

1 Study name

Short title: Patch-test study of STS01 (dithranol/ProSilic) cream – safety phase

Full title: A repeat open application patch test (ROAT) using a new controlled release formulation of dithranol (dithranol/ProSilic®) cream in healthy volunteer subjects, preceded by a preliminary safety phase

Study phase: 1 (healthy subjects)

Study number: SOT03 (Safety Phase)

EudraCT number: 2022-001272-34

SAFETY PHASE Basic Summary Results

Table 1: Disposition

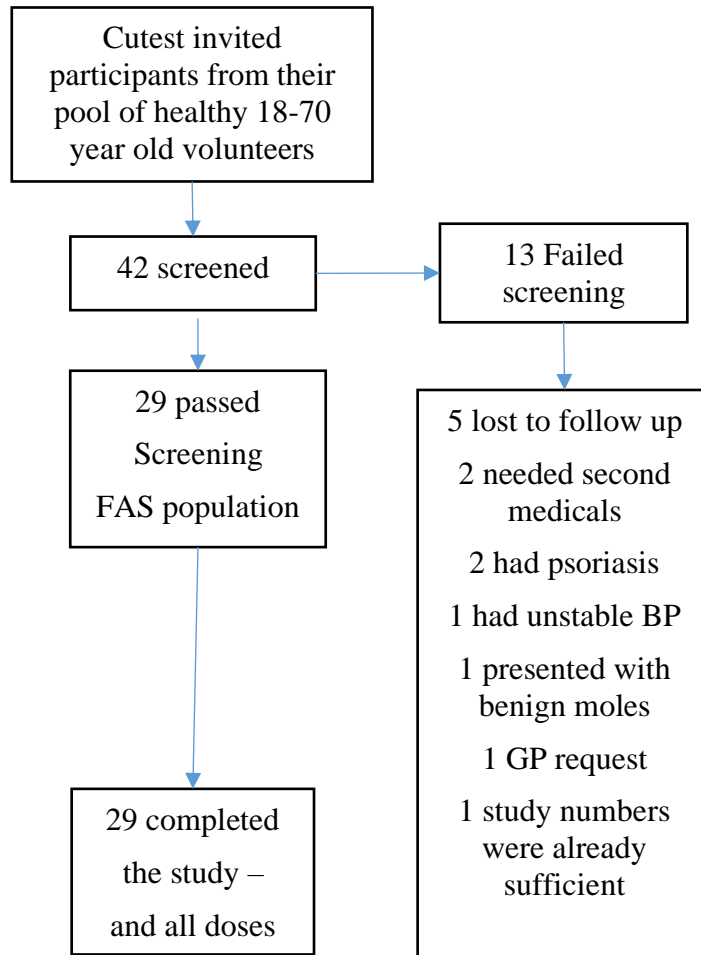


Table 2: Demographics

Observation		Statistic	Overall (N=29)
Age		N	29
		MEAN	44.3
		SD	14
		MEDIAN	43
		LQ	34
		UQ	56
		MINIMUM	21
		MAXIMUM	69
Gender	Female	n (%)	20 (69.0)
	Male	n (%)	9 (31.0)

OUTCOME MEASURES**Table 3: Adhesion - Grade Score Summary**

Removal Time	Grade	2%	1%	0.5%	0.25%	Placebo (N=29)	E45 Cream (N=29)
		dithranol/ ProSilic (N=29)	dithranol/ ProSilic (N=29)	dithranol/ ProSilic (N=29)	dithranol/ ProSilic (N=29)		
1 Hour Removal	0	29 (100)	29 (100)	29 (100)	28 (96.55)	29 (100)	29 (100)
	0.5	0 (0)	0 (0)	0 (0)	1 (3.45)	0 (0)	0 (0)
	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
2 Hour Removal	0	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4 Hour Removal	0	29 (100)	29 (100)	29 (100)	29 (100)	28 (96.55)	29 (100)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.45)	0 (0)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
8 Hour Removal	0	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	

0=> 90% (essentially no lifting/detachment of Scanpor® tape).

1=75% to < 90% adhered (some edges of Scanpor® tape detached from the skin, patch not affected).

2=50% to < 75% adhered (up to half the Scanpor® tape detached).

3=< 50% adhered (Scanpor® more than half detached).

4= Test patch detached.

Table/Item 4: Other Clinical Outcomes

Few other clinical signs other than erythema were actually reported. Of those reported 'Reaction Spreading Outside Patch Area' (SO) appeared to be dose related although the incidence diminished over application time from 1h (2%-9,1%-7,0.5%-6,0.25%-2 subjects) to 2h (2%-5,1%-2,0.5%-0,0.25%-1), 4h (2%-4,1%-1,0.5%-0,0.25%-1 subject) respectively, until actually there were no reports after 8h application suggesting a waning of this initial effect.

There were only either 1 or 2 reports of Oedema (OE) with each active dose (STS01 0.25, 0.50, 1.0, 2.0%) for all application times (1, 2, 4, 8h) with no obvious relationship to dose received.

There were only 2 reports (1 at 1% and 1 at 0.5%) of Papiloma (P) with both occurring after 8h application.

