " 8/12 | | Red-purple | " 3.5/11 |
| | Dark yellow | " 5.5/6 | | Dark red-purple | " 2.5/6 |
| Yellow-Green, 2.5GY | Light yellow-green | 2.5GY 8.5/6 | Achromatic colors | White | N9.5, N9 |
| | Yellow-green | " 7/10 | | Light gray | N7, N6 |
| | Dark yellow-green | " 4/5 | | Grey | N5, N4 |
| Green, 2.5G | Light green | 2.5G 7/6 | Black | Dark gray | N3, N2 |
| | Green | " 5/9 | | N1.5, N1 | |
| | Dark green | " 3.5 | | | |
| Blue-green, 2.5BG | Light blue-green | 2.5BG 7/6 | Nearly white | Nearly white | 9/1, 9/2, N8, 8/1 |
| | Blue-green | " 4.5/8 | Brown, 5YR | Light brown | 5YR 7/2 |
| | Dark blue-green | " 3/5 | | Brown | " 5/2 |
| Blue 2.5PB | Light blue | 2.5PB 6.5/7 | | Dark brown | " 3/2 |
| | Blue | " 4/10 | | | |
| | Dark blue | " 2.5/5 | | | |

Note: Substances that do not have hue or brightness based on 3 color parameters, such as clear liquids (e.g., water) and transparent solids (e.g., glass) are indicated as colorless.

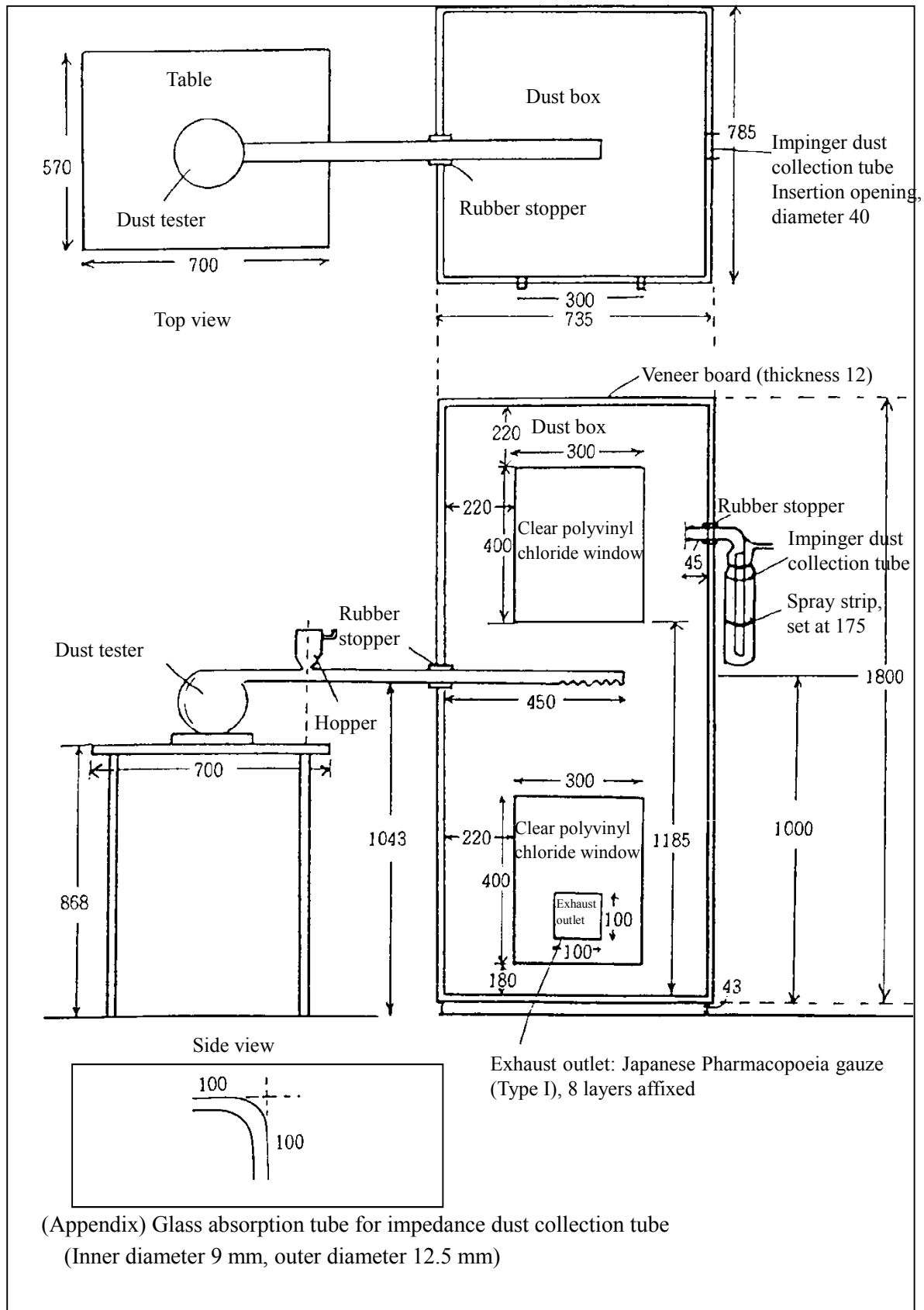
(Appendix Table 2) Chemical composition, etc. of standard powder

