

## Existing Chemical Substances

The Ministry of Health, Labour and Welfare (MHLW) needs not be notified of the chemical substances defined as “existing chemical substances” in the Industrial Safety and Health Act. The existing chemical substances mean chemical substances that fall in any of the four categories (1–4) listed below.

For the existing chemical substances designated in the Industrial Safety and Health Act, please check at the following website:

“職場のあんぜんサイト” (Workplace Safety Site) in the MHLW website

<http://anzeninfo.mhlw.go.jp/index.html>

### 1 Existing chemical substances designated by a cabinet order

The existing chemical substances designated by a cabinet order mean the chemical substances specified in Paragraph 3, Article 18 of the Order for Enforcement of the Industrial Safety and Health Act which meet the definition of any of the following ((1)–(4)).

#### (1) Elements

All states (including excited state, radical, etc.) of substances that are composed of a single kind of atom (regardless of what isotope it has) and contain an elemental substance.

#### (2) Chemical substances produced naturally

Ores, crude oil, natural gas, and other chemical substances that have a state in which they occur naturally, and primary products obtained from rice, wheat, beef and other animal meats and plants, or chemical substances which are manufactured utilizing such primary products through methods such as fermentation and are not separated/refined.

#### (3) Radioactive materials

The radioactive materials specified in Paragraph 2, Article 2 of the Ordinance on Prevention of Ionizing Radiation Hazards (Labour Ministry Ordinance No. 41, 1972)

#### (4) Chemical substances the names etc. of which the Minister of Labour announced in accordance with Paragraph 2, Article 9 of the Supplementary Provisions of the Order for Enforcement of the Industrial Safety and Health Act

These are the chemical substances manufactured or imported on or before June 29, 1979, which were announced in official gazettes as listed below:

February 5, 1979: Announcement No. 9 by the Ministry of Labour (MOL)  
(May 31, 1979: Partly revised in Announcement No. 49 by the MOL)

May 31, 1979: Announcement No. 50 by the MOL

August 31, 1979: Announcement No. 98 by the MOL

Since the chemical substances that the Minister of Labour and the Minister of International Trade and Industry announced in accordance with Paragraph

3, Article 4 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. ([1] chemical substances the serial numbers for announcements in official gazettes of which are younger than those shown below, [2] chemical substances listed in the 8th Revision (1971) of the Japanese Pharmacopoeia (having no serial numbers for announcements in official gazettes)) on or before June 29, 1979 were announced simultaneously in Announcement No. 9 on February 5, 1979, these are regarded as existing chemical substances in the Industrial Safety and Health Act.

- (1) — 1197
- (2) — 3166
- (3) — 3535
- (4) — 1365
- (5) — 5363
- (6) — 1553
- (7) — 2117
- (8) — 652
- (9) — 2607

## 2 New chemical substances the names of which were announced by the Minister of Health, Labour and Welfare

These are the new chemical substances the names etc. of which the Minister of Health, Labour and Welfare announced in official gazettes in accordance with Item 3, Paragraph 3, Article 57 of the Industrial Safety and Health Act in response to notifications etc. of new chemical substances.

## 3 Specific chemical substances regarded as existing chemical substances (Notification No. 132 of March 23, 1979 by Director-General of the Labour Standards Bureau, the MHLW)

These are specific compounds etc. which are composed only of existing chemical substances and belong to any of the categories listed below:

### (1) Intermolecular compounds etc.

As listed below ([1]–[6]), when chemical substances are regarded as having a single chemical structure composed of two or more chemical substances and the individual chemical substances in the aggregate are all existing chemical substances, the chemical substances having a single chemical structure are regarded as existing chemical substances. Therefore, if any of the individual chemical substances in the aggregate is not an existing chemical substance, the MHLW needs to be notified of the aggregate of such chemical substances as a new chemical substance.

#### [1] Intermolecular compounds

Generally speaking, intermolecular compounds are compounds which are

formed by two or more kinds of stable molecules being directly bonded with one another and can be resolved into the original constituents relatively easily. They are also known as molecular compounds.

Examples:  $\text{CaCl}_2 \cdot 4\text{CH}_3\text{OH}$ ,  $\text{CoCl}_2 \cdot 6\text{NH}_3$

[2] Hydrates

Hydrates are intermolecular compounds that are formed by water and other molecules directly bonded with each other. When the compound is a crystal, the water is called crystal water.

