事　務　連　絡
平成２７年９月９日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬食品局審査管理課

浴用剤製造販売承認基準の英訳について

医薬部外品のうち、浴用剤の製造販売の承認基準については、「浴用剤製造販売承認基準について」（平成２７年３月２５日付け薬食発 0325 第 39 号厚生労働省医薬食品局長通知）により示してきたところであるが、別添のとおり、当該基準の英訳を作成したのでお知らせいたします。

Provisional Translation
from Japanese Original

Mar 25, 2015
Notification PFSB No.0325-39

The Standards for Marketing Approval of Bath Additives

1 Scope of the standards

The standards shall apply to external preparations (hereinafter referred to as "bath additives") that contain the active ingredients listed in the attached Table and claim efficacy when used during bathing.

2 Standards

The following standards are applied to bath additives of quasi-drugs.

For bath additives that do not meet these standards, the submission of materials clearly indicating previous approval or necessary documents regarding their efficacy and safety shall be required for review.

(1) Types, standards, and quantities of active ingredients

A. Types, standards, and quantities of active ingredients that can be used in bath additives are listed in the attached Table.

B. Active ingredients that must be used are listed in Column I of the attached Table and those listed in the Column I of the attached Table must constitute 70% or more of the bath additive.

C. Any single active ingredient listed in Column I of the attached Table must constitute 25% or more of the bath additive.

(2) Standards of the active ingredients

Each active ingredient must meet the standards in accordance with the Japanese Pharmacopoeia (indicated as "P" in the attached Table), the Japanese Standards of Quasi-Drug Ingredients (indicated as "Q" in the Table), or Japan's Specifications and Standards for Food Additives (indicated as "F" in the Table).

(3) Types, standards, and quantities of additives

The types, standards, and quantities of each additive shall be provided by the notification from the Director of the Evaluation and Licensing Division in Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare. However, the quantities of active ingredients that are essentially identical to the active ingredients specified in the attached Table must not exceed the corresponding lower limits indicated in the Table.

(4) Dosage forms

Dosage forms of bath additives include powder, granule, tablet, capsule, or liquid, etc.

(5) Dose regimen and dosage

The recommended amounts of bath additives range from 10.0 g to 50.0 g (or mL) per 100 L of bath water. The labels of the products must clearly indicate instructions for correct usage, leaving no room for possible misuse.

(6) Indications and usage

To alleviate the following symptoms depending on purpose: heat rash, rough skin, bruises, sprains, stiff shoulders, neuralgia, eczema, chilblains, hemorrhoids, cold hypersensitivity, backache, rheumatism, fatigue, chapped skin, cracked skin, cold hypersensitivity before or after childbirth, and acne.

Attached Table

Column	Ingredient standard	Component name	Combination concentration (%)
I	P, Q,F	Potassium Chloride	1.0-99.0
I	P, Q	Sodium Chloride	1.0-99.0
I	F	Magnesium Chloride	1.0-99.0
I	Q	Sodium Sesquicarbonate	1.0-99.0
I	P, Q,F	Sodium Bicarbonate	1.0-99.0
I	F	Sodium Carbonate (anhydrous)	1.0-99.0
I	F	Sodium Carbonate (crystal)	1.0-99.0
I	P	Sodium Carbonate Hydrate	1.0-99.0
I	P	Dried Sodium Carbonate	1.0-99.0
I	P	Sodium Thiosulfate Hydrate	1.0-99.0
I	Q	Anhydrous Sodium Thiosulfate	1.0-99.0
I	Q	Sodium Sulfate	1.0-99.0
I	Q	Exsiccated Sodium Sulfate	1.0-99.0
I	F	Sodium Sulfate (anhydrous)	1.0-99.0
I	F	Magnesium Sulfate (crystal)	1.0-99.0
I	F	Magnesium Sulfate (dried)	1.0-99.0
II	P	Potassium Bromide	2.0-4.0
II	F	Calcium Carbonate	1.5-10.0
II	Q	Precipitated Calcium Carbonate	1.5-10.0
II	P	Precipitated Calcium Carbonate	1.5-10.0
II	Q	Alum	1.0-20.0
II	P	Aluminum Potassium Sulfate Hydrate	1.0-20.0
II	Q	Exsiccated Alum	1.0-20.0
II	F	Aluminum Potassium Sulfate (dried)	1.0-20.0
II	P	Ferrous Sulfate Hydrate	0.05-20.0