| | | |
|--|--|---|
| 1. Chemical composition | Components | Percentage of Mass |
| | SiO ₂ Fe ₂ O ₃ Al ₂ O ₃ TiO ₂ MgO Ignition loss | $\geq 97\%$ $\left. \begin{array}{l} \\ \\ \\ \\ \\ \end{array} \right\} \text{Total } \leq 3\%$ |
| 2. Particle diameter distribution | Particle diameter (μm) | After Sieving (%) |
| | 5 | 88 ± 3 |
| | 10 | 76 ± 3 |
| | 20 | 62 ± 3 |
| | 30 | 50 ± 3 |
| | 40 | 39 ± 3 |
| | 74 | ≤ 20 |
| 3. Average particle diameter (μm) | | 22 ± 2 |
| 4. Apparent specific gravity | | 0.9-1.0 |
| 5. Moisture content (%) | | $\leq 0.5\%$ |

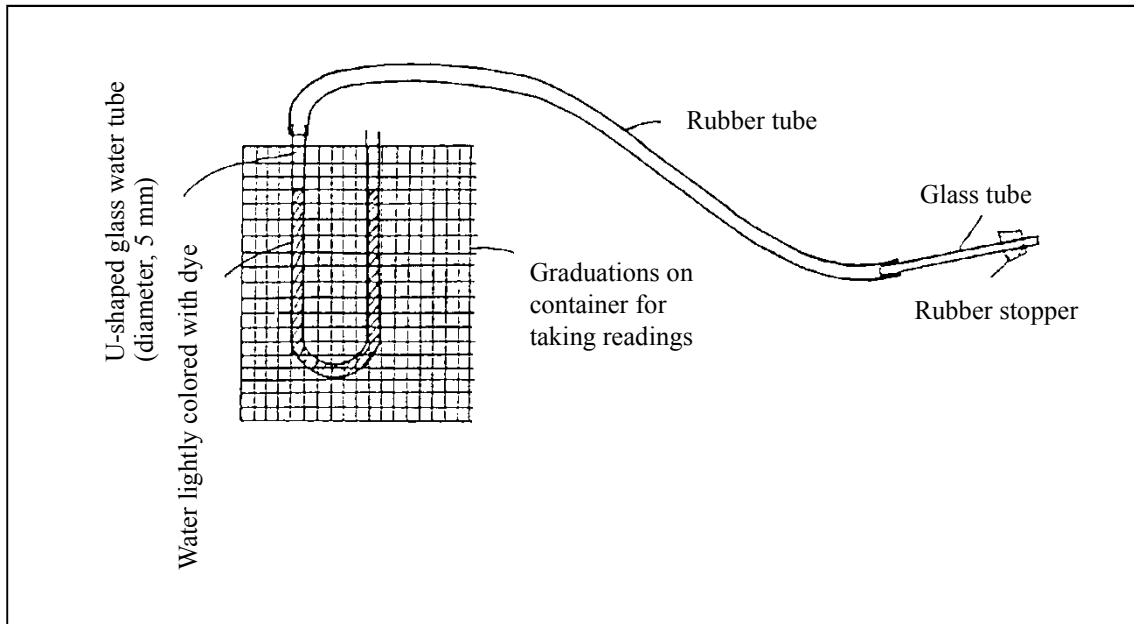
(Appendix Table 3) Specifications of working standard powder

| Item | Specification · Standard |
|--|--------------------------|
| 1. Drift index | 10-15 |
| 2. Contents of particles of particle size ≥ 300 mesh ($45 \mu\text{m}$) | $\geq 95\%$ |
| 3. Average particle diameter | 20-30 μm |
| 4. Content of particles of $\leq 10 \mu\text{m}$ | 10-20% |
| 5. Apparent specific gravity | 0.7-1.1 |
| 6. Flowability | 1-15 seconds |
| 7. Moisture content | $\leq 0.5\%$ |

