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Voluntary Standards for Safety and Hygiene of Nonwoven Fabrics for Disposable Diapers

October 16, 2015

1. Purpose

To ensure safety and hygiene of nonwoven fabrics used in disposable diapers, which are hygiene products, in order to minimize the impact on consumers and environment.

2. Scope

Nonwoven fabrics used in various parts of disposable diapers, and those for packaging materials which are in direct contact with the products.

3. Overview

(1) Manufacturing environment

- ① Disposable diapers shall be manufactured under a hygiene management environment

(2) Quality

- ① Significant discoloration, unusual smell and impurities shall not be permitted.

(3) Constitution

- ① Chemical safety of raw materials to the human body and environment shall be confirmed.
- ② Safety of final existing compositions shall be confirmed, regardless of by-product or additives during the production process.

4. Safety and hygiene standards

Safety and hygiene control shall be enforced in accordance with the

“Voluntary Standards for Chemical Substances” and “Standards for Manufacturing Management” set forth in the supplementary provisions. Conformity to the “Voluntary Standards for Chemical Substances” shall be confirmed with raw material manufacturers on an as-necessary basis.

- ① Safety assurance of chemical substances used in nonwoven fabrics shall be confirmed by complying with the supplementary provision 1 “Voluntary Standards for Chemical Substances.”
- ② Hygiene assurance of production process of nonwoven fabrics shall be confirmed by fulfilling the supplementary provision 2 “Standards for Manufacturing Management.”
- ③ Safety of nonwoven fabrics shall be confirmed.

5. Traceability

In case of the occurrence of defective products, an immediate response and cause investigation system shall be established.

Additional note: Regarding the definition of nonwoven fabrics, JIS L0222 shall be complied.

Supplementary Provision 1: Voluntary Standards for Chemical Substances

1. Prohibited Chemical Substances

To specify substances currently prohibited by law or convention, and furthermore, the substances which are confirmed to have serious impact on the human body and ecosystem.

Specifically, to specify those chemical substances potentially having a negative health effect, such as carcinogenicity, mutagenicity, reproductive toxicity and sensitizing properties.

Moreover, in light of the recent increase concern about ecological effects, influencing substances on aquatic organisms shall also be subject to the standards.

The following (1) to (10) shall be specified as prohibited chemical substances, and intentional inclusion to nonwoven fabrics shall be prevented.

(1) Carcinogenicity, Class 1 substances: ECHA ANNEX6 CLP Table 3.1

- (2) Mutagenicity, Class 1 substances: ECHA ANNEX6 CLP Table 3.1
- (3) Reproductive toxicity, Class 1 substances: ECHA ANNEX6 CLP Table 3.1
- (4) Sensitizing properties (skin/expiration), Class 1 substances: ECHA ANNEX6 CLP Table 3.1
- (5) Impact on aquatic organisms, acute/chronic, Class 1 substances: ECHA ANNEX6 CLP Table 3.1
- (6) Preservatives: BIT, OIT, MIT, CMI
- (7) Plasticizers: BPA, phthalic acid esters
- (8) Heavy metals: Pb, Cd, Hg, Cr(VI), +As
- (9) Ozone depleting substances and substances manufactured using these ODSs.
- (10) Dioxins: PCDDs, PCDFs, DL-PCBs

The list above of prohibited chemical substances is shown in the table in the attached page and shall be updated on an as-necessary basis.

2. Restricted Chemical Substances

When substances that are difficult to substitute or remove are used for a specific purpose, limits shall be established to manage these substances. The following (1) to (7) shall be specified as restricted chemical substances, and when intentional inclusion exists in nonwoven fabrics, the sale destination shall be notified and an allowable range shall be established in order to manage these substances.