Table 5: Outcome Measures - Erythema, Colorimetry and Thermometry – LSMeans (+/-95% CI) Worst Case (N=29)

Outcome	Treatment Estimates LSMeans (+/-95% CI)						Treatment Differences LSMeans (+/-95% CI)				
	0.25% STS01	0.5% STS01	1% STS01	2% STS01	Placebo	E45 Cream	0.25% STS01 - E45	0.5% STS01 - E45	1% STS01 - E45	2% STS01 - E45	Placebo -E45
Erythema											
1h	1.28 (1.00, 1.55)	1.57 (1.29, 1.85)	1.78 (1.50, 2.05)	1.97 (1.69, 2.24)	0.02 (-0.26, 0.29)	0.07 (-0.21, 0.35)	1.21 (0.82, 1.60)	1.50 (1.11, 1.89)	1.71 (1.32, 2.10)	1.90 (1.51, 2.29)	-0.05 (-0.44, 0.34)
2h	2.16 (1.92, 2.39)	2.26 (2.02, 2.50)	2.52 (2.28, 2.76)	2.34 (2.11, 2.58)	0.05 (-0.19, 0.29)	0.03 (-0.21, 0.27)	2.12 (1.78, 2.46)	2.22 (1.89, 2.56)	2.48 (2.14, 2.82)	2.31 (1.97, 2.65)	0.02 (-0.32, 0.36)
4h	2.69 (2.52, 2.86)	2.66 (2.49, 2.82)	2.66 (2.49, 2.82)	2.69 (2.52, 2.86)	0.03 (-0.13, 0.20)	0.02 (-0.15, 0.18)	2.67 (2.44, 2.91)	2.64 (2.40, 2.87)	2.64 (2.40, 2.87)	2.67 (2.44, 2.91)	0.02 (-0.22, 0.25)
8h	2.97 (2.90, 3.03)	3.03 (2.97, 3.10)	3.07 (3.00, 3.14)	3.07 (3.00, 3.14)	0.00 (-0.07, 0.07)	0.00 (-0.07, 0.07)	2.97 (2.87, 3.06)	3.03 (2.94, 3.13)	3.07 (2.97, 3.16)	3.07 (2.97, 3.16)	-0.00 (-0.10, 0.10)
Colorimetry											
L* Average											
1h	62.69 (60.14, 65.25)	62.57 (60.02, 65.13)	61.66 (59.11, 64.22)	60.54 (57.98, 63.09)	63.78 (61.22, 66.33)	63.51 (60.95, 66.06)	-0.81 (-4.43, 2.80)	-0.93 (-4.55, 2.68)	-1.84 (-5.46, 1.77)	-2.97 (-6.58, 0.64)	0.27 (-3.34, 3.88)
2h	62.01 (59.61, 64.41)	61.75 (59.35, 64.16)	60.14 (57.73, 62.54)	59.44 (57.04, 61.85)	63.65 (61.25, 66.06)	64.09 (61.68, 66.49)	-2.08 (-5.48, 1.32)	-2.34 (-5.74, 1.06)	-3.95 (-7.35, -0.55)	-4.65 (-8.05, -1.25)	-0.44 (-3.84, 2.96)
4h	60.75 (58.41, 63.08)	60.49 (58.16, 62.83)	59.22 (56.89, 61.55)	58.51 (56.17, 60.84)	63.60 (61.27, 65.93)	63.97 (61.63, 66.30)	-3.22 (-6.52, 0.08)	-3.47 (-6.77, -0.17)	-4.74 (-8.04, -1.45)	-5.46 (-8.76, -2.16)	-0.36 (-3.66, 2.94)
8h	59.11 (56.71, 61.50)	59.81 (57.42, 62.21)	57.99 (55.60, 60.38)	57.80 (55.40, 60.19)	63.54 (61.15, 65.94)	63.71 (61.32, 66.11)	-4.61 (-7.99, -1.22)	-3.90 (-7.28, -0.52)	-5.72 (-9.11, -2.34)	-5.92 (-9.30, -2.53)	-0.17 (-3.55, 3.21)
a* Average											
1h	11.18 (10.25, 12.12)	11.66 (10.73, 12.59)	12.54 (11.60, 13.47)	13.78 (12.84, 14.71)	9.56 (8.63, 10.49)	9.98 (9.04, 10.91)	1.21 (-0.11, 2.53)	1.69 (0.37, 3.00)	2.56 (1.24, 3.88)	3.80 (2.48, 5.12)	-0.41 (-1.73, 0.90)
2h	12.25 (11.33, 13.17)	12.45 (11.53, 13.37)	14.04 (13.12, 14.96)	14.73 (13.81, 15.64)	9.75 (8.83, 10.67)	9.62 (8.70, 10.54)	2.63 (1.33, 3.93)	2.84 (1.54, 4.14)	4.43 (3.13, 5.73)	5.11 (3.81, 6.41)	0.13 (-1.17, 1.43)
4h	13.52 (12.58, 14.46)	13.56 (12.62, 14.50)	14.85 (13.91, 15.79)	15.08 (14.14, 16.02)	9.84 (8.90, 10.78)	9.28 (8.33, 10.22)	4.24 (2.91, 5.57)	4.29 (2.95, 5.62)	5.57 (4.24, 6.90)	5.80 (4.47, 7.13)	0.56 (-0.77, 1.89)
8h	14.29 (13.29, 15.29)	13.92 (12.92, 14.92)	15.35 (14.35, 16.35)	15.18 (14.18, 16.18)	10.42 (9.42, 11.41)	9.80 (8.80, 10.80)	4.49 (3.08, 5.90)	4.12 (2.71, 5.53)	5.55 (4.14, 6.96)	5.38 (3.97, 6.79)	0.62 (-0.79, 2.03)
b* Average											
1h	15.46 (14.44, 16.48)	16.07 (15.05, 17.08)	16.52 (15.51, 17.54)	17.14 (16.12, 18.15)	14.90 (13.89, 15.92)	14.64 (13.63, 15.66)	0.82 (-0.62, 2.25)	1.43 (-0.01, 2.86)	1.88 (0.44, 3.32)	2.49 (1.06, 3.93)	0.26 (-1.18, 1.70)
2h	15.76 (14.79, 16.72)	15.82 (14.86, 16.79)	16.23 (15.27, 17.19)	16.55 (15.59, 17.52)	14.89 (13.93, 15.86)	14.79 (13.82, 15.75)	0.97 (-0.39, 2.34)	1.04 (-0.33, 2.40)	1.44 (0.08, 2.81)	1.77 (0.40, 3.13)	0.11 (-1.26, 1.47)
4h	15.67 (14.75, 16.60)	15.70 (14.78, 16.63)	16.24 (15.32, 17.16)	16.46 (15.54, 17.39)	14.90 (13.97, 15.82)	15.20 (14.28, 16.12)	0.47 (-0.83, 1.78)	0.50 (-0.80, 1.81)	1.04 (-0.26, 2.34)	1.26 (-0.04, 2.57)	-0.31 (-1.61, 1.00)
8h	15.85 (14.93, 16.77)	15.81 (14.90, 16.73)	16.44 (15.52, 17.36)	16.64 (15.73, 17.56)	14.46 (13.54, 15.38)	14.52 (13.60, 15.44)	1.32 (0.02, 2.62)	1.29 (-0.01, 2.59)	1.91 (0.61, 3.21)	2.12 (0.82, 3.42)	-0.06 (-1.36, 1.24)
Delta E											
1h	5.16 (4.23, 6.08)	5.62 (4.70, 6.54)	6.86 (5.94, 7.79)	8.67 (7.74, 9.59)	3.81 (2.89, 4.74)	4.03 (3.10, 4.95)	1.13 (-0.18, 2.44)	1.59 (0.28, 2.90)	2.84 (1.53, 4.14)	4.64 (3.33, 5.95)	-0.22 (-1.52, 1.09)
2h	6.34 (5.32, 7.35)	6.68 (5.66, 7.69)	8.84 (7.83, 9.85)	9.89 (8.88, 10.90)	3.52 (2.51, 4.53)	3.21 (2.19, 4.22)	3.13 (1.70, 4.56)	3.47 (2.04, 4.90)	5.63 (4.20, 7.06)	6.68 (5.25, 8.12)	0.31 (-1.12, 1.75)