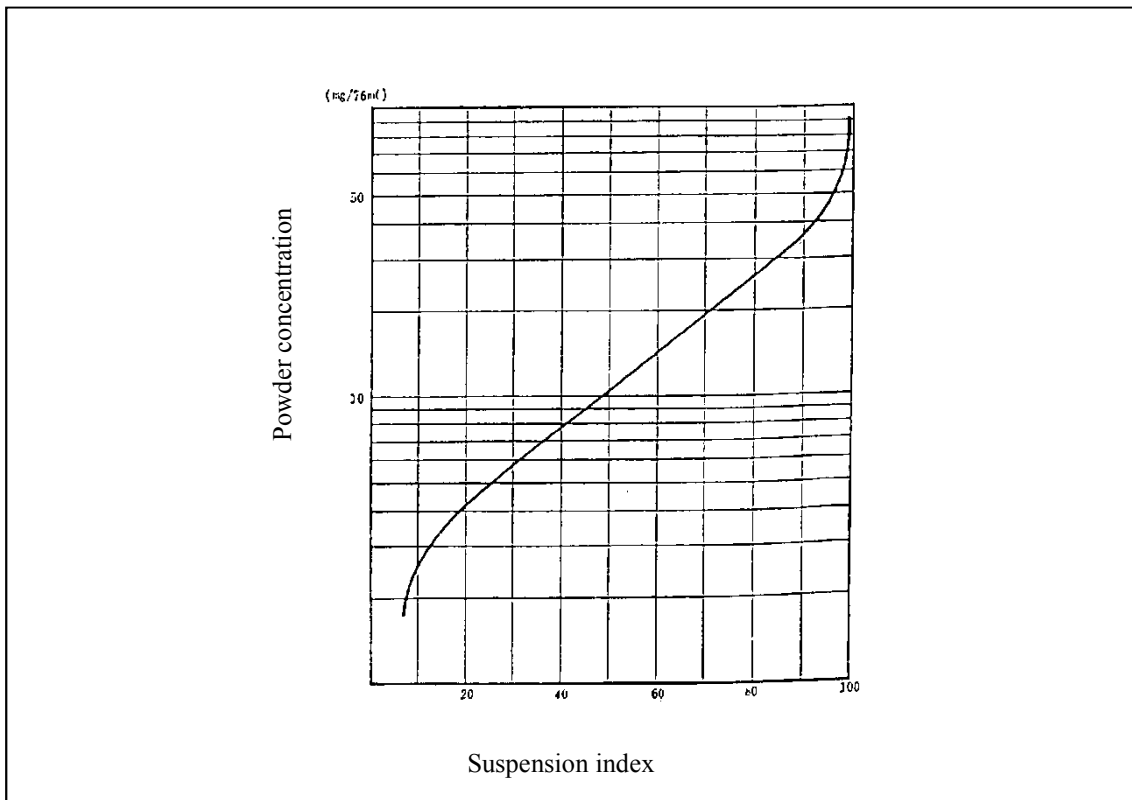
(Appended Figure 1) Device for determining suspension index (Units: mm)



