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○Standards Regarding New Chemical Substances which are polymers and which are not thought to pose a risk of harming human health or damaging the inhabitation and/or growth of flora and fauna in the living environment by causing environmental pollution

(2nd Public Notice by the Ministry of Health, Labour and Welfare/Ministry of Economy, Trade and Industry/Ministry of the Environment, February 28th, 2009)
Final Revision July 1st, 2019, 1st Public Notice by the Ministry of Health, Labour and Welfare/Ministry of Economy, Trade and Industry/Ministry of the Environment, enforced as of July 1st, 2019.

No.1 Polymers means chemical substance corresponding to the following 1 and 2.

1 A 'Polymer' means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units, comprising 50 weight % and more of the molecules containing at least three monomer units, and comprising less than 50 weight % of the molecules of the same molecular weight.

2 The number average molecular weight is 1,000 or more.

No. 2 New chemical substances which are polymers and which are not thought to pose a risk of harming human health or damaging the inhabitation and/or growth of flora and fauna in the living environment by causing environmental pollution means chemical substances corresponding to the following 1 or 2.

1 A polymer that meets all the requirements listed below.

⑴ A polymer that meets the following stability criteria based on the physicochemical stability tests.

A. There is no change in the dissolved organic carbon (hereafter referred to as “DOC”) concentration exceeding 1 % (or change in the weight of test substances exceeding 2% when the decision based on the change in DOC is not appropriate) under any pH conditions of test solutions before and after the test.

B. There is no change in the IR spectrum under any pH conditions of test solutions before and after the test.

C. There is no change in the molecular weight of test substance under any pH conditions of test solutions before and after the test.

⑵ Based on solubility test in acid/alkali, there is no change in the DOC exceeding 1 % (or change in the weight of test substances exceeding 2% when the decision based on the change in DOC is not appropriate) before and after the test, or no cationic properties is indicated in the main structure of the test substance.

⑶ Based on solubility test in water and organic solvents, there is no change in the DOC exceeding 1 % (or change in the weight of test substances exceeding 2% when the decision based on the change in DOC is not appropriate) in water test solution and no change in the weight of test substances exceeding 2% in organic solvent test solution before and after the test.

⑷ No metal except for sodium, magnesium, potassium, and calcium is contained in the chemical structure.

2 A polymer that meets all the requirements of (1), (2) and (4) of item 1, as well as the following (1) to (3).

⑴ A polymer that does not fall under ⑶ of item 1 and has equal to or less than 1% of components with molecular weight less than 1,000, and is not known to be highly bioaccumulative.

⑵ The chemical structure contains neither arsenic nor selenium.

⑶ A polymer that falls under the following A or B.

A. The number average molecular weight is 10,000 or more.

B. A polymer that does not fall under A and consists of monomers that are existing chemical substances, etc. and does not contain carbon-carbon double bonds, carbon-carbon triple bonds, carbon-nitrogen double bonds, carbon-nitrogen triple bonds, aziridinyl groups, amino groups, epoxy groups, sulfonate groups, hydrazino groups, phenolic hydroxyl groups, and fluoro groups in its chemical structure.

No.3 The compliance of the chemical substance with the requirements of the criteria shall be evaluated by the test method described below.

1 Terminology

The terms used in the test methods are in accordance with the Japan Industrial Standards (JIS K 0211 (Technical terms for analytical chemistry (General part)), JIS K 0215 (Technical terms for analytical chemistry (analytical instrument part)), JIS K 7252 (Plastics - Determination of average molecular mass and molecular mass distribution of polymers using size-exclusion chromatography), and JIS Z 8801 (Test sieves, etc.,).

2 Preparation of test substances

A chemical substance with the smallest average molecular weight is selected as a test substance. However, if it is dissolved or dispersed in a solvent during polymer synthesis, the polymer isolated from the solvent without changing the properties of the chemical substance shall be used as the test substance.

3 Test methods

⑴ Physicochemical stability test and solubility test in acid/alkali

A. Granularity of test substances: The test substance shall be targeted to have particle size of between 60 to 80 mesh.

B. pH of test solutions and its preparation: The pH values of 4.0 and 9.0, which are adopted in the OECD (Organization for Economic Cooperation and Development) Guidelines for Testing of Chemicals (OECD Council Decision [C(81)30 Final Appendix 1]) 111 “Hydrolysis as a Function of pH” (hereafter referred to as “TG111”) shall be used. The pH4.0 test solution may also be prepared by inorganic solvents that are not prescribed in TG 111 under the condition that pH level is confirmed to be maintained before and after the test.

C. Test temperature: 40±2℃

D. Light: Indoor light

E. Air: The test solution shall be stirred to facilitate contact between the test substance and air.

F. Test period: 2 weeks

G. The concentration of the test substance shall be 1,000 mg/L. However, if there are any difficulties in conducting the test with test concentration 1,000mg/L due to the nature of test substance, the test concentration can be altered within the range of 100mg/L to 10,000mg/L.

