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Technical Report

SmartSan S-1 Patch Tests

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Confidential

1. Introduction

In this report, the effect of SmartSan S-1 on skin was investigated by performing safety tests utilizing the Patch Test Method.

2. Methodology

2-1 Test volunteers

Twenty healthy individuals (12 male, 8 female) with no evidence of skin abnormalities and employed in the Biochemical Laboratory volunteered to take part in SmartSan S-1 skin safety tests.

2-2 Test solutions

a) SmartSan S-1

b) 58.8w/w% ethanol (control)

2-3 Patch tests

Ten microliters of each solution was spread onto the left forearm of each volunteer, in the area midway between the inner left elbow and the left wrist. After 30 minutes of spread, the presence or absence of skin reaction in the form of erythema on the skin areas that came into spread with the test solutions was visually observed, and judged using the evaluation standards shown in Table 1 below.

Table 1. Japanese evaluation standards

Evaluation	Description
−	No reaction
±	Slight erythema
+	Erythema
++	Erythema & dropsy, popular eruption
+++	Erythema, dropsy, popular eruption & small blisters
++++	Large blisters

3. Results and Discussion

Patch test results are shown in Table 2 below. No reaction was observed in 16 volunteers. While slight erythema was observed in 4 volunteers, slight erythema was also observed with control, indicating that the effect of SmartSan S-1 on skin was low.

Table 2. Patch test results

Volunteer	Test solution	
	SmartSan S-1	58.8w/w% ethanol
Volunteer A	±	±
Volunteer B	−	−
Volunteer C	−	−
Volunteer D	−	−
Volunteer E	−	−
Volunteer F	−	−
Volunteer G	±	±
Volunteer H	−	−
Volunteer I	−	−
Volunteer J	±	±
Volunteer K	−	−
Volunteer L	−	−
Volunteer M	−	−
Volunteer N	−	−
Volunteer O	−	−
Volunteer P	−	−
Volunteer Q	−	−
Volunteer R	±	±
Volunteer S	−	−
Volunteer T	−	−