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4h	7.98 (6.90, 9.06)	8.23 (7.15, 9.31)	10.09 (9.01, 11.16)	10.84 (9.76, 11.92)	3.58 (2.51, 4.66)	3.26 (2.18, 4.33)	4.73 (3.20, 6.25)	4.97 (3.45, 6.50)	6.83 (5.30, 8.35)	7.58 (6.06, 9.11)	0.33 (-1.20, 1.85)
8h	9.76 (8.60, 10.92)	8.98 (7.82, 10.14)	11.31 (10.14, 12.47)	11.36 (10.20, 12.52)	4.11 (2.95, 5.28)	3.89 (2.73, 5.05)	5.87 (4.23, 7.51)	5.09 (3.45, 6.73)	7.42 (5.77, 9.06)	7.47 (5.83, 9.11)	0.23 (-1.42, 1.87)
Thermometry											
Temperature (C)											
1h	30.70 (30.30, 31.10)	30.82 (30.42, 31.22)	31.16 (30.77, 31.56)	31.33 (30.93, 31.72)	30.42 (30.03, 30.82)	30.24 (29.84, 30.64)	0.46 (-0.11, 1.02)	0.58 (0.02, 1.14)	0.92 (0.36, 1.48)	1.09 (0.52, 1.65)	0.18 (-0.38, 0.74)
2h	31.18 (30.80, 31.56)	31.18 (30.80, 31.56)	31.38 (31.00, 31.76)	31.65 (31.27, 32.03)	31.11 (30.73, 31.49)	30.97 (30.59, 31.35)	0.22 (-0.32, 0.75)	0.21 (-0.33, 0.75)	0.41 (-0.12, 0.95)	0.68 (0.14, 1.22)	0.14 (-0.40, 0.68)
4h	31.41 (31.05, 31.77)	31.36 (31.00, 31.72)	31.65 (31.29, 32.01)	31.82 (31.46, 32.18)	31.36 (31.00, 31.72)	31.45 (31.09, 31.81)	-0.04 (-0.55, 0.47)	-0.09 (-0.60, 0.42)	0.20 (-0.31, 0.71)	0.37 (-0.14, 0.88)	-0.09 (-0.60, 0.42)
8h	30.69 (30.25, 31.13)	30.92 (30.48, 31.36)	31.20 (30.76, 31.64)	31.64 (31.20, 32.08)	30.03 (29.60, 30.47)	29.92 (29.49, 30.36)	0.77 (0.15, 1.39)	1.00 (0.38, 1.62)	1.28 (0.66, 1.90)	1.72 (1.10, 2.34)	0.11 (-0.51, 0.73)

¹ Erythema best score=0, L*Average best scores are higher numbers and for a*Average, b*Average and Delta E best scores are lower numbers.

² Repeated Mixed Measures Model analysis are also displayed in the main report.

1h, 2h, 4h and 8h removal times

Table 6: Outcome Measures - Erythema, Colorimetry and Thermometry – LSMeans (+/-95% CI) Last Observation Carried Forward (N=29)