Examples:  $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ ,  $\text{MgSO}_4 \cdot \text{H}_2\text{O}$ ,  $\text{MgCl}_2 \cdot \text{H}_2\text{O}$

[3] Inclusion compounds

Inclusion compounds are compounds that have a structure in which one of the two kinds of molecules forms tunnel-shaped, layered, or three-dimensional net-like crystals with the other kind of molecule filling the gaps between the said crystals, forming a crystal as a whole.

Examples: Inclusion compounds composed of hydroquinone and methanol

[4] Organic acid salt or organic base salt (excluding metallic salt)

Organic acid salt or organic base salt.

Any of (I) salt composed of organic acid and inorganic base, (II) salt composed of organic base and inorganic acid, and (III) salt composed of organic acid and organic base are included in this category.

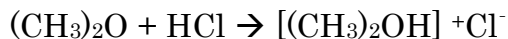
Examples of (III): Reaction products of acetic acid and pyridine

[5] Onium salt (only if both the cations and anions are generated from existing chemical substances)

Onium salt is a compound generated from a compound that has an electron pair not participating in chemical bonding being coordinate-bonded with another cationic compound using the said electron pair.

Both the cations and anions being generated from existing chemical substances means that the counterions in onium salt are constituents of the existing chemical substances.

Example 1: Dimethyloxonium chloride generated from dimethyl ether and hydrogen chloride



Example 2: Tetraethylammonium bromide (tetraethylammonium chloride and bromide ion are existing chemical substances)



[6] Double salt

Compound that is produced by two or more kinds of salt being bonded with one another in which the ions composing each salt remain as they are.

Example: Alum generated from  $\text{K}_2\text{SO}_4$  and  $[\text{Al}(\text{H}_2\text{O})_6](\text{SO}_4)_3$

(2) Block polymer and graft polymer

Block polymers and graft polymers in which the polymers constituting their

building blocks are all existing chemical substances are regarded as existing chemical substances.

[1] Block polymers

Macromolecules obtained by bonding two or more kinds of polymers of low polymerization degree (including both polymers composed of simple monomers and polymers composed of multiple monomers. The same applies to [2] Graft polymers below).

[2] Graft polymers

Macromolecules obtained by bonding (grafting) branch polymers to a trunk macromolecule.

Note: The existing chemical substances described in 3-(1) and (2) above include the substances for which notification of manufacture/import of a new chemical substance was made in accordance with Item 1, Paragraph 3, Article 57 of the Industrial Safety and Health Act, but the names of which have not been announced in official gazettes. These substances are regarded as existing chemical substances even before official announcement, and 3-(1) and (2) are applied to them.

\* The scope of application of Notification No. 132 of March 23, 1979 by Director-General of the Labour Standards Bureau, the MHLW was partly revised in February 2012.

\* Examples were added to [1]–[6] under 3-(1) in March 2013.

4 Specific macromolecules regarded as existing chemical substances

(1) Macromolecules regarded as existing chemical substances in accordance with Notification No. 504 of August 27, 1986 by Director-General of the Labour Standards Bureau, the MHLW

Macromolecules to be newly manufactured or imported which are composed of monomers etc. that are existing chemical substances (see “\*” below), the number average molecular weight of which is 2,000 or more, and which do not meet the following definitions [1]–[8] are regarded as existing chemical substances.

[1] Macromolecules having positive charge

[2] Macromolecules in which the carbon weight is less than 32% of the total weight

[3] Macromolecules in which elements other than sulfur, silicon, oxygen, hydrogen, carbon, and nitrogen are covalently bonded

[4] Macromolecules in which metal ions other than aluminum, potassium, calcium, sodium, and magnesium (including metal complex ions) are ionically bonded

- [5] Macromolecules extracted from living bodies and separated and macromolecules produced in a chemical reaction from such macromolecules, and macromolecules having a chemical structure similar to these macromolecules
- [6] Macromolecules produced from compounds containing a halogen group or a cyano group
- [7] Macromolecules having reactive functional groups (see Note 2), and the value obtained by dividing the number average molecular weight of which by the number of reactive functional groups (see “\*\*” below) in the molecular structure corresponding to the said number average molecular weight is 10,000 or smaller
- [8] Macromolecules that may resolve or depolymerize at ordinary temperature and pressure

\*: Scope of existing chemical substances defined in (1) above

The existing chemical substances defined in (1) above include substances for which notification of manufacture/import of a new chemical substance was made in accordance with Item 1, Paragraph 3, Article 57 of the Industrial Safety and Health Act, but the names of which have not been announced in official gazettes. These substances are regarded as existing chemical substances even before official announcement, and 4-(1) is applied to them.

