



EFFICACY TEST OF SCH SHELLCARE® TRAX

Safety: Summary of toxicological information

TEST ITEMS	TEST METHODS	TEST RESULTS
Cytotoxicity Test	SN/T 2328-2009, MTT method	No toxicity at < 10,8 mg/mL
In vitro skin irritation - EpiSkin (Recombinant human epidermal model)	OECD 439	Not irritating
In vivo skin irritation - Human patch test	Single occlusive patch test	Not irritating
In vitro eye irritation - BCOP (Bovine corneal opacity and permeability test)	OECD 437	IVIS: 0,95, mild irritant
In vitro skin sensitization - KeratinoSens test	OECD 442D	Not sensitizing
In vitro skin sensitization - DPRA test	OECD 442C	Not sensitizing
In vitro skin sensitization - DEREK prediction	QSAR	Not sensitizing
Germ cell mutagenicity - AMES (Bacterial Reverse Mutation Assay)	OECD 471	Not mutagenic

Safety: Chemical test & microbial test

Test requested

- 1) Chemical test: Arsenic, Antimony, Cadmium, Chromium, Cobalt, Lead, Mercury, Nickel, Platinum
- 2) Microbial test: *Staphylococcus aureus*, *Canadida albicans*, bile-tolerant Gram-negative bacteria

Test methods

- 1-1) Arsenic, Antimony, Cadmium, Chromium, Cobalt, Lead, Mercury, Nickel: analysis was performed by ICP-MS/ICP-OES
- 1-2) Platinum: with reference to US EPA 3052: 1996, analysis was performed by ICP-OES
- 2) European Pharmacopoeia 8.02.6.13A

Test results

- 1) Chemical test: Arsenic, Antimony, Cadmium, Chromium, Cobalt, Lead, Mercury, Nickel, Platinum) were all not detected.
- 2) Microbial test: *Staphylococcus aureus*, *Canadida albicans*, bile-tolerant Gram-negative bacteria) were all not detected.



TEST ITEM(S)	UNIT(S)	TEST METHOD(S)	TEST RESULT(S)	METHOD DETECTION LIMIT
Arsenic	mg/kg	1-1)	Not detected	0,2
Antimony	mg/kg		Not detected	0,2
Cadmium	mg/kg		Not detected	0,2
Chromium	mg/kg		Not detected	0,2
Cobalt	mg/kg		Not detected	0,2
Lead	mg/kg		Not detected	0,2
Mercury	mg/kg		Not detected	0,2
Nickel	mg/kg	1-2)	Not detected	0,2
Platinum	mg/kg		Not detected	10

TEST ITEMS	TEST METHODS	TEST RESULTS
<i>Staphylococcus aureus/g</i>	2)	Not detected
<i>Bile-tolerant Gram-negative bacteria/g</i>		Not detected
<i>Canadida albicans/g</i>		Not detected



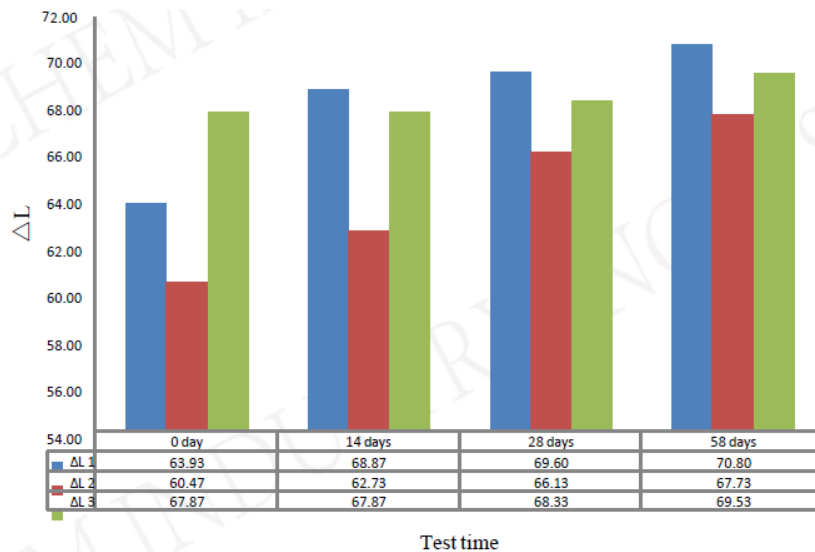
In-vivo test: Skin lightening, whitening & anti-spot

Product	2,5% and 0,5% SCH ShellCare® TRAX whitening gel
Subjects	2,5%: 15 females, 0,5%: 15 females
Age range	27 - 53 years old
Test zone	Face
Period	8 weeks
Test parameters	Determination of skin color difference is expressed in ΔL and ΔE ; ΔL (skin brightness value); ΔE (comprehensive value of skin (including brightness, glossiness, smoothness...))
Temperature	20°C- 25°C
Humidity	40% - 60%
Frequency	Twice a day after cleaning face in the morning and evening
Design of Study	Aim to assess the lightening effect of the test cosmetic product after 14 days, 28 days and 56 days application in the female subjects

Skin lightening & whitening results

The ΔL and ΔE improved when using **0,5%** SCH ShellCare® TRAX whitening gel, comparing with the untreated.