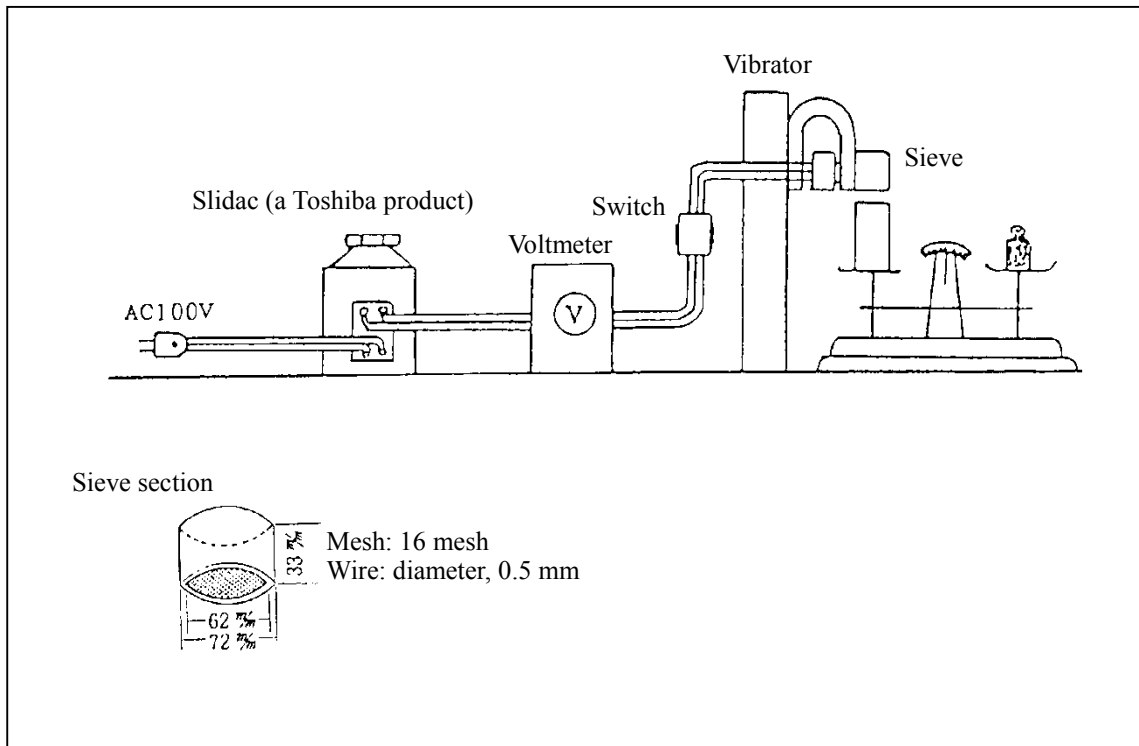
(Appended Figure 2) Device for measuring internal pressure



(Appended Figure 3) Graph showing the relationship between powder concentration and drift index



(Appended Figure 4) Schematic diagram of a device for measuring flowability



Annex2

Derivation of Predicted Environmental Concentration for short-term risk assessment on aquatic organisms

1. Definition

Predicted Environmental Concentration for short-term risk assessment on aquatic organisms (hereinafter referred to as “short-term PEC”) hereby means the one stated in 3 of the “Criteria for whether to come under any of Subparagraphs 4 to 7 of Paragraph 1 of Article 3 of Agricultural Chemicals Regulation Law” (Notification No. 246 issued in 1971 by the Ministry of Agriculture and Forestry).

2. Specific procedures etc. for short-term PEC derivation

Short-term PEC shall be derived for each combination of the site to be pest controlled (either paddy fields or other fields), in accordance with the usage stated in the application of the said agricultural chemicals. It shall be calculated under the usage that would potentially result in the highest short-term PEC, and for the period that corresponds to the test period of the study on acute influence on each aquatic organism (for 2, 3, and 4 days). Specific method for short-term PEC derivation shall be one as described in the Appendix.

Short-term PEC shall be tiered according to the site to pest controlled and the control method (either ground application or aerial application), based on the supporting data shown in Table 1, and each short-term PEC shall be calculated in the order of tiers, starting from Tier 1 on each site to pest controlled. In addition, provided that the derived short-term PEC is, in the light of study results concerning influence on aquatic organism, found not to fall in the cases stated in Subparagraph 6 of Paragraph 1 of Article 3 of the Law (including the *mutatis mutandis* application as provided by Paragraph 6 of Article 15-2 of the Law), short-term PEC derivation for the next tier may be omitted.

Table 1. Data basis for short-term PEC derivation for each tier

| Exposure Route | Site to be pest controlled / control methods | Tier 1 | Tier 2 | Tier 3 |
|--|--|-------------------------------|---|---|
| Surface runoff | Paddy fields | Runoff table ^{Note1} | Agricultural chemical concentration measurement test in paddy water of model paddy. | Agricultural chemical concentration measurement test in paddy water of actual paddy |
| | Other fields | Runoff table | Agricultural chemical runoff test in the model field | — |
| Drift into the river | Paddy fields (ground application) | Drift table ^{Note 2} | Same as on the left | Drift test |
| | Other fields (ground application) | Drift table | Drift test | — |
| | Aerial application | Drift table | Same as on the left | Same as on the left (Paddy fields alone) |
| Drift into the ditch (only paddy fields) | Ground application | Drift table | Same as on the left | Same as on the left |
| | Aerial application | Drift table | Same as on the left | Same as on the left |

Note 1: Runoff table

| Site to be pest controlled | | Paddy fields | | | Other fields |
|----------------------------|--------------------|--------------|--------|--------|--------------|
| Toxicity study period | | 2 days | 3 days | 4 days | — |
| control methods | Ground application | 15.6% | 22.4% | 29.1% | 0.02% |
| | Aerial application | 19.0% | 27.1% | 34.4% | 0.02% |

Note 2: Drift table

| Site to be pest controlled | Paddy fields | | Other fields |
|----------------------------|----------------------|----------------------|---|
| control methods | Drift into the river | Drift into the ditch | Drift into the river |
| Ground application | 0.3 % | 4 % | Other than fruit trees 0.1 % Fruit trees 3.4 % |
| Aerial application | 1.9 % | 100 % | 1.7 % |

3. Considerations in short-term PEC derivation

It shall be considered the following points in deriving short-term PEC.