Outcome	Treatment Estimates LSMeans (+/-95% CI)						Treatment Differences LSMeans (+/-95% CI)					
	0.25% STS01	0.5% STS01	1% STS01	2% STS01	Placebo	E45 Cream	0.25% STS01 - E45	0.5% STS01 - E45	1% STS01 - E45	2% STS01 -E45	Placebo -E45	
Erythema												
1h	1.21 (0.94, 1.48)	1.53 (1.27, 1.80)	1.78 (1.51, 2.04)	1.93 (1.66, 2.20)	0.00 (-0.27, 0.27)	0.00 (-0.27, 0.27)	1.21 (0.83, 1.59)	1.53 (1.16, 1.91)	1.78 (1.40, 2.16)	1.93 (1.55, 2.31)	-0.00 (-0.38, 0.38)	
2h	2.03 (1.77, 2.30)	2.12 (1.85, 2.39)	2.34 (2.08, 2.61)	2.17 (1.90, 2.44)	0.00 (-0.27, 0.27)	0.00 (-0.27, 0.27)	2.03 (1.66, 2.41)	2.12 (1.74, 2.50)	2.34 (1.97, 2.72)	2.17 (1.79, 2.55)	-0.00 (-0.38, 0.38)	
4h	2.62 (2.42, 2.82)	2.57 (2.37, 2.77)	2.52 (2.32, 2.71)	2.55 (2.36, 2.75)	-0.00 (-0.20, 0.20)	0.00 (-0.20, 0.20)	2.62 (2.34, 2.90)	2.57 (2.29, 2.85)	2.52 (2.24, 2.79)	2.55 (2.27, 2.83)	-0.00 (-0.28, 0.28)	
8h	2.97 (2.92, 3.01)	3.00 (2.95, 3.05)	3.03 (2.99, 3.08)	3.03 (2.99, 3.08)	0.00 (-0.05, 0.05)	0.00 (-0.05, 0.05)	2.97 (2.90, 3.03)	3.00 (2.93, 3.07)	3.03 (2.97, 3.10)	3.03 (2.97, 3.10)	0.00 (-0.07, 0.07)	
Colorimetry												
L* Average												
1h	64.15 (61.61, 66.69)	63.48 (60.94, 66.02)	62.49 (59.95, 65.02)	61.29 (58.75, 63.82)	65.80 (63.26, 68.34)	64.87 (62.33, 67.41)	-0.72 (-4.31, 2.87)	-1.39 (-4.98, 2.20)	-2.38 (-5.97, 1.21)	-3.58 (-7.17, 0.01)	0.93 (-2.66, 4.52)	
2h	62.94 (60.50, 65.38)	63.39 (60.95, 65.83)	61.06 (58.62, 63.50)	60.42 (57.98, 62.86)	65.75 (63.31, 68.19)	65.62 (63.19, 68.06)	-2.68 (-6.13, 0.77)	-2.23 (-5.68, 1.21)	-4.57 (-8.02, -1.12)	-5.20 (-8.65, -1.76)	0.12 (-3.33, 3.57)	
4h	61.85 (59.49, 64.20)	61.30 (58.95, 63.66)	60.14 (57.79, 62.50)	59.62 (57.27, 61.98)	65.61 (63.25, 67.97)	65.58 (63.22, 67.93)	-3.73 (-7.06, -0.40)	-4.28 (-7.61, -0.94)	-5.44 (-8.77, -2.11)	-5.96 (-9.29, -2.62)	0.03 (-3.30, 3.36)	
8h	60.78 (58.34, 63.22)	61.43 (58.99, 63.87)	59.20 (56.76, 61.65)	59.16 (56.72, 61.60)	65.58 (63.14, 68.02)	65.34 (62.90, 67.78)	-4.55 (-8.01, -1.10)	-3.90 (-7.36, -0.45)	-6.13 (-9.58, -2.68)	-6.18 (-9.63, -2.72)	0.24 (-3.21, 3.70)	
a* Average												
1h	10.59 (9.70, 11.49)	11.14 (10.25, 12.04)	12.31 (11.42, 13.21)	13.35 (12.46, 14.25)	8.13 (7.24, 9.02)	8.78 (7.89, 9.68)	1.81 (0.55, 3.08)	2.36 (1.09, 3.62)	3.53 (2.27, 4.79)	4.57 (3.31, 5.83)	-0.65 (-1.92, 0.61)	
2h	11.87 (10.93, 12.81)	11.37 (10.43, 12.32)	13.54 (12.60, 14.48)	13.80 (12.86, 14.74)	8.24 (7.29, 9.18)	8.30 (7.35, 9.24)	3.57 (2.24, 4.91)	3.08 (1.74, 4.41)	5.24 (3.91, 6.58)	5.50 (4.17, 6.84)	-0.06 (-1.39, 1.28)	
4h	12.61 (11.67, 13.54)	12.85 (11.91, 13.78)	14.01 (13.08, 14.95)	14.34 (13.41, 15.28)	8.48 (7.54, 9.41)	8.13 (7.20, 9.07)	4.47 (3.15, 5.80)	4.71 (3.39, 6.03)	5.88 (4.56, 7.20)	6.21 (4.89, 7.53)	0.35 (-0.98, 1.67)	
8h	13.13 (11.99, 14.26)	12.73 (11.60, 13.86)	14.49 (13.36, 15.63)	14.11 (12.97, 15.24)	8.53 (7.39, 9.66)	7.87 (6.73, 9.00)	5.26 (3.66, 6.87)	4.86 (3.26, 6.47)	6.63 (5.02, 8.23)	6.24 (4.64, 7.85)	0.66 (-0.94, 2.27)	
b* Average												
1h	14.42 (13.40, 15.44)	14.76 (13.75, 15.78)	15.07 (14.05, 16.09)	15.30 (14.28, 16.32)	13.95 (12.93, 14.97)	13.93 (12.91, 14.94)	0.49 (-0.94, 1.93)	0.84 (-0.60, 2.27)	1.14 (-0.29, 2.58)	1.37 (-0.06, 2.81)	0.02 (-1.41, 1.46)	
2h	14.70 (13.74, 15.66)	14.92 (13.96, 15.89)	15.31 (14.35, 16.27)	15.81 (14.85, 16.77)	14.10 (13.14, 15.06)	14.17 (13.21, 15.13)	0.53 (-0.83, 1.89)	0.76 (-0.60, 2.12)	1.14 (-0.22, 2.50)	1.64 (0.28, 3.00)	-0.07 (-1.43, 1.29)	
4h	14.91 (14.04, 15.79)	14.92 (14.05, 15.80)	15.44 (14.57, 16.32)	15.51 (14.63, 16.38)	14.33 (13.46, 15.21)	14.31 (13.43, 15.19)	0.60 (-0.64, 1.84)	0.61 (-0.63, 1.85)	1.13 (-0.11, 2.37)	1.19 (-0.04, 2.43)	0.02 (-1.22, 1.26)	
8h	15.14 (14.21, 16.06)	15.03 (14.10, 15.95)	15.44 (14.52, 16.37)	15.74 (14.82, 16.67)	13.86 (12.93, 14.78)	13.92 (12.99, 14.84)	1.22 (-0.09, 2.52)	1.11 (-0.20, 2.42)	1.52 (0.22, 2.83)	1.82 (0.51, 3.13)	-0.06 (-1.37, 1.25)	
Delta E												
1h	4.03 (3.14, 4.93)	4.75 (3.86, 5.64)	6.09 (5.20, 6.99)	7.60 (6.71, 8.50)	2.91 (2.02, 3.80)	3.13 (2.23, 4.02)	0.91 (-0.35, 2.17)	1.62 (0.36, 2.89)	2.97 (1.71, 4.23)	4.48 (3.21, 5.74)	-0.22 (-1.48, 1.05)	

