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Concerning Testing Methods Required for Listing on the PL

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Japan BioPlastics Association

Introduction

This document explains the testing methods required for listing on the PL in relation to the GreenPla Positive List (PL) Formulation Standards (June 2007 [1st Revision]) and the BiomassPla Positive List (PL) Formulation Standards (June 2006 [1st Edition]) prescribed by the Identification Committee of the Japan BioPlastics Association (hereafter referred to as the JBPA).

1. General Provisions

- (1) The substances here are components (materials) that are used or are due to be used in GreenPla and BiomassPla.
- (2) When requesting the addition of a substance to the PL, in addition to the application form indicated in the PL Formulation Standards, applicants must submit to the Chairman of the JBPA Identification Committee the test reports listed below or other relevant documents that are deemed necessary by this Committee.
- (3) The test reports listed below must clearly set forth the results of tests conducted by testing institutions approved and registered by the JBPA (listed below) or the results of tests or testing methods certified by assessors approved by the JBPA (listed below). The applicant shall take full responsibility for the content of the test report.
- (4) The applicant shall bear all costs arising from the testing. If there are any queries regarding the content of the test or the method of carrying out the test, applicants can refer these to the Identification Committee in order to obtain further guidance.

2. Biodegradability Tests

The biodegradability testing methods prescribed by this Committee are as follows. The most up-to-date list of testing methods shall be used.

- (1) OECD 301C (Modified MITI Test – Ready Biodegradability):

Chemical substances: Aerobic biodegradability testing method using activated sludge

(Note) Testing period: 28 days

- (2) JIS K 6950 (ISO 14851)

Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium

(Method by measuring the oxygen demand in a closed respirometer)

(Note) Testing period: Within 6 months

- (3) JIS K 6951 (ISO 14852)

Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium

(Method by analysis of evolved carbon dioxide)

(Note) Testing period: Within 6 months

- (4) JIS K 6955 (ISO 17556)

Plastics – Determination of the ultimate aerobic biodegradability in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved

(Note) Testing period: Within 6 months

- (5) JIS K 6953 (ISO 14855)

Determination of the ultimate aerobic biodegradability and disintegration of plastic materials under controlled composting conditions

(Method by analysis of evolved carbon dioxide)

Part1:General Method

(Note) Testing period: Within 6 months

- (6) ISO 14855-2

Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions

(Method by analysis of evolved carbon dioxide)

Part2:Gravimetric measurement of carbon dioxide evolved in a laboratory-scale test)

(Note) Testing period: Within 6 months

Please refer to the relevant standard for the details of each of the abovementioned tests.

3. Oral Acute Toxicity Tests

The oral acute toxicity testing methods prescribed by this Committee are as follows. The most up-to-date list of testing methods shall be used.

(1) OECD Test Guideline 420

Acute Oral Toxicity—Fixed Dose Procedure

(2) OECD Test Guideline 423

Acute Oral Toxicity—Acute Toxic Class Method

(3) OECD Test Guideline 425

Acute Oral Toxicity—Up-And-Down Procedure

Note: It is also permissible to use only limit confirmation tests that indicate that the LD₅₀ is in excess of 2,000mg/kg.

4. Environmental Safety Tests

The environmental safety tests prescribed by this Committee are as follows.

① **Freshwater Alga and Cyanobacteria, Growth Inhibition Test: OECD Test Guidelines 201 DIG 19**

- The impact on the growth of unicellular green algae of chemical substances under test conditions
- Evaluation: After exposure of the algae for 96 hours to various concentrations of the substance being tested, the EC₅₀ value at 96 hours is evaluated

② **Daphnia sp. Two-week Propagation: OECD Test Guidelines 202 DIG 20**

- Including acute immobilization
- Evaluation: The test consists of the following two stages:
 - Acute toxicity: The EC₅₀ value at 24 hours, the maximum concentration at which immobilization is not caused, and the minimum concentration at which 100% immobilization is caused are obtained.
 - Reproductive capacity: The EC₅₀ value (immobilization) and the LC₅₀ (death rate) at 24, 48 and 96 hours, 7 and 14 days, and the day on which the test ends are obtained. Evaluation is based on the EC₅₀ value at 24 hours and the LC₅₀ (death rate) at the end of the test.

③ **Fish, Acute Toxicity Test: OECD Test Guidelines 203 DIG 21**

- This determines the 50% lethal dosage of the substance being tested in fish under test conditions.
- Evaluation: The evaluation is based on the LC₅₀ (death rate) in fish (orange *Oryzias latipes*) after at least 96 hours of continuous exposure to various concentrations of the substance being tested.

For further details concerning the tests, refer to *OECD Guidelines for Testing of Chemicals*.