(1) Tier 1 short-term PEC

Use the single dose of agricultural chemical stated in the application for registration of an agricultural chemical for calculation.

(2) Tier 2 short-term PEC

1) Agricultural chemical for use in paddy fields

This PEC shall be calculated by using the single dose of agricultural chemical stated in the application for registration of an agricultural chemical, measurement results of **studies of agricultural chemical concentration measurement in paddy water of model paddy (2-10-2)** and **Soil adsorption studies (2-9-10)**, using the model paddy field. The static period shall also be added to the calculation basis, if the period is set for these tests. In addition, test results of **fate in water (2-6-1~2)**, **Hydrolysis studies (2-9-13)**, and **Photolysis study in water (2-9-16)** may also be used for calculation as needed.

Short-term PEC derivation shall be performed for each experimental section of an agricultural chemical concentration measurement test in the paddy water, and the higher resulting value shall be deemed as Tier 2 short-term PEC.

If there is any missing observation data, the concentration on the data-missing day shall be estimated referring to the degradation curve in principle. The missing observations shall be estimated by distributing the measured values around the data-missing day. The resulting daily concentration shall be applied to the short-term PEC derivation formula, and the mean concentration of the 2 days, 3 days, and 4 days that show the maximum resultant values shall be calculated. When the crops are cultivated in the experimental section, the correction factor for agricultural chemical runoff shall not be applied to short-term PEC calculation formula. In the case of setting static period, runoff into the rice field ridges within the static period shall also be considered to calculate the mean concentration of 2 days, 3 days, and 4 days that show the maximum resultant values.

2) Agricultural chemical for use in fields other than paddy fields

First, the single dose of agricultural chemical stated in the application for registration of an agricultural chemical, the results from **studies of surface soil runoff in model field** (2-10-4), and results from **soil adsorption studies** (2-9-10) shall be used to calculate a PEC (hereinafter referred to as “short-term PEC based on agricultural chemical runoff”). Then the single dose of agricultural chemical stated in the application for registration of an agricultural chemical, the results from **drift study** (2-10-5), and **soil adsorption studies** (2-9-10) shall be used to calculate another short-term PEC (herein after referred to as “short-term PEC based on drift”). Compare the two short-term PEC values and the higher value shall be deemed as Tier 2 short-term PEC.

However, as to either short-term PEC based on agricultural chemical runoff or short-term PEC based on drift, the values used in calculation for Tier 1 short-term PEC may be used.

As to the calculation of short-term PEC on the basis of agricultural chemical runoff and short-term PEC on the basis of drift, test results of **fate in water** (2-6-1~2), **Hydrolysis studies** (2-9-13), and **Photolysis study in water** (2-9-16) shall be used as needed.

In the calculation of short-term PEC on the basis of the drift stated above, the maximum drift rate at the evaluation distance (18 m) shall be used.

(3) Tier 3 short-term PEC (agricultural chemical for use in paddy fields alone)

This short-term PEC shall be calculated by using the single dose of agricultural chemical stated in the application for registration of an agricultural chemical, measurement results for **studies of agricultural chemical concentration measurement in paddy water of actual paddy** (2-10-3) and **soil adsorption studies** (2-9-10), using the actual paddy fields. In addition, results from **a drift study** (2-10-5), **fates in water** (2-6-1~2), **Hydrolysis studies** (2-9-13), and **Photolysis study in water** (2-9-16) may

also be used for calculation as needed. Static period shall also be added to the calculation basis, if the period is set in these tests.

This derivation shall be performed for each experimental section of an agricultural chemical concentration measurement in the water of the actual paddy fields, and the mean for the values of each experimental section shall be deemed as Tier 3 short-term PEC.

If there is any missing observation data, the concentration on the data-missing day shall be estimated referring to the degradation curve in principle. The missing observations shall be estimated by distributing the measured values around the data-missing day. The resulting daily concentration shall be applied to the short-term PEC derivation formula (the correction factor for agricultural chemical runoff shall not be applied), and the mean concentration shall be calculated, for each test paddy field, by taking an average of the concentrations of 2, 3, and 4 days that show the maximum resultant values. In the case of setting a static period, runoff into the rice-field ridges within the static period shall also be considered to calculate the mean concentration of 2 days, 3 days, and 4 days that show the maximum resultant values.