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Outcome	Treatment Estimates LSMeans (+/-95% CI)						Treatment Differences LSMeans (+/-95% CI)					
	0.25% STS01	0.5% STS01	1% STS01	2% STS01	Placebo	E45 Cream	0.25% STS01 - E45	0.5% STS01 - E45	1% STS01 - E45	2% STS01 -E45	Placebo -E45	
Thermometry Temperature (C)	2h	5.40 (4.35, 6.44)	4.82 (3.77, 5.87)	7.84 (6.79, 8.88)	8.73 (7.69, 9.78)	2.32 (1.27, 3.36)	2.20 (1.15, 3.25)	3.20 (1.72, 4.68)	2.62 (1.14, 4.11)	5.64 (4.16, 7.12)	6.54 (5.05, 8.02)	0.12 (-1.36, 1.60)
	4h	6.64 (5.55, 7.74)	7.19 (6.10, 8.29)	8.84 (7.74, 9.94)	9.52 (8.42, 10.62)	2.32 (1.22, 3.42)	2.40 (1.30, 3.49)	4.25 (2.69, 5.80)	4.80 (3.24, 6.35)	6.44 (4.89, 7.99)	7.12 (5.57, 8.67)	-0.07 (-1.63, 1.48)
	8h	7.76 (6.43, 9.08)	7.01 (5.69, 8.34)	9.81 (8.48, 11.13)	9.60 (8.27, 10.92)	2.58 (1.26, 3.91)	3.58 (2.26, 4.91)	4.17 (2.30, 6.05)	3.43 (1.56, 5.30)	6.22 (4.35, 8.10)	6.01 (4.14, 7.89)	-1.00 (-2.87, 0.87)
	1h	29.73 (29.32, 30.14)	29.98 (29.57, 30.39)	30.26 (29.85, 30.67)	30.37 (29.96, 30.78)	29.38 (28.97, 29.79)	29.30 (28.89, 29.71)	0.42 (-0.16, 1.01)	0.68 (0.10, 1.26)	0.96 (0.38, 1.54)	1.07 (0.49, 1.65)	0.07 (-0.51, 0.66)
	2h	30.55 (30.15, 30.94)	30.50 (30.10, 30.89)	30.64 (30.25, 31.04)	30.80 (30.40, 31.19)	30.41 (30.02, 30.81)	30.41 (30.02, 30.81)	0.13 (-0.43, 0.69)	0.08 (-0.48, 0.64)	0.23 (-0.33, 0.79)	0.38 (-0.18, 0.94)	-0.00 (-0.56, 0.55)
	4h	30.78 (30.38, 31.18)	30.68 (30.28, 31.08)	30.84 (30.45, 31.24)	30.98 (30.59, 31.38)	30.75 (30.35, 31.14)	30.85 (30.46, 31.25)	-0.08 (-0.64, 0.49)	-0.17 (-0.74, 0.39)	-0.01 (-0.57, 0.55)	0.13 (-0.43, 0.69)	-0.11 (-0.67, 0.45)
	8h	29.92 (29.42, 30.43)	30.25 (29.74, 30.75)	30.43 (29.92, 30.94)	30.76 (30.25, 31.26)	29.41 (28.91, 29.92)	29.19 (28.68, 29.70)	0.73 (0.01, 1.45)	1.06 (0.34, 1.77)	1.24 (0.52, 1.96)	1.57 (0.85, 2.28)	0.22 (-0.50, 0.94)

¹ Erythema best score=0, L*Average best scores are higher numbers and for a*Average, b*Average and Delta E best scores are lower numbers.

² Repeated Mixed Measures Model analysis are also displayed in the main report.