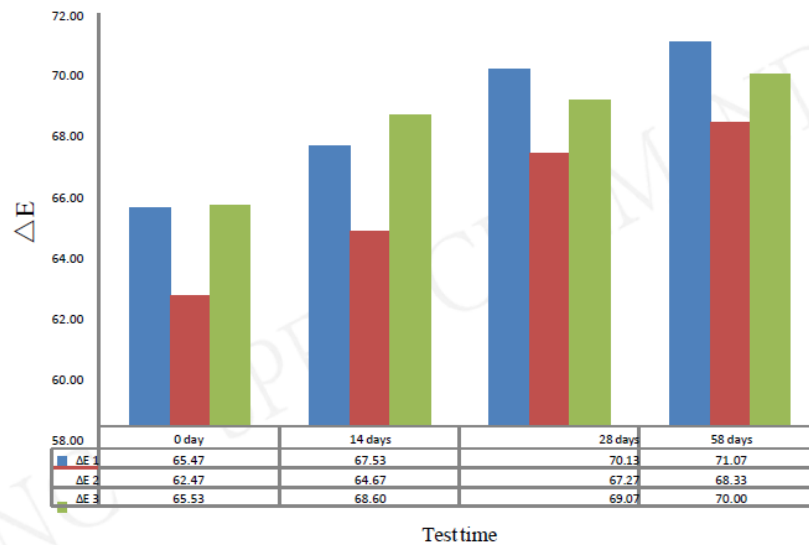
The value of ΔL (skin lightness) at different time when used 0,5% SCH ShellCare® TRAX



Comparing with the untreated, skin lightness improved significantly, which increased by 3,74% after 14 days, 6,13% after 28 days, 8,21% after 56 days by treating with 0,5% SCH ShellCare® TRAX whitening gel, respectively.



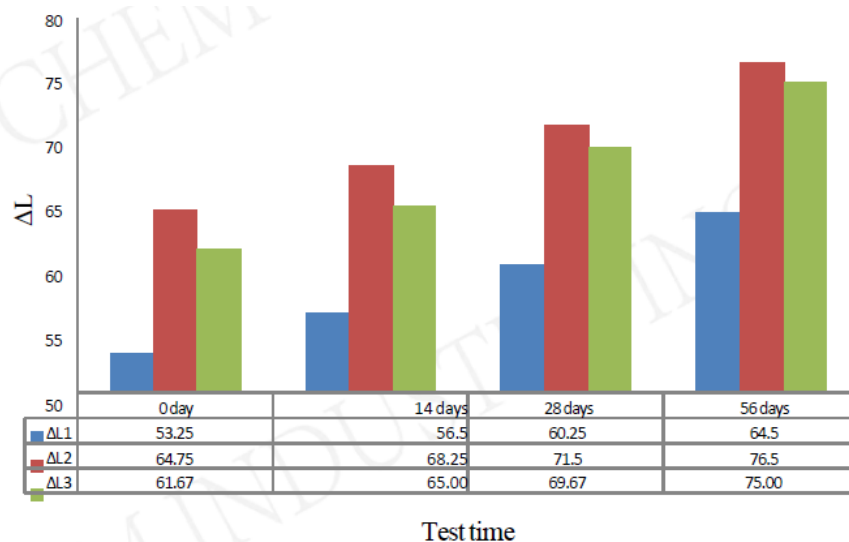
The value of ΔE (skin sensed color) at different time when used 0,5% SCH ShellCare® TRAX



Comparing with the untreated, skin sensed color improved significantly, which improved by 3,74% after 14 days, 6,68% after 28 days, 8,23% after 56 days by treating with 0,5% SCH ShellCare® TRAX whitening gel, respectively.

The ΔL and ΔE improved when using **2,5%** SCH ShellCare® TRAX whitening gel, comparing with the untreated.