H. Number of cycles (repetition): 2 cycles

I. Analysis: The DOC, IR spectrum and molecular weight distribution shall be analyzed before and after the test in order to examine whether there is any chemical change, and when a test substance has any side chains that can be hydrolyzed, a direct analysis shall be conducted to assess its physicochemical stability. However, if DOC analysis is not applicable; the test substance is an inorganic polymer or a buffer solution adopted in TG111 is applied for pH4.0 test solution, the weight shall be analyzed. However, some deviation may be allowed for cases with inevitable reasons.

⑵ Solubility test methods in water and organic solvents

A. Test solvents

(A) Water

(B) Tetrahydrofuran (hereafter referred to as “THF”) and dimethylformamide (hereafter referred to as “DMF”).

(Note 1) The solubility in n-octanol and n-heptane (affinity index to fat) can be determined by the solubility in THF and DMF.

(Note 2) Dimethyl sulfoxide (hereafter referred to as “DMSO”) or 1-methyl-2-pyrrolidone (hereafter referred to as “NMP”) can be used in place of DMF.

B. Test temperature: Between 35℃ to 40℃.

C. Test period: 1 hour of stirring

D. Equilibrium: Maintain equilibrium for 24 hours at 25±2℃.

E. Test concentration of test substance: 2,000mg/L

F. Granularity: The test substance shall be targeted to have particle size of between 60 to 80 mesh.

G. Number of cycles (repetition): 2 cycles

H. Stirring: The test solution should be gently and constantly stirred or agitated in order to facilitate contact between the test substance and air.

I. Analysis:

(A)The DOC analysis shall be conducted for the water test solution. However, if the DOC analysis is not applicable for water test solution, the weight change shall be assessed on constant weight of residue sample obtained by filtering the test solution. If the filtering method cannot be used due to the nature of the test substance such as swelling and adherence to test vessel, etc., other methods can be used to separate the test solution and the residue sample. If the weight analysis of the residue samples is not feasible, the weight analysis can be carried out on test sample obtained by drying filtrate.

(B) For THF and DMF test solution, the weight change shall be assessed on constant weight of residue sample obtained by filtering the test solution. If filtration is not applicable due to the nature of the test substance such as swelling and adherence to test vessel, etc., another method can be used to separate the test solution and the residue sample. If the weight analysis of the residue samples is not feasible, the weight analysis can be carried out on test sample obtained by drying filtrate.

J. Solubility assessment: in principle, insolubility is, confirmed by the fact that the test substance is insoluble in water and in 2 organic solvents. If the substance dissolves in 1 out of the 3 types of solvents (water and 2 organic solvents), the water solubility shall be provided.

(3) Measurement method for molecular weight distribution:

When the test sample is confirmed to be soluble in accordance with (2) J., Size-Exclusion Chromatography method (hereafter referred to as “SEC”) is carried out with consideration of the following points.

A. Eluant:

Any of the following general eluants shall be used. If the test substance does not dissolve in the eluants, the special eluants prescribed in item (B) shall also be considered. If the test substance does not dissolve at the temperature prescribed by Japan Industrial Standards (JIS K 7252), solubility study can be carried out with o-dichlorobenzene (hereafter referred to as “ODCB”), toluene, DMF, or water under heated condition.

(A) General eluants: THF, chloroform, dichloromethane, DMF, water (including buffer solutions), etc.

(B) Special eluants: 1, 1, 1, 3, 3, 3, hexafluoro-2-propanol (HFIP), 1, 2, 4-trichlorobenzene (TCB), ODCB, toluene, 1,2-dichloroethane, NMP, m-cresol, benzene, DMSO, tetrachloroethylene, 2-chlorophenol, trifluoroethanol, etc.

B. Method to convert the molecular weight: A method shall be selected from the following methods that is suitable for the test substance.

(A) Methods using standard samples of monodisperse molecular weight.

(Polyethylene oxide, polystyrene, etc. shall be used as standard samples.)

(B)Methods using standard samples of polydisperse molecular weight: 1 to 2 types of standard samples with number average molecular weight, weight average molecular weight, and Z average molecular weight determined by absolute method (membrane osmotic method, light scattering method, ultracentrifugal method, etc.) shall be used.

(C) Methods using elongated chain length

(D) Methods using hydrodynamic volume

(E) SEC-viscosity detector method

(F) The SEC-LS method

C. Stability: The baseline shall be linear.

D. Response sensitivity of detector: The response sensitivity shall not have any molecular weight dependency. (The response sensitivity shall be calibrated if any dependency observed.)

E. Separation: The peaks of polymers shall not be overlapped by any other peaks (additives and other impurities in solvents, etc.). However, it shall not apply to cases where it is technically not feasible to separate the peaks and the molecular weight is calculated up to a point that represents a range corresponding to the whole molecular weight region including monomers and oligomers. In this case, if it is clearly confirmed that the peaks are originating from additives or other impurities, etc. in the solvent, such peaks can be excluded from the molecular weight calculation.

F. The method used to draw the baseline for low molecular region: Calculations shall be made for 2 charts with stable baseline and the average value should be obtained.

G. Data processing: The number average molecular weight (Mn), weight average molecular weight (Mw), Z average molecular weight (Mz), dispersity (Mw/Mn), and the concentration of molecules with molecular weight under 1,000, shall be determined based on the data acquired by the SEC method or any other measurement methods.