1h, 2h, 4h and 8h removal times

Table 7: Safety Phase – Numeric Summaries of Outcomes – Actual Scores

Outcome	Visit	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Erythema 1H removal	DAY 1- 1 HOUR	29	0.10	0.21	29	0.07	0.18	29	0.07	0.18	29	0.03	0.13	29	0.02	0.09	29	0.07	0.22
	DAY 1- 2 HOURS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 1- 4 HOURS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 1- 8 HOURS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 2	29	0.19	0.34	29	0.12	0.26	29	0.09	0.23	29	0.07	0.22	29	0.00	0.00	29	0.00	0.00
	DAY 3	29	1.17	0.72	29	1.00	0.65	29	0.88	0.69	29	0.78	0.66	29	0.00	0.00	29	0.00	0.00
	DAY 4	29	1.93	0.94	29	1.78	0.94	29	1.53	0.91	29	1.21	0.79	29	0.00	0.00	29	0.00	0.00
	WC	29	1.97	0.93	29	1.78	0.94	29	1.57	0.94	29	1.28	0.85	29	0.02	0.09	29	0.07	0.22
Erythema 2H removal	DAY 1- 2 HOURS	29	0.10	0.21	29	0.12	0.22	29	0.12	0.22	29	0.07	0.18	29	0.05	0.15	29	0.03	0.13
	DAY 1- 4 HOURS	29	0.03	0.13	29	0.00	0.00	29	0.00	0.00	29	0.02	0.09	29	0.00	0.00	29	0.00	0.00
	DAY 1- 8 HOURS	29	0.10	0.25	29	0.12	0.39	29	0.12	0.39	29	0.07	0.18	29	0.00	0.00	29	0.00	0.00
	DAY 2	29	1.10	0.81	29	1.22	0.85	29	1.03	0.82	29	0.91	0.76	29	0.00	0.00	29	0.00	0.00
	DAY 3	29	2.03	0.85	29	2.16	0.75	29	1.95	0.76	29	1.81	0.78	29	0.00	0.00	29	0.00	0.00
	DAY 4	29	2.17	0.93	29	2.34	0.97	29	2.12	0.86	29	2.03	0.81	29	0.00	0.00	29	0.00	0.00
	WC	29	2.34	0.86	29	2.52	0.83	29	2.26	0.79	29	2.16	0.70	29	0.05	0.15	29	0.03	0.13
Erythema 4H removal	DAY 1- 4 HOURS	29	0.17	0.31	29	0.19	0.34	29	0.22	0.32	29	0.22	0.34	29	0.03	0.13	29	0.02	0.09
	DAY 1- 8 HOURS	29	0.21	0.28	29	0.33	0.47	29	0.31	0.49	29	0.28	0.47	29	0.00	0.00	29	0.00	0.00
	DAY 2	29	1.81	0.89	29	1.86	0.81	29	1.84	0.85	29	2.02	0.81	29	0.00	0.00	29	0.00	0.00
	DAY 3	29	2.41	0.63	29	2.45	0.57	29	2.31	0.71	29	2.38	0.68	29	0.00	0.00	29	0.00	0.00

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	DAY 4	29	2.55	0.69	29	2.52	0.63	29	2.57	0.73	29	2.62	0.56	29	0.00	0.00	29	0.00	0.00
	WC	29	2.69	0.54	29	2.66	0.48	29	2.66	0.61	29	2.69	0.54	29	0.03	0.13	29	0.02	0.09
Erythema 8H removal	DAY 1- 8 HOURS	29	1.52	1.17	29	1.50	1.12	29	1.31	1.21	29	1.12	1.21	29	0.00	0.00	29	0.00	0.00
	DAY 2	29	2.66	0.55	29	2.83	0.38	29	2.79	0.49	29	2.72	0.53	29	0.00	0.00	29	0.00	0.00
	DAY 3	29	3.03	0.33	29	3.07	0.26	29	2.97	0.33	29	2.90	0.31	29	0.00	0.00	29	0.00	0.00
	DAY 4	29	3.03	0.19	29	3.03	0.19	29	3.00	0.00	29	2.97	0.19	29	0.00	0.00	29	0.00	0.00
	WC	29	3.07	0.26	29	3.07	0.26	29	3.03	0.19	29	2.97	0.19	29	0.00	0.00	29	0.00	0.00
L* Avg 1H removal	BASELINE ASSESSMENTS	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08
	DAY 1- 1 HOUR	29	64.89	7.04	29	65.41	7.18	29	65.83	7.27	29	65.50	7.30	29	65.39	7.26	29	65.21	7.09
	DAY 1- 2 HOURS	29	64.91	7.11	29	65.23	7.33	29	65.60	7.43	29	65.32	7.24	29	65.33	7.33	29	65.02	7.30
	DAY 1- 4 HOURS	29	63.83	7.37	29	64.22	7.48	29	64.71	7.53	29	64.61	7.41	29	64.84	7.28	29	64.77	7.25
	DAY 1- 8 HOURS	29	63.23	6.96	29	63.65	7.04	29	64.05	7.15	29	64.29	7.26	29	64.21	7.18	29	64.63	7.27
	DAY 2	29	63.77	6.64	29	64.37	7.06	29	64.79	7.34	29	64.81	7.33	29	65.06	6.95	29	64.95	7.21
	DAY 3	29	61.99	7.19	29	62.90	7.04	29	63.80	7.36	29	64.08	7.20	29	65.10	7.05	29	64.82	7.19
	DAY 4	29	61.29	6.71	29	62.49	6.92	29	63.48	7.11	29	64.15	6.73	29	65.80	6.90	29	64.87	7.17
	WC	29	60.54	6.69	29	61.66	6.96	29	62.57	7.05	29	62.69	6.96	29	63.78	7.03	29	63.51	7.09
L* Avg 2H removal	BASELINE ASSESSMENTS	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08
	DAY 1- 2 HOURS	29	63.11	6.55	29	63.56	6.70	29	64.58	7.08	29	64.70	6.98	29	65.26	7.16	29	65.09	7.01
	DAY 1- 4 HOURS	29	63.20	6.70	29	63.84	6.88	29	64.32	6.93	29	64.36	7.32	29	65.04	7.28	29	65.32	7.05
	DAY 1- 8 HOURS	29	62.62	6.17	29	62.83	6.59	29	63.46	7.03	29	63.81	7.06	29	64.65	7.11	29	64.87	6.97
	DAY 2	29	61.67	6.43	29	62.23	6.32	29	63.94	7.00	29	63.84	7.06	29	64.91	7.15	29	65.22	6.82