Furthermore, for the drift test results above, the maximum drift rate at the assessed distance (13 m) shall be used.

4. Common cautions

As to K_{oc} (based on **soil adsorption studies** (2-9-10) for calculation, the arithmetic mean value of the results from each soil adsorption study (K_{Foc}^{ads}) shall be used.

5. Matters to report

The data used for derivation, the process of derivation, and the derivation results shall be reported for each tier of short-term PEC.

Appendix

Method for short-term PEC Derivation

1. Tier 1

1-1. Concept of short-term PEC of an agricultural chemical for use in paddy fields

The predicted environmental concentration in the river of an agricultural chemical for use in paddy fields in Tier 1 shall be determined using the following formula;

$$\text{PEC in the river} = (\text{maximum amount of agricultural chemical runoff} + \text{amount of drift into the river} + \text{amount of drift into the ditch}) \div (3 \times \text{toxicity study period})$$

• Specific formula

$$PEC_{\text{Tier 1}} = \frac{M_{\text{runoff}} + M_{\text{Dr}} + M_{\text{Dd}}}{3 \times 86400 \times T_e} \quad (1)$$

In (1),

$PEC_{\text{Tier 1}}$: PEC in the river in Tier 1 (g/m³)

M_{runoff} : maximum amount of agricultural chemical runoff (g)

M_{Dr} : amount of drift into the river for the number of days involved (g)

M_{Dd} : amount of drift into the ditch for the number of days involved (g)

T_e : toxicity study period (day).

Each term shall be obtained using the following formulae.

$$M_{\text{runoff}} = I \times \frac{R_p}{100} \times A_p \times f_p \quad (2)$$

$$M_{\text{Dr}} = I \times \frac{D_{\text{river}}}{100} \times Z_{\text{river}} \times N_{\text{drift}} \quad (3)$$

$$M_{Dd} = I \times \frac{D_{ditch}}{100} \times Z_{ditch} \times N_{drift} \quad (4)$$

In (2) - (4),

- I : single dose of agricultural chemical stated in the application for registration of an agricultural chemical (g/ha)
 R_p : agricultural chemical runoff rate from the paddy fields (%)
 A_p : agricultural chemical application area (ha)
 D_{river} : drift rate into the river (%)
 Z_{river} : area of drift into the river per day (ha/day)
 D_{ditch} : drift rate into the ditch (%)
 Z_{ditch} : area of drift into the ditch per day (ha/day)
 N_{drift} : number of days involved in drift (day)
 f_p : correction factor for agricultural chemical runoff in application method to paddy fields (-).

Table 1. Parameters for agricultural chemical for use in paddy fields (Tier 1)

| Parameter (Unit) | Ground application | Aerial application |
|----------------------|-------------------------------|----------------------------|
| A_p (ha) | 50 | 50 |
| R_p (%) | $T_e = 2$ days | 15.6 |
| | $T_e = 3$ days | 22.4 |
| | $T_e = 4$ days | 29.1 |
| D_{river} (%) | 0.3 | 1.9 |
| Z_{river} (ha/day) | 0.16 | 0.8 |
| D_{ditch} (%) | 4 | 100 |
| Z_{ditch} (ha/day) | 0.07 | 0.33 |
| N_{drift} | $T_e = 2$ days | 1 |
| | $T_e = 3$ days | 2 |
| | $T_e = 4$ days | 2 |
| f_p (-) | 1 (paddy water application) | 0.3 (foliar application) |
| | 0.5 (foliar application) | 1 (other than those above) |
| | 0.2 (nursery box application) | |

1-2. Concept of short-term PEC of an agricultural chemical for use in fields other than paddy fields

The predicted environmental concentration in the river of an agricultural chemical for use in fields other than paddy fields in Tier 1 shall be the larger value of the following.

| | |
|---------------------------------|--|
| Predicted river concentration = | $\left\{ \begin{array}{l} \text{Maximum amount of agricultural chemical runoff} \div \\ (11 \times \text{toxicity study period}) \\ \\ \text{or} \\ \\ \text{Amount of drift into the river} \div (3 \times \text{toxicity study} \\ \text{period}) \end{array} \right.$ |
|---------------------------------|--|

• Specific formula

$$PEC_{\text{Tier1}} = \frac{M_{\text{runoff}}}{11 \times 86400 \times T_e}, \text{ or } PEC_{\text{Tier1}} = \frac{M_{\text{Dr}}}{3 \times 86400 \times T_e} \quad (5)$$

In (5),

PEC_{Tier1} : PEC in the river (g/m³)

M_{runoff} : maximum amount of agricultural chemical runoff (g)

M_{Dr} : amount of drift into the river for the number of days Involved (g).

