Polymer Flow Scheme (PFS) under Japan's Chemical Substance Control Law (CSCL)

The PFS tests were simplified in April, 2018.

Polymer Flow Scheme

New polymer

PSF test for reactant is necessary

Stability test in acid and alkali
Stability at pH 4.0 and 9.0
(measurement of DOC or weight, IR, molecular weight)

Simplification (See back for details)

Is reactant produced in the stability test a polymer?
- Yes
- No
- Unstable

Stable

Solubility test in water and organic solvents
Solubility in water, THF or DMF
(measurement of DOC in water or weight in organic solvents)

Insoluble → Application for approval as Polymers of Low Concern
DOES NOT contain metals other than Na, Mg, K and Ca

Soluble

Measurement of molecular weight
Is molecular weight <1000 below 1%?

- Yes → Is Mn ≥ 10,000 ?
  - Yes → Application for approval as Polymers of Low Concern
    DOES NOT contain As and Se
  - No → Are monomers existing chemical substances? Are there no specific functional groups*1 in polymer?
    - Yes → Application for approval as Polymers of Low Concern
      DOES NOT contain As and Se
    - No
- No → Is molecular weight <1000 less than 10%?
  - Yes → Bioaccumulation test
    Is molecular weight <1000 highly bioaccumulative?
    - Yes → NOT readily biodegradable and NOT highly bioaccumulative
    - No → Long-term toxicity evaluation
      Product can be neither manufactured nor imported if it has long-term toxicity.
  - No → Evaluation method equivalent to that of low-molecular-weight substances (NOT subject to PFS)

NOT readily biodegradable and NOT highly bioaccumulative

1) DOES NOT contain heavy metals.
2) If soluble in water, acid or alkali, basic skeleton is NOT cationic.
3) Chemical structure etc. poses no risk of impairing human health.
4) Chemical structure etc. poses no risk of ecotoxicity.

- No (≤10 ton/year) → Acceptable for low volume application
- No (>10 ton/year) → Screening toxicity test and/or Ecotoxicity test
- Yes → Normal application

*1 C-C double bond, C-C triple bond, C-N double bond, C-N triple bond, aziridyl group, amino group, epoxy group, sulfonic acid group, hydrazino group, phenolic hydroxyl group, fluoro group

Definition of polymer in CSCL

- The molecules are chains of one or more types of monomer units.
- ≥50% by weight is molecules containing at least 3 monomer units.
- <50% by weight is molecules of the same molecular weight.
- The number average molecular weight (Mn) is ≥ 1,000.

What is a Polymers of Low Concern (PLC) ?

A high-molecular-weight compound that meets certain requirements, such as physicochemical stability or absence of functional groups of concern

	Application for approval as Polymers of Low Concern	Normal application
Time to approval	1 to 2 months	4 to 5 months
Public announcement	Not publicized	After 5 years
Official Gazette notice reference number	Not granted	Granted
Acceptance	Anytime	10 times a year
Notification of manufacturing quantity	Unnecessary	Necessary

Relaxation of the 98% rule
(Expansion of the definition of existing chemical substances)

If a polymer consisted of >90% monomer units by weight is an existing chemical substance and the remaining each monomer is <2% (for existing monomer) or <1% (for new monomer) by weight, the polymer can be treated as the existing chemical substance.

Registration unnecessary

Main conditions: Monomers D+E+··· <10 wt.%
Monomers D, E, ··· +each new chemical substance <1 wt.%, each existing chemical substance <2 wt.%

Existing chemical substance

Monomer A — Monomer B — Monomer C — Monomer D — Monomer E ···

Monomers D and E must meet several requirements.

Amended contents of PFS test and criteria

Stability test in acid and alkali

POINT1 Decrease in number of pH conditions
(4 conditions ⇒ 2 conditions)

POINT2 Decrease in weight measurements
(new use of inorganic buffer pH4.0)

Before revision

Measurement Item	pH1.2	pH4.0	pH7.0	pH9.0
Weight	✓	✓	✓	✓
DOC	✓	Unmeasurable	✓	✓
IR/GPC	✓	✓	✓	✓

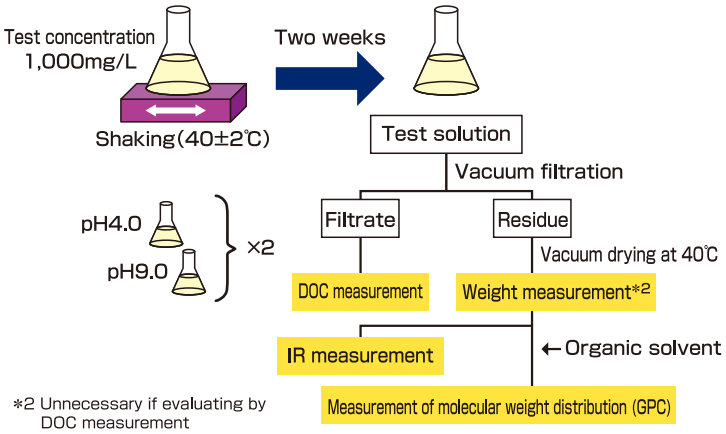
After revision

(In case of organic polymer)

Measurement Item	pH4.0		pH9.0
	Inorganic buffer *1	TG111 buffer *1	
Weight	–	✓	–
DOC	✓	Unmeasurable	✓
IR/GPC	✓		✓

*1 Consider properties of the polymer when selecting

Example of stability test



*2 Unnecessary if evaluating by DOC measurement

Criteria

Weight	Change ≤2% (n=2)
DOC	Change ≤1% (n=2)
IR spectrum	No change (n=2)
Molecular weight	No change (n=2)

Solubility test in water and organic solvents

POINT3 Decrease in number of test solvents
(5 solvents ⇒ 3 solvents)

POINT4 No need for weight measurement in water if organic polymer

Before revision

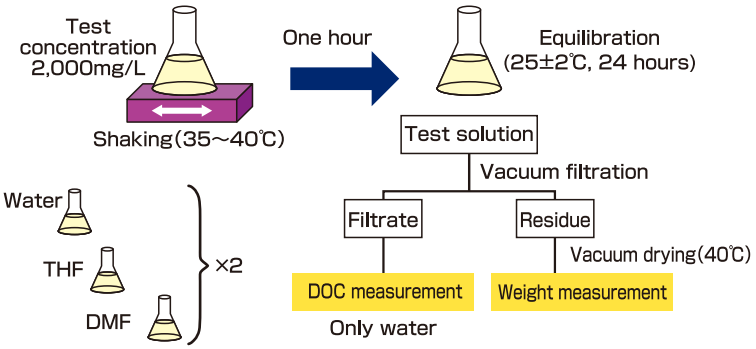
Measurement Item	Water	General-purpose solvents		Fat-soluble solvents	
		THF	DMF	Octanol	Heptane
Weight	✓	✓	✓	✓	✓
DOC	✓	–			

After revision

(In case of organic polymer)

Measurement Item	Water	General purpose solvents	
		THF	DMF
Weight	–	✓	✓
DOC	✓	–	

Example of solubility test



Criteria

DOC	Change ≤1%
Weight	Change ≤2%
【Soluble case】 Content of components of molecular weight less than 1,000	1% or less
【Soluble case】 Content of components of molecular weight <1000 exceeds 1%	No results show high bioaccumulation, and components of molecular weight <1000 are not bioaccumulative.

CERI propose suitable test designs to meet for customer requests.

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