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	DAY 3	29	60.58	6.49	29	61.35	6.51	29	62.69	6.89	29	63.14	6.67	29	65.60	7.15	29	65.49	6.84
	DAY 4	29	60.42	6.51	29	61.06	6.37	29	63.39	6.60	29	62.94	6.28	29	65.75	7.34	29	65.62	6.76
	WC	29	59.44	6.15	29	60.14	6.08	29	61.75	6.73	29	62.01	6.50	29	63.65	7.00	29	64.09	6.85
L* Avg 4H removal	BASELINE ASSESSMENTS	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08
	DAY 1- 4 HOURS	29	61.89	6.60	29	62.66	6.88	29	63.00	7.05	29	62.93	7.14	29	64.61	7.26	29	65.05	7.06
	DAY 1- 8 HOURS	29	62.52	6.17	29	62.58	6.43	29	63.26	6.71	29	63.52	6.79	29	65.00	6.95	29	65.45	7.03
	DAY 2	29	60.85	6.20	29	60.98	6.35	29	62.65	6.63	29	62.33	6.38	29	65.28	6.95	29	65.57	6.89
	DAY 3	29	59.42	6.24	29	60.27	6.30	29	61.44	6.62	29	61.73	6.61	29	65.54	7.14	29	65.50	6.96
	DAY 4	29	59.62	6.02	29	60.14	6.13	29	61.30	6.19	29	61.85	6.38	29	65.61	6.97	29	65.58	6.80
	WC	29	58.51	5.70	29	59.22	5.91	29	60.49	6.39	29	60.75	6.30	29	63.60	7.03	29	63.97	6.75
L* Avg 8H removal	BASELINE ASSESSMENTS	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08	29	66.39	7.08
	DAY 1- 8 HOURS	29	61.00	6.15	29	60.98	6.60	29	61.71	7.16	29	61.75	6.94	29	64.15	7.23	29	64.39	7.22
	DAY 2	29	60.48	6.29	29	60.34	6.37	29	62.56	6.58	29	61.96	6.86	29	65.16	7.06	29	64.94	7.17
	DAY 3	29	59.46	6.52	29	59.62	6.50	29	60.95	6.72	29	60.64	7.01	29	65.31	7.29	29	65.02	7.31
	DAY 4	29	59.16	5.91	29	59.20	6.27	29	61.43	6.97	29	60.78	6.35	29	65.58	7.06	29	65.34	7.28
	WC	29	57.80	5.61	29	57.99	5.84	29	59.81	6.62	29	59.11	6.53	29	63.54	7.17	29	63.71	7.23
a* Avg 1H removal	BASELINE ASSESSMENTS	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04
	DAY 1- 1 HOUR	29	8.96	2.32	29	8.79	2.46	29	8.74	2.65	29	8.82	2.52	29	8.95	2.39	29	9.25	2.31
	DAY 1- 2 HOURS	29	8.64	2.10	29	8.45	2.06	29	8.29	2.44	29	8.46	2.15	29	8.75	2.29	29	8.72	2.21
	DAY 1- 4 HOURS	29	8.87	3.99	29	8.75	3.04	29	8.78	2.41	29	8.83	2.31	29	8.81	2.09	29	8.81	2.04
	DAY 1- 8 HOURS	29	9.73	2.36	29	8.40	3.89	29	9.00	2.29	29	8.73	2.19	29	8.77	2.15	29	8.45	2.58

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	DAY 2	29	9.72	2.45	29	8.89	2.19	29	8.44	2.20	29	8.51	2.62	29	8.02	1.84	29	8.46	1.79
	DAY 3	29	12.09	3.03	29	11.02	3.20	29	10.20	2.68	29	9.66	2.81	29	8.08	1.77	29	8.63	1.89
	DAY 4	29	13.35	2.73	29	12.31	2.83	29	11.14	2.66	29	10.59	2.34	29	8.13	1.73	29	8.78	2.14
	WC	29	13.78	2.80	29	12.54	2.74	29	11.66	2.61	29	11.18	2.71	29	9.56	2.13	29	9.98	2.16
a* Avg 2H removal	BASELINE ASSESSMENTS	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04
	DAY 1- 2 HOURS	29	10.32	2.62	29	10.24	2.69	29	9.55	2.49	29	9.28	2.39	29	9.14	2.26	29	9.23	2.47
	DAY 1- 4 HOURS	29	9.49	3.22	29	9.57	2.28	29	9.28	2.08	29	9.29	2.24	29	9.02	2.06	29	8.66	2.01
	DAY 1- 8 HOURS	29	9.61	2.48	29	9.92	2.25	29	9.60	2.57	29	9.33	2.06	29	8.74	2.00	29	8.93	2.18
	DAY 2	29	11.19	3.45	29	11.13	2.17	29	9.48	2.62	29	9.79	2.12	29	8.45	1.99	29	8.23	1.92
	DAY 3	29	13.54	2.78	29	13.07	2.49	29	11.85	2.71	29	11.26	2.24	29	8.02	1.69	29	8.15	1.67
	DAY 4	29	13.80	3.97	29	13.54	2.68	29	11.37	2.16	29	11.87	2.40	29	8.24	1.85	29	8.30	1.74
	WC	29	14.73	3.13	29	14.04	2.54	29	12.45	2.55	29	12.25	2.26	29	9.75	2.12	29	9.62	2.31
a* Avg 4H removal	BASELINE ASSESSMENTS	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04
	DAY 1- 4 HOURS	29	10.89	2.63	29	10.47	2.57	29	10.23	2.67	29	10.17	2.78	29	9.16	2.78	29	8.59	2.58
	DAY 1- 8 HOURS	29	10.07	1.98	29	10.04	2.18	29	9.71	2.45	29	9.64	2.42	29	8.90	2.15	29	7.72	5.32
	DAY 2	29	12.26	2.67	29	12.44	2.75	29	11.00	2.51	29	11.30	2.40	29	8.21	1.90	29	8.00	1.90
	DAY 3	29	14.43	2.87	29	14.03	2.50	29	12.90	2.94	29	12.64	3.08	29	8.11	1.86	29	8.12	1.71
	DAY 4	29	14.34	2.96	29	14.01	2.73	29	12.85	2.39	29	12.61	2.93	29	8.48	2.39	29	8.13	1.67
	WC	29	15.08	2.72	29	14.85	2.41	29	13.56	2.70	29	13.52	2.90	29	9.84	2.70	29	9.28	1.85
a* Avg 8H removal	BASELINE ASSESSMENTS	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04	29	8.11	2.04
	DAY 1- 8 HOURS	29	11.83	2.82	29	11.91	2.94	29	11.43	2.92	29	11.06	2.44	29	10.06	2.82	29	9.66	2.16