- (1) PCB, HCB — by-products in pigment: pigments managed under BAT.
- (2) Chlorine gas, sodium hypochlorite — for use other than bleaching.
- (3) Phthalic acid esters — for use as catalyst: use under the management using BAT.
- (4) Azo pigments which generate certain amines — for use in parts that don't come in contact with skin and body fluid.
- (5) Metal elements — for use as delivery materials within the elusion standards.
- (6) Polycyclic aromatic compounds — limited to less than 3% as impurities.
- (7) Volatile organic compounds — formaldehyde: less than 5ppm

3. Others

When inclusion of restricted substances is predicted, a quantitative analysis of target components in an appropriate measurement method shall be conducted.

However, this shall not apply when safety based on scientific evidence can be proved.

4. List of Prohibited Chemical Substance (as of Oct. 16, 2015)

Targeted Substance	List of Substance
1) Carcinogenicity, Class 1 substances ECHA ANNEX6 CLP Table3.1 Refer to the Table 3.1 Carc.Cat 1 at the URL in the right section.	Table 3.1 and Table 3.2 (Annex 1) of REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
2) Mutagenicity, Class 1 substances ECHA ANNEX6 CLP Table3.1 Refer to the Table 3.1 Muta.Cat1 at the URL in the right section.	
3) Reproductive toxicity, Class 1 substances ECHA ANNEX6 CLP Table3.1 Refer to the Table 3.1 Repr.Cat1 at the URL in the right section.	
4) Sensitizing property (skin/expiration), Class 1 substances ECHA ANNEX6 CLP Table3.1 Refer to the Table 3.1 at the URL in the right section.	
5) Impact on aquatic organisms, acute/chronic, Class 1 substances ECHA ANNEX6 CLP Table3.1 Refer to the Table 3.1 at the URL in the right section.	
6) Preservatives: BIT, OIT, MIT, CMI	None
7) Plasticizers: BPA, phthalic acid esters Refer to the URL in the right section.	Structural formula, name and physico-chemical characteristics as well as usage of phthalic acid esters. URL: http://www.mhlw.go.jp/shingi/2009/06/dl/s0608-8g.pdf
8) Heavy metals: Pb, Cd, Hg, Cr(VI), +As	None
9) Ozone depleting substances and substances manufactured using these	Substances subject to restriction in the Montreal Protocol on Substances that

ODSs. Refer to the URL in the right section.	Deplete the Ozone Layer. URL: http://www.meti.go.jp/policy/chemical_management/ozone/files/law_ozone/law_ozone_laws/Montreal_Protocol_Annex.pdf
10) Dioxins: PCDDs, PCDFs, DL-PCBs	None

Supplementary Provision 2: Standards for Manufacturing Management

Manufacturing Facility

- (1) Manufacturing areas shall be structured with due consideration to daylighting, illumination and ventilation.
- (2) Restrooms shall be sectioned from manufacturing areas by partition walls.
- (3) Manufacturing buildings shall be provided with anti-insect and anti-rodent measures.
- (4) Hand-washing equipment shall be provided for workers.

Hygiene Management

- (1) Employees shall change into clothes and footwear appropriate for manufacturing.
- (2) Cleanliness shall always be maintained in the manufacturing areas, where all unsanitary objects are prohibited.
- (3) Hands and fingers shall always be kept clean using hand wash/sterilizing agents.
- (4) Clothes shall always be clean and caps/hats shall be worn to prevent hair from falling.
- (5) Facilities and equipment handling raw materials shall always be maintained in a sanitary condition before and after operation.

Supplementary provisions, October 16, 2015

Abbreviations

1. ECHA: European Chemicals Agency
2. BIT : 1, 2-Benzisothiazolin-3-one
3. OIT : 2-n-Octyl-4-isothiazoline-3-one

4. MIT: : 2-methy-4-isothiazolin-3-one
5. CMI : 5-Chloro-2-methyl-4-isothiazolin-3-one
6. BPA : bisphenol A
7. PCDDs : polychlorinated dibenzo-p-dioxins
8. PCDFs : polychlorinated dibenzofurans
9. DL-PCBs : dioxin-like polychlorinated biphenyls