Each term shall be obtained by the following formulae.

$$M_{\text{runoff}} = I \times \frac{R_u}{100} \times A_u \times f_u \quad (6)$$

$$M_{\text{Dr}} = I \times \frac{D_{\text{river}}}{100} \times Z_{\text{river}} \times N_{\text{drift}} \quad (7)$$

In (6) – (7),

I : the single dose of agricultural chemical stated in the application for registration of an agricultural chemical (g/ha)

D_{river} : drift rate into the river (%)

- Z_{river} : area of drift into the river per day (ha/day)
 N_{drift} : number of days involved in drift (day)
 R_u : agricultural chemical runoff rate from the sprayed area (%)
 A_u : agricultural chemical sprayed area (ha)
 f_u : correction factor for agricultural chemical runoff in application to the sprayed area (-).

Table 2. Parameters for agricultural chemical for use in fields other than paddy fields (Tier 1)

| Parameter (unit) | Ground application | Aerial application |
|----------------------|---|--|
| A_u (ha) | 37.5 | 37.5 |
| R_u (%) | 0.02 | 0.02 |
| D_{river} (%) | 0.1 (other than fruit trees) 3.4 (fruit trees) | 1.7 |
| Z_{river} (ha/day) | 0.12 | 0.6 |
| N_{drift} (day) | T_e | 1 |
| f_u (-) | 0.1 (soil incorporation and soil injection) 1 (other than those above) | 0.3 (foliar application) 1 (other than those above) |

2. Tier 2

2-1. Concept of short-term PEC of an agricultural chemical for use in paddy fields

The predicted environmental concentration in the river of an agricultural chemical for use in paddy fields in Tier 2 shall be obtained by the following formula.

$$\begin{aligned}
 \text{PEC in the river} = & (\text{maximum agricultural chemical runoff from the drainage outlet of the} \\
 & \text{paddy fields} + \text{maximum agricultural chemical runoff from seepage} \\
 & \text{into the ridge} + \text{amount of drift into the river} + \text{amount of drift into the} \\
 & \text{ditch} - \text{amount of adsorption into the sediment of the tributary stream}) \\
 & \div (3 \times \text{toxicity study period})
 \end{aligned}$$

The short-term PEC in the river shall be derived separately for each of the two cases; 1) when the static period is not set, and 2) when the static period is set. However, when the relevant agricultural chemical has properties such that it is decomposed rapidly in river water, PEC shall be derived in consideration of 3) degradability.

• Specific formula

(1) When the static period is not set

$$PEC_{Tier2} = \frac{M_{out} + M_{seepage} + M_{Dr} + M_{Dd} - M_{se}}{3 \times 86400 \times T_e} \quad (8)$$

In (8),

PEC_{Tier2} : PEC in the river in Tier 2 (g/m³)

M_{out} : maximum agricultural chemical runoff from the drainage outlet of the paddy fields (g)

$M_{seepage}$: maximum agricultural chemical runoff due to seepage into the ridge (g)

M_{Dr} : amount of drift into the river (g)

M_{Dd} : amount of drift into the ditch (g)

M_{se} : adsorption to the sediment of the tributary stream (g).

Each term shall be obtained by the following formulae.

$$M_{out} = \begin{cases} \frac{\sum \sum C_i}{5} \times Q_{out} \times A_p \times f_p & \text{(in case of ground application)} \\ \sum_{i=0}^{T_e-1} C_i \times Q_{out} \times A_p \times f_p & \text{(in case of aerial application)} \end{cases} \quad (9)$$

$$M_{seepage} = \begin{cases} \left(\frac{\sum \sum C_i}{5} \times Q_{seepage} \times A_p \times f_p \right) / K_{levee} & \text{(in case of ground application)} \\ \left(\sum_{i=0}^{T_e-1} C_i \times Q_{seepage} \times A_p \times f_p \right) / K_{levee} & \text{(in case of aerial application)} \end{cases} \quad (10)$$

$$M_{Dr} = I \times \frac{D_{river}}{100} \times Z_{river} \times N_{drift} \quad (11)$$

$$M_{Dd} = I \times \frac{D_{ditch}}{100} \times Z_{ditch} \times N_{drift} \quad (12)$$

$$M_{se} = (M_{out} + M_{seepage} + M_{Dr} + M_{Dd}) \times \frac{K_{oc} \times oc_{se} / 100 \times \rho_{se} \times V_{se}}{K_{oc} \times oc_{se} / 100 \times \rho_{se} \times V_{se} + V_w} \quad (13)$$

