

Outline of the partial revision of “the Cabinet Order specifying the substances under Paragraph (2) of Article 2 of the Act on Control of Household Products Containing Harmful Substances”, and “the Ordinance for enforcement of the Act on Control of Household Products Containing Harmful Substances”

The household products which contain harmful substances designated by Act on Control of Household Products Containing Harmful Substances (hereafter referred to as “the Act”) shall not be marketed in Japan if household products do not conform to the criteria (e.g., the standard value) stipulated by the Ordinance for Enforcement of the Act.

Note: The scope of household in the Act is defined in the Ordinance for Enforcement of the Act on harmful substances by harmful substance basis.

MHLW intends to designate azo compounds as harmful substances in the Act and stipulate the scope of household products, the criteria and test method concerning azo compounds by amending (i) Cabinet Order specifying the substances under Paragraph (2) of Article 2 of the Act and (ii) Ordinance for enforcement of the Act.

1. Outline of the partial revision of Cabinet Order specifying the substances under Paragraph (2) of Article 2 of the Act on Control of Household Products Containing Harmful Substances

Ministry of Health Labour and Welfare (MHLW) designates azo compounds that may cause any of the following 24 aromatic amines as “harmful substances”.

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| (1) 4-aminoazobenzene | (13) 3,3'-dichlorobenzidine |
| (2) 2-amino-4-nitrotoluene | (14) 3,3'-dimethyl-4,4'-diaminodiphenylmethane |
| (3) 4-aminobiphenyl | (15) 3,3'-dimethylbenzidine |
| (4) 4,4'-oxydianiline | (16) 3,3'-dimethoxybenzidine |
| (5) <i>o</i> -anisidine | (17) 4,4'-thiodianiline |
| (6) <i>o</i> -aminoazotoluene | (18) 2,4,5-Trimethylaniline |
| (7) <i>o</i> -toluidine | (19) 2,4-toluyldiamine |
| (8) 2,4-xylylidine | (20) 2-naphtylamine |
| (9) 2,6-xylylidine | (21) <i>p</i> -cresidine |
| (10) 4-chloro- <i>o</i> -toluidine | (22) <i>p</i> -chloroaniline |
| (11) 2,4-diaminoanisole | (23) benzidine |
| (12) 4,4'-diaminodiphenylmethane | (24) 4,4'-methylene-bis-(2-chloro-aniline) |

2. Outline of the partial revision of Ordinance for enforcement of the Act on Control of Household Products Containing Harmful Substances

(1) the scope of “household products containing the azo compounds” that are subject to the regulation will be stipulated as follow;

- The textile products with azo dyes: diapers, diaper covers, underwear, sleepwears, gloves, socks, intermediate garments, outer garments, caps, hats, beddings, floor coverings, tablecloths, collar ornaments, handkerchiefs, and towels, bath mats and related products
- The leather and/or fur products with azo dyes: underwear, gloves, intermediate garments, outer garments, caps, hats and floor coverings

(2) The criteria and test methods for the household products containing the azo compounds will be stipulated as follow:

Any of the specified 24 aromatic amines must be less than 30µg/g when tested with a gas chromatograph mass spectrometer.

(3) the test method for the household products containing triphenyltin compounds and tributyltin compounds will be revised as follow:

The test method using a gas chromatograph mass spectrometer will be used instead of flameless atomic absorption spectrometry and two-dimensional thin layer chromatography.

(4) The test method for the household products containing formaldehyde will be revised as follow.

In some operations, the test method for acetic acid and aqueous solution of ammonium acetate will be used instead of those using purified water.

3. Proposed date of adoption and Proposed date of entry into force

Proposed date of adoption: March 2015 (scheduled)

Proposed date of entry into force: 1 April 2016 (scheduled)