**Concerning "Available Information on Compositions and Properties of Chemical Substances"**

(March 25, 2004: No. 0325002, Pharmaceutical and Food Safety Bureau, MHLW;
No. 4, Manufacturing Industries Bureau, METI;
No. 040325002, Environmental Policy Bureau, MOE)

Final amendment: September 16, 2004

The following is applied to the treatment of "available Information on compositions and properties" stipulated in Article 4, Paragraph 1 (including the application mutatis mutandis in Article 5.2, Paragraph 2) and Article 4.2, Paragraph 1 of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Law No. 117, 1973, hereinafter referred to as the Law)

1 Polymers that meet all the conditions from (1) to (3) described below are considered to be chemically stable against natural processes and not accumulative in living organisms; and polymers that meet all the conditions from (1) to (4) described below are regarded as those that do not correspond to Class II Monitoring Chemical substances, and polymers that meet all the conditions from (1) to (3) and (5) described below are regarded as those that do not correspond to Class III Monitoring Chemical Substances. Tests to determine whether the following conditions from (1) to (3) are satisfied shall be conducted on the attached safety evaluation test methods for polymers.

(1) Chemical substances with a number-average molecular weight of 1,000 or higher and a distribution of molecular weights that are characterized by poorly defined physicochemical properties such as solubility and melting point.

(2) No weight change exceeding the error range of the measurement shall be caused by light, heat, and change in pH. When a weight change exceeding the error range is observed, it must be proved by using other analytical methods that the polymer is physically and chemically stable e.g. no structural changes.

(3) Either condition of (i) or (ii) must be satisfied.

(i) No weight change exceeding the error range of the measurement shall occur when treated with water, lipophilicity solvents, or general-purpose solvents, therefore, the polymer is confirmed to insoluble in these solvents, and it must be confirmed that the polymer has a specific structural characteristic (such as a cross-linked structure and crystallinity) or is insoluble to acids and alkalis.

(ii) When solubility in water, lipophilicity solvents, and general-purpose solvents is confirmed and (i) are not satisfied, the content of polymers with a molecular weight of less than 1,000 is 1% or less and no information to indicate high accumulation in living organisms.

(4) No heavy metal content and, judging from information on the relationship between the chemical structure and long-term toxicity, etc. there is no indication that long-term ingestion causes adverse effects on human health.

(5) No heavy metal content, and cationic behavior is not shown when soluble in water, acids or alkalis; and judging from information on the relationship between chemical structure and toxicity to animals and plants, etc., there is no indication that there is no potential for adverse effects on the habitats or development of animals and plants.

2 Inorganic compounds that are chemically stable under light in air and water are regarded as persistent

against chemical changes due to natural processes.

3 Chemical substances with a molecular weight of 800 or higher (1,000 or higher for compounds containing two or more halogen elements) are regarded as non-accumulative in living organisms. However, this principle does not apply when the application is inappropriate judging from the structure of the chemical substance, etc.

4 Chemical substances (including elements) generated by degradability tests of chemical substances using microorganisms, etc. that do not correspond to Article 2, Paragraph 2, Clause 1 of the Law or Paragraph 6, Clause 1 of the same Article, and those that are regarded, without doubt, as chemical substances that do not correspond to Paragraph 3, Clause 1.a of the same Article are published separately.

**Handling of chemical substances generated by degradability tests, etc**.

September 16, 2004

Office of Chemical Safety,
Evaluation and Licensing Division,
Pharmaceutical and Medical Safety Bureau,
Ministry of Health, Labour and Welfare

Chemical Safety Office,
Chemical Management Policy Division,
Manufacturing Industries Bureau,
Ministry of Economy, Trade and Industry

Chemical Evaluation Office,
Policy Planning Division,
Environmental Health Department,
Environmental Policy Bureau,
Ministry of the Environment

Chemical substances (including elements) to be separately published described in Item 4 of Concerning "Information on known compositions and properties" (March 25, 2004: No. 0325002, Pharmaceutical and Food Safety Bureau, MHLW; No. 4, Manufacturing Industries Bureau, METI; No. 040325002, Environmental Policy Bureau, MOE) are as follows:

1 Chemical substances that do not correspond to Article 2, Paragraph 2, Item 1 and Paragraph 6, Item 1 of the Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the Law) and chemical substances that are regarded, without doubt, as not corresponding to Paragraph 3, Clause 1.a of the same Article are as follows:

$Na^{+}$, $K^{+}$, $NH_4^{+}$, $Mg^{2+}$, $Ca^{2+}$, $BO_3^{3-}$, $SiO_4^{4-}$, $PO_4^{3-}$, $SO_4^{2-}$, $F^{-}$, $Cl^{-}$, $Br^{-}$, $I^{-}$

2 Chemical substances that do not correspond to Article 2, Paragraph 2, Clause 1 of the Law and chemical substances that are regarded, without doubt, as not corresponding to Paragraph 3, Clause 1.a of the same Article are as follows:

$Fe^{2+}$, $Fe^{3+}$, $Zn^{2+}$, $Al^{3+}$