[Reference: Explanation of Terms]

LD₅₀: 50% lethal dose

This is an indicator of the acute toxicity of a chemical substance and refers to the quantity administered that is estimated to result in the death of half (50%) of the animals to which it is administered; it is also referred to as the half lethal dose or 50% lethal dose.

Generally, the dose is set on the basis of a particular proportion and each dosage is administered to around 10 animals, with the death rate being measured and the LD₅₀ being calculated from the results of this.

The distinction between toxic substances, deleterious substances and normal substances in Japan is determined in accordance with the LD₅₀ value obtained from tests on mice (The foregoing is quoted from the second edition of the Tokyo Kagaku-Dojinsha Dictionary of Biochemistry).

Environmental Risk Evaluation:

Acute toxicity tests are conducted using freshwater organisms.

Normally, three types of test are conducted: alga growth inhibition tests, Daphnia acute immobilization tests, and fish acute toxicity tests.

In general, green algae are used for the alga tests, Daphnia magna are used for the Daphnia tests, and orange Oryzias latipes are used for the fish tests; toxicity in alga and Daphnia is evaluated on the basis of EC₅₀, while toxicity in fish is evaluated on the basis of LC₅₀.

EC₅₀: Median Effective Concentration

This is the concentration of the substance being tested at which it is estimated that the impact will emerge in 50% of the test organisms, compared with the control group, that is to say the test organisms that are not exposed to the substance.

Where the test organisms are algae, this is the concentration at which the cell density is reduced by half after 72 hours.

LC₅₀: Median Lethal Concentration

This is the concentration of the substance being tested at which it is estimated that 50% of the test organisms, such as fish, will die.

(The foregoing is quoted from the Ministry of the Environment website, section relating to businesses testing the ecological effects of chemical substances)

5. Biomass Carbon Measurement Tests

ASTM D6866-5 Standard Test Methods for Determining the Biobased Content of Natural Range Materials Using Radiocarbon and Isotope Ratio Mass Spectrometry Analysis

Using the *Testing Method for Determining the Biobase Rate of Materials in the Natural Domain Using Radioactive Carbon and Isotope Ratio Gravimetric Analysis*.

Concerning Testing Results and Testing Institutions

Normal chemical analysis, biodegradability tests, oral acute toxicity tests and environmental safety tests shall conform to the following test results or be conducted by the following testing institutions.

(Accredited Test Results)

- ① Test results recognized in the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (1973 Law No.117; abbreviated to “Chemical Substances Control Law”)
- ② Test results prescribed by this Committee or accredited by assessors recognized by this Committee
- ③ Test results from a testing institution accredited by the BPI (International Biodegradable Products Institute; headquarters: New York), DIN Certco (headquarters: Berlin), and BMG (Biodegradable Materials Group; headquarters: Beijing)

(Accredited Testing Institutions)

- ④ GLP-certified testing institutions in relation to the Chemical Substances Control Law
- ⑤ Testing institutions prescribed by this Committee or accredited by assessors recognized by this Committee
- ⑥ Testing institutions accredited by the BPI in the USA, DIN Certco in Germany, or BMG in China

Note 1:

The latest information concerning the abovementioned assessors and testing institutions will be published on this Committee’s website.

Note 2:

As of June 13, 2006, the following testing institutions have been accredited:

■JBPA – 1:

Chemicals Evaluation and Research Institute, Japan

Tokyo Laboratory

1600 Shimotakano, Sugito-machi, Kitakatsushika-gun, Saitama 345-0043, Japan

Tel: 0480-37-2601 Fax: 0480-37-2521

Focus: General chemical analysis

Biodegradability tests (OECD 301C, JIS K 6950, 6951, 6953)

Oral acute toxicity tests and environmental safety tests

■JBPA – 2:

Japan Food Research Laboratories

Tama Laboratory

6-11-10 Nagayama, Tama City, Tokyo 206-0025, Japan

Tel: 042-372-6711 Fax: 042-372-6700

Focus: General chemical analysis

Oral acute toxicity tests and environmental safety tests

■JBPA – 3:

Organic Waste Systems n.v.

4, Dok Noord, 9000 GENT, Belgien

Tel: Bel-00 32 92 33 02 04 Fax: Bel-00 32 92 33 28 25

Focus: General chemical analysis

Biodegradability tests (ISO 14851, 14852, 14855)

Compostability

Note: Japanese agent

DJK International Inc.

Hakua Building, 2-4-1 Akasaka, Minato-ku, Tokyo 107-0052, Japan

Tel: 03-3585-8131 Fax: 03-3588-1830

■JBPA – 4:

Mitsui Chemical Analysis & Consulting Service Inc.

1-10-2 Kyobashi, Chuo-ku, Tokyo 104-0031, Japan

Tel: 03-3566-3161 Fax: 03-3566-3165

Focus: General chemical analysis

Oral acute toxicity tests and environmental safety tests

Biodegradability tests (OECD 301C, JIS K 6950, 6951, 6953)

■JBPA – 5:

Himeji Research Center, Daicel Chemical Industries, Ltd.