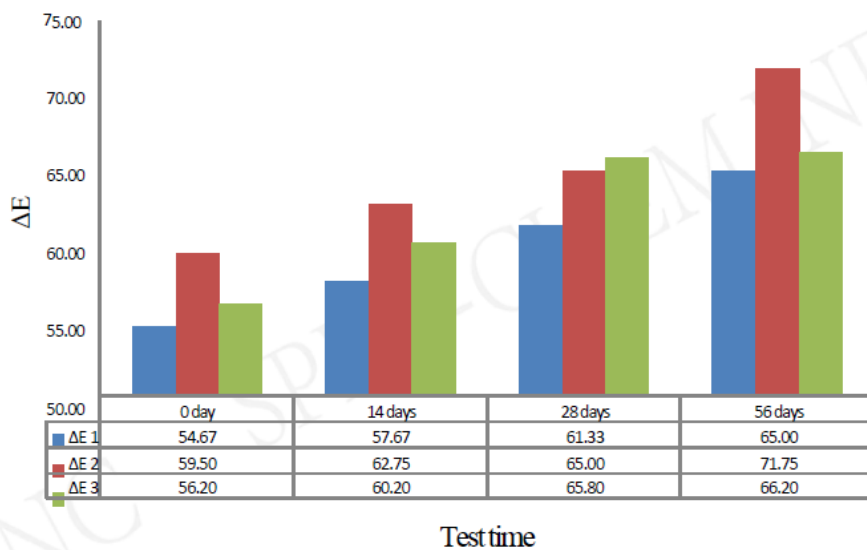
The value of ΔL (skin lightness) at different time when used 2,5% SCH ShellCare® TRAX



Comparing with the untreated, skin lightness improved significantly, which increased by 7,83% after 14 days, 12,11% after 28 days, 20,22% after 56 days by treating with 2,5% SCH ShellCare® TRAX whitening gel, respectively.



The value of ΔE (skin sensed color) at different time when used 2,5% SCH ShellCare® TRAX



Comparing with the untreated, skin sensed color improved significantly, which improved by 6,02% after 14 days, 12,77% after 28 days, 19,12% after 56 days by treating with 2,5% SCH ShellCare® TRAX whitening gel, respectively.



Lightening & whitening pictures (0,5% SCH ShellCare® TRAX whitening gel subject):



Day 0



Day 14



Day 28



Day 56



Anti-spot results

Anti-spot pictures (0,5% SCH ShellCare® TRAX whitening gel subject):



Day 0



Day 14



Day 28



Day 56

Comparing with the untreated, spot amount & spot area & spot area ratio declined significantly after 14 days. Spot amount declined by 4,17% after 14 days, 8,37% after 28 days, 12,50% after 56 days. Spot area decline 12,04% after 14 days, 18,52% after 28 days, 25,73% after 56 days. Spot area ratio decline 10,81% after 14 days, 18,92% after 28 days, 29,73% after 56 days when treating with 0,5% SCH ShellCare® TRAX whitening gel.



Anti-spot: Comparison with HQ (hydroquinone)

Comparison studies:

- Ebrahimi et al. performed a randomized, split-face trial with 3% topical tranexamic acid (TXA) versus 3% HQ + 0,01% dexamethasone twice daily for 12 weeks. The improvement in MASI (Melasma Area and Severity Index) was higher in the topical TXA group (74% vs. 65% for HQ + dexamethasone) but this was not statistically significant.
- Banihashemi et al. performed a study comparing 5% liposomal TXA versus 4% HQ cream, again failing to show a statistically significant difference between groups (54% vs. 48%).
- Atefi et al. compared 5% topical TXA twice daily with 2% HQ, with no significant difference in MASI score between groups, despite a higher patient satisfaction rate in the TXA group.

Conclusions:

- In the above trials, the adverse effects of topical TXA tended to be less common than HQ.
- Adverse events from all treatments tend to be mild, and mainly consist of skin irritation, dryness, burning, erythema, and post-inflammatory hyperpigmentation.



In-vivo test: Moisturizing

Product	2% SCH ShellCare® TRAX water solution, purified water
Subjects	10 females, 2 males
Test zone	Inside of arms
Period	0h, 1h, 2h, 3h, 4h, 5h, 7h, 24h, 48h
Test parameters	TEWL: Transepidermal water loss, WCSC: Water content in stratum corneum
Test instrument	MoistureMeter SC, VapoMeter SWL5
Temperature	20°C- 25°C
Humidity	40% - 60%
Usage	Apply quantified (0,1g ± 0,01g) samples at the labeled site
Design of Study	Aim to assess the moisturizing ability of SCH ShellCare® TRAX in 48h

Conclusions:

According to the experimental results, water content in stratum corneum showed a trend of increasing, and transepidermal water loss showed a trend of decreasing first and then increasing after using SCH ShellCare® TRAX. SCH ShellCare® TRAX can increase water content within 48h, and reduce water loss within 4h, indicating that SCH ShellCare® TRAX has good moisturizing ability.