\*\* : Examples of macromolecules containing reactive functional groups

Macromolecules having a structure of isocyanic acid group, branched acrylic acid group, branched methacrylic acid group, epoxy group, acid anhydride, acid halide, aldehyde, amine, phenols, thiophenols, sulfur-containing acid group or its derivatives, aziridines, protected isocyanic acid group, imine, isothiocyanic acid group, vinyl sulfone, halosilane group, alkoxysilane group, 3- or 4-membered ring lactone, and so on.

[Diagram]

1) Branched acrylic acid group  
Examples:

2) Branched methacrylic acid group  
Examples:

- Abolition of reports on manufacture/import of macromolecules

The announcement of August 27, 1986 required submission of reports on manufacture/import of macromolecules for macromolecules that meet the definition of 4-(1) above. The announcement was abolished on November 12, 2012, and submission of such reports has been unnecessary thereafter.

- (2) Macromolecules regarded as existing chemical substances in accordance with Notification No. 1112-2 of November 12, 2012 by the Chemical Hazards Control Division, the Industrial Safety and Health Department, the Labour Standards

Bureau, the MHLW

To ensure international conformity, the macromolecules that meet the definition of [1] or [2] listed below are also regarded as existing chemical substances, and notification of manufacture/import of a new chemical substance or confirmation application of a low-volume new chemical substance for them were made unnecessary.

In [1] and [2] below, existing chemical substances include (a) substances regarded as existing chemical substances in accordance with Notification No. 504 of August 27, 1986 by Director-General of the Labour Standards Bureau, the MHLW (see 4-(1) above) and (b) substances for which notification of manufacture/import of a new chemical substance has already been submitted, but the names of which have not been announced in official gazettes. Therefore, these substances are regarded as existing chemical substances, and [1] and [2] are applied to them.

- [1] Organic macromolecules composed of two or more kinds of monomers etc. when the other organic macromolecules composed of monomers etc. the total weight of which accounts for more than 99% are existing chemical substances. In the case of manufacturing the target organic macromolecules, if the monomers etc. the weight of which accounting for less than remaining 1% are new chemical substances, notification of manufacture/import of a new chemical substance, confirmation application of a low-volume new chemical substance for them, and so on need to have been completed.  
(Example: An A-B-C copolymer in which the A-B copolymer is an existing chemical substance and the total weight of A and B is higher than 99% of the entire copolymer)
- [2] Organic macromolecules composed of two or more kinds of monomers etc. when the other organic macromolecules composed of monomers etc. the total weight of which accounts for more than 98% of the entire macromolecule are existing chemical substances, the monomers etc. accounting for less than remaining 2% are existing chemical substances, and the monomers etc. do not meet any of the definitions (i–vi) listed below:
  - i Hazardous materials specified in Paragraph 1, Article 16 of the Order for Enforcement of the Industrial Safety and Health Act the manufacture of which is prohibited (excluding Item 9) and so on
  - ii Specific chemical substances listed in Appended Table 3 of the Order for Enforcement of the Industrial Safety and Health Act (excluding Item 1-8, Item 2-38, and Item 3-9)
  - iii Tetraalkyllead and leaded gasoline listed in Items 1 and 4 of Appended Table 5 of the Order for Enforcement of the Industrial Safety and Health Act
  - iv Organic solvents listed in Item 2 of Appended Table 5 of the Order for Enforcement of the Industrial Safety and Health Act
  - v Lead, lead alloys, and lead compounds listed in Paragraphs 1, 3, and 4, Article 1 of the Ordinance on the Prevention of Lead Poisoning (Ministry of

Labour Ordinance No. 37 of 1972)

- vi 1,3-butadiene, 1,4-dichloro-2-butene, diethyl sulfate, and 1,3-propane sultone for which the measures to be taken are specified by Paragraph 17, 18, or 19, Article 38 of the Ordinance on the Prevention of the Hazard due to Specified Chemical Substances (Ministry of Labour Ordinance No. 39 of 1972)

(Example: An A-B-C copolymer in which the A-B copolymer is an existing chemical substance, the total weight of A and B is higher than 98% of the entire copolymer, and C is an existing chemical substance (and which does not meet the definition of any of i–vi above))

Source: <https://www.mhlw.go.jp/bunya/roudoukijun/anzenisei06/01c.html>