TO WHOM IT MAY CONCERN

Subject:
Registration of Bepanthen Anti Scar Gel in Vietnam

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April 14, 2022

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We, **Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel, Switzerland, Registration No. CHE-107.359.454**, hereby confirm that, the product specifications for our Consumer Health Product named Bepanthen Anti Scar Gel are defined in dossier sections STED.2.2.01_008832790_02 and STED.2.2.01_008823918_01 for the Silicone gel and Massage ball, respectively. We also confirm that the silicone gel was named Bepanthol Gel in our technical dossier.

Yours sincerely,

Bayer Consumer Care AG

Bayer Consumer Care AG BAYER

Mercy Amoussouvi
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Bepanthol gel (1610443)

STED.2.2.01 - 02

Product Specification

Signatures:

content approved	Pommerehne Diamanto (geadf)	2016-01-04 11:48:47
document approved	Fraisse Christine (gdxbc)	2016-01-04 16:25:00

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DCTM-version: 2.2

Bayer Consumer Care AG

4.7 Final Product Release Criteria (= Final product specifications)

Table 1: Specifications

TESTS[a]	THEORY	SPECIFICATIONS	
		At release	During shelf life
GENERAL CHARACTERS			
Appearance	Complies	Opalescent colourless to white gel	
Odour	Complies	Gel with specific odour	
Viscosity at 20°C	-	5 to 100 Pa.s	
MICROBIOLOGICAL QUALITY [b]		Complies with EP current edition, § 5.1.4, cutaneous use	
ASSAY OF REFERENCE INGREDIENT			
Panthenol	3.50 % (w/w)	3.15 to 3.85 %(w/w)	
POTENTIAL DEGRADATION PRODUCT OF THE REFERENCE INGREDIENT			
3-Aminopropanol (as mass fraction of Panthenol)	-	≤ 1%	≤ 5%

a Descriptions of the methods are available at the manufacturing site
b Non-routine test. Tests have to be performed at least once a year.

4.7. Final Product Release Specifications

The final product release specifications, applied by GP Grenzach (manufacturing site of the silicone gel, filling and labeling site of the finished product BEPANTHEN® Anti-Scar Gel), are presented hereunder in Table 1.

Table 1 Specifications of the final product

TESTS*	ACCEPTANCE CRITERIA
Removal force of the massage ball(1)	≥ 100 N
Identification of Polyethylene (material in contact)(2)	Complies with EP(3)

* Descriptions of the methods are available at the manufacturing site

(1) Internal test
(2) For in-house identification in case of thorough study, as for example: new supplier
(3) Refer to the IR identification method in the current Edition of the European Pharmacopoeia (§ 3.1.5).