1239, Shinzaike, Aboshi-Ku, Himeji City, Hyogo 671-1283, Japan

Tel: 0792-74-4077 Fax: 0792-74-4153

Focus: General chemical analysis

Oral acute toxicity tests and environmental safety tests

Biodegradability tests (OECD 301C, JIS K 6950, 6951, ISO 17556)

■JBPA – 6:

Osaka Municipal Technical Research Institute

1-6-50 Morinomiya, Joto-Ku, Osaka 536-8553, Japan

Tel: 06-6963-8065 Fax: 06-6963-8079

Focus: General chemical analysis

Biodegradability tests (OECD 301C, JIS K 6950)

■JBPA – 7:

Institute of Accelerator Analysis Ltd.

129-1 Shinmachi, Noborito, Tama-ku, Kawasaki City, Kanagawa 214-0013, Japan

Tel: 044-934-0020 Fax: 044-931-5812

Focus: Radiocarbon measurement

■ **JBPA – 8:**

Beta Analytic, Inc

4985 S.W. 74th Court

Miami, FL, USA 33155

Tel: (01) 305-667-5167

Focus: Radiocarbon measurement

Note: Japanese agent

Chikyu Kagaku Kenkyusho

1-608 Uedahonmachi, Tenpaku-ku, Nagoya City, Aichi, 468-0007, Japan

Tel: 052-802-0703

■ **JBPA – 9:**

National Institute of Advanced Industrial Science and Technology (AIST)

Research Institute for Innovation in Sustainable Chemistry

Central 5, 1-1-1 Higashi, Tsukuba, Ibaraki 305-8565, Japan

Tel: 029-861-4584

Focus: Biodegradability tests (ISO 14855-2)

■ **BPI – 1:**

Advanced Materials Center, Inc

125 Swanson Street, Ottawa, IL 61350-5114, US

Tel: USA-815-422-1495 FAX: USA-815-433-1795

■ **BPI – 2:**

Organic Waste Systems

3155 Research Blvd, Suite 104, Dayton, OH 45420, US

Tel: USA-937-253-6888 FAX: USA-937-253-3455

EMAIL: rtillinger@worldnet.att.net

■ **DIN Certco – 1:**

Dr. U. Noack-Laboratorium für angewandte Biologie

Käthe-Paulus-Straße 1, 31157 Sarstedt, Germany

Tel: Ger-0 50 66/70 67-0 Fax: Ger-0 50 66/70 67 89

E-Mail: info@noack-lab.de Web: www.noack-lab.de

■ **DIN Certco – 2:**

Fraunhofer-Institut für Verfahrenstechnik und Verpackung

Giggenhauser Straße 35, 85354 Freising, Germany

Tel: Ger-0 81 61 49 10 Fax: Ger-0 81 61 49 14 91

■ **DIN Certco – 3:**

Fraunhofer-Institut für Umwelt-, Sicherheits-, Energietechnik UMSICHT Lab.

Osterfelder Straße 3, 46047 Oberhausen, Germany

Tel: Ger-02 08/85 98-0 Fax: Ger-02 08/85 98-12 90

E-Mail: ute.merrettig-bruns@umsicht.fhg.de

■ **DIN Certco – 4:**

Ingenieurgesellschaft für Umweltplanung mbH Geschäftsbereich PlanCoTec

Karlsbrunnenstraße 11, 37249 Neu-Eichenberg, Germany

Tel: Ger-0 55 42/93 19-30 Fax: Ger-0 55 42/93 19-79

E-Mail : plancotec@plancotec.de

■ **DIN Certco – 5:**

ISEGA - Forschungs- und Untersuchungs-Gesellschaft mbH

Zeppelinstraße 3-5, 63741 Aschaffenburg, Germany

Tel: Ger-0 60 21/49 89-0 Fax: Ger-0 60 21/49 89-30

E-Mail: isega@t-online.de Web: www.isega.de

■ **DIN Certco – 6:**

Materialforschungs- und Prüfanstalt an der Bauhaus-Universität Weimar

Fachgebiet Umwelt

Amalienstraße 13, 99423 Weimar, Germany

Tel: Ger-0 36 43/5 64-0 Fax: Ger-0 36 43/5 64-2 01

Fax: Ger-0 36 43/5 64-2 02

■ **DIN Certco – 7:**

OrganicWaste Systems n.v.

4, Dok Noord, 9000 GENT, BELGIUM

Tel: Bel-00 32 92 33 02 04 Fax: Bel-00 32 92 33 28 25

E-Mail: mail@ows.be

■ **DIN Certco – 8:**

Universität GH Essen

Fachbereich 10, Bauwesen/Abfallwirtschaft Universitätsstraße 15, 45141 Essen, Germany