In (9) – (13),

- Q_{out} : effluent discharge from the drainage outlet per day (m³/ha/day)
- $Q_{seepage}$: effluent discharge due to seepage into the ridge (m³/ha/day)
- C_i : concentration of an agricultural chemical in the paddy field water for *i* days, based on the concentration measurement test of an agricultural chemical in the water of the model paddy field (g/m³)
- K_{levee} : ridge adsorption coefficient (-)
- V_w : volume of water in the tributary stream (m³)
- V_{se} : volume of sediment of the tributary stream (m³)
- ρ_{se} : specific gravity of the sediment (g/cm³)
- oc_{se} : content of organic carbon in the sediment of the tributary stream (%).

The ridge adsorption coefficient shall be obtained by the following formula.

$$K_{levee} = \frac{\rho_{levee}}{r_{ws}} \times K_{oc} \times oc_{levee} / 100 + 1 \quad (14)$$

In (14),

- ρ_{levee} : specific gravity of the ridge soil (g/cm³)
- r_{ws} : volume ratio of catalytic water and catalytic soil (-)
- K_{oc} : constant in organic carbon adsorption in the soil (cm³/g)
- oc_{levee} : content of organic carbon in the ridge soil (%).

(2) When the static period is set

When the static period is set, there arise discrepancies in the following two results. 1), The time that gives the maximal value with respect to the sum of the amount of drift that arises during application, and the amount of effluent discharge due to seepage into the ridge that arises immediately after the application (the amount of effluent discharge from part of the drainage outlet of the paddy fields may also be added, depending on the setting status of static period). 2) The time that shows the maximal value as for the sum of the effluent discharge from the drainage outlet of the paddy fields that occurs from

the completion of the static period, and effluent discharge due to seepage into the ridge. Therefore, the maximum agricultural chemical runoff shall be calculated for both 1) and 2) separately, and the larger value shall be deemed as the predicted environmental concentration in the river.

- In case of ground application

$$PEC_{Tier2} = \frac{\frac{\sum m_{out,i}}{5} + \frac{\sum m_{seepage,i}}{5} + M_{Dr} + M_{Dd} - M_{se}}{3 \times 86400 \times T_e}$$

or

$$(15)$$

$$PEC_{Tier2} = \frac{\frac{\sum m_{out,i}}{5} + \frac{\sum m_{seepage,i}}{5} - M_{se}}{3 \times 86400 \times T_e}$$

In (15),

$m_{out,i}$: agricultural chemical runoff from the drainage outlet of the paddy fields i days after application (g)

$m_{seepage,i}$: agricultural chemical runoff due to seepage into the ridge i days after application (g).

Each term shall be obtained from the following formulae.

$$m_{out,i} = C_i \times Q_{out} \times A_p \times f_p \quad (16)$$

$$m_{seepage,i} = (C_i \times Q_{seepage} \times A_p \times f_p) / K_{levee} \quad (17)$$

M_{Dr} , M_{Dd} , and M_{se} shall be obtained by Formula (11), (12), and (13), respectively.

- In case of aerial application

$$PEC_{Tier2} = \frac{M_{out} + M_{seepage} + M_{Dr} + M_{Dd} - M_{se}}{3 \times 86400 \times T_e}$$

or

(18)

$$PEC_{Tier2} = \frac{M_{out} + M_{seepage} - M_{se}}{3 \times 86400 \times T_e}$$

where M_{out} and $M_{seepage}$ shall be obtained by the following formulae.

$$M_{out} = \Sigma C_i \times Q_{out} \times A_p \times f_p \quad (19)$$

$$M_{out} = (\Sigma C_i \times Q_{seepage} \times A_p \times f_p) / K_{levee} \quad (20)$$

M_{Dr} , M_{Dd} , and M_{se} shall be obtained by Formula (11), (12), and (13), respectively.

(3) When the degradability in the river water is considered

$$PEC_{Tier2-deg} = PEC_{Tier2} \times e^{-0.17 \times k} \quad (21)$$

In (21),

$PEC_{Tier2-deg}$: PEC in the river when the degradability is considered
(g/m³)

k : degradation rate constant in water (1/day).

The degradation rate constant in water shall be obtained by the following formula.

$$k = \frac{\ln 2}{DT50_h} + \frac{\ln 2}{DT50_p} \quad (22)$$

