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**Testing for skin primary irritation on
textile products — In vitro human skin
model method**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Textile Evaluation Technology Council (JTETC)/ Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS L 1918:2005** is replaced with this Standard.

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Testing for skin primary irritation on textile products — In vitro human skin model method

Introduction

This Japanese Industrial Standard was established in 2005 for the purpose of standardizing the in vitro test method which uses in vitro human skin model to estimate and predict primary skin irritation caused by textile products without using human or animal organisms, and has continued till today. As advancement has been seen in development of new skin model in recent years, this Standard has been revised to correspond to the necessity of reviewing the previously specified test procedure and test method.

No corresponding International Standard has been established at this point.

1 Scope

This Standard specifies the in vitro test method to estimate and predict chemical irritation on skin caused by the textile products using the in vitro human skin model.

NOTE : Due to the characteristics intrinsic to the in vitro test method, the results obtained by the test of this Standard cannot guarantee safety from clinical standpoint. This in vitro human skin model can only estimate and predict chemical irritation, and not heat and physical irritation, of primary skin irritation which directly affects the horny layer and/or keratinized cells of the skin. Furthermore, since this model does not include the cells associated with immunologic response, it cannot be used to estimate or predict allergic or chronic irritation observed on the actual skin.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS K 0115 *General rules for molecular absorptiometric analysis*

JIS K 0557 *Water used for industrial water and wastewater analysis*

JIS K 3600 *Biotechnology — Vocabulary*

JIS K 8101 *Ethanol (99.5) (Reagent)*

JIS K 8150 *Sodium chloride (Reagent)*

JIS K 8180 *Hydrochloric acid (Reagent)*

JIS K 8839 *2-Propanol (Reagent)*

JIS K 9009 *Sodium dihydrogenphosphate dihydrate (Reagent)*

- JIS K 9019 *Disodium hydrogenphosphate 12-water (Reagent)*
JIS K 9050 *L-Histidine hydrochloride monohydrate (Reagent)*
JIS L 0803 *Standard adjacent fabrics for staining of colour fastness test*
JIS L 0848 *Test method for colour fastness to perspiration*
JIS R 3505 *Volumetric glassware*
JIS Z 8401 *Guide to the rounding of numbers*
JIS Z 8805 *Glass electrodes for measurement of pH*

3 Terms and definitions

For the purposes of this Standard, the following terms and definitions apply.

3.1 in vitro human skin model

skin model having horny layer three-dimensionally reconstituted using human skin origin cells

3.2 cell survival rate

ratio (%) of the viable cell amount of in vitro human skin model under irritation to that under non-irritation

3.3 skin primary irritation

acute irritation affecting the horny layer and keratinized cells of the skin caused by textile products

3.4 chemical irritation

irritation directly affecting the horny layer and/or keratinized cells of the skin caused by chemicals included in the textile products

It is differentiated from physical skin irritation caused by such as heat and friction, etc.

3.5 in vitro testing method

method to conduct a test of tissue components and cells extracted from the living organisms ex vivo, such as in a test tube

3.6 MTT method

method to detect the cell viability of in vitro human skin model

Living cells are stained in violet.

3.7 patch test

the test to attach the test sample on the in vitro human skin model and incubate for 24 h or 48 h