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	DAY 2	29	12.70	2.85	29	13.00	3.14	29	11.26	2.54	29	11.49	2.93	29	8.64	1.95	29	8.67	1.81
	DAY 3	29	13.92	3.17	29	14.03	3.07	29	13.18	3.05	29	13.14	3.32	29	8.43	1.93	29	8.46	1.67
	DAY 4	29	14.11	3.01	29	14.49	3.26	29	12.73	2.89	29	13.13	3.01	29	8.53	1.79	29	7.87	4.15
	WC	29	15.18	2.87	29	15.35	2.91	29	13.92	2.75	29	14.29	3.09	29	10.42	2.53	29	9.80	2.05
b* Avg 1H removal	BASELINE ASSESSMENTS	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52
	DAY 1- 1 HOUR	29	16.45	2.53	29	15.83	2.66	29	15.59	3.19	29	15.00	2.90	29	14.50	3.03	29	14.22	2.83
	DAY 1- 2 HOURS	29	16.13	2.80	29	15.64	2.67	29	15.21	2.72	29	14.85	2.72	29	14.34	2.97	29	14.02	2.84
	DAY 1- 4 HOURS	29	15.78	2.77	29	15.25	2.64	29	14.48	2.83	29	14.29	2.85	29	13.66	3.03	29	13.39	2.89
	DAY 1- 8 HOURS	29	14.87	2.89	29	14.31	3.16	29	13.71	2.93	29	13.29	2.93	29	12.81	2.99	29	12.88	3.02
	DAY 2	29	15.44	3.11	29	14.74	3.21	29	14.01	2.99	29	13.58	3.11	29	13.08	3.33	29	13.44	2.87
	DAY 3	29	15.26	2.34	29	14.90	2.47	29	14.26	2.46	29	13.91	3.05	29	13.42	3.32	29	13.82	2.68
	DAY 4	29	15.30	2.40	29	15.07	2.44	29	14.76	2.70	29	14.42	2.88	29	13.95	3.30	29	13.93	2.81
	WC	29	17.14	2.49	29	16.52	2.57	29	16.07	3.01	29	15.46	2.72	29	14.90	2.99	29	14.64	2.81
b* Avg 2H removal	BASELINE ASSESSMENTS	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52
	DAY 1- 2 HOURS	29	15.77	2.53	29	15.39	2.52	29	15.24	2.50	29	14.95	2.51	29	14.44	2.80	29	14.15	2.90
	DAY 1- 4 HOURS	29	15.57	2.44	29	15.14	2.48	29	14.98	2.62	29	14.79	2.73	29	14.02	2.79	29	14.00	2.85
	DAY 1- 8 HOURS	29	14.72	2.65	29	14.46	2.88	29	14.08	2.42	29	13.96	2.88	29	13.14	3.06	29	13.39	3.05
	DAY 2	29	15.07	2.82	29	14.91	3.06	29	14.32	3.02	29	14.17	2.98	29	13.59	3.26	29	13.81	3.01
	DAY 3	29	15.31	2.38	29	15.00	2.43	29	14.64	2.32	29	14.44	2.62	29	13.74	2.92	29	14.14	2.85
	DAY 4	29	15.81	2.53	29	15.31	2.47	29	14.92	2.49	29	14.70	2.51	29	14.10	2.82	29	14.17	2.91
	WC	29	16.55	2.33	29	16.23	2.37	29	15.82	2.64	29	15.76	2.66	29	14.89	2.79	29	14.79	2.94

Outcome	Visit	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
b* Avg 4H removal	BASELINE ASSESSMENTS	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52
	DAY 1- 4 HOURS	29	15.79	2.23	29	15.60	2.41	29	15.23	2.46	29	15.07	2.76	29	14.23	2.96	29	13.95	2.85
	DAY 1- 8 HOURS	29	15.37	2.57	29	15.12	2.67	29	14.41	2.58	29	14.50	2.67	29	13.70	3.01	29	13.78	3.16
	DAY 2	29	15.21	2.55	29	14.79	2.53	29	14.58	2.43	29	14.51	2.57	29	13.78	2.91	29	14.40	2.98
	DAY 3	29	15.29	2.10	29	15.20	2.29	29	14.69	2.14	29	14.78	2.44	29	13.85	2.74	29	14.22	2.84
	DAY 4	29	15.51	2.07	29	15.44	2.07	29	14.92	2.30	29	14.91	2.33	29	14.33	2.74	29	14.31	2.74
	WC	29	16.46	2.07	29	16.24	2.12	29	15.70	2.37	29	15.67	2.48	29	14.90	2.74	29	15.20	3.16
	b* Avg 8H removal	BASELINE ASSESSMENTS	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21	2.52	29	15.21
b* Avg 8H removal	DAY 1- 8 HOURS	29	16.35	1.96	29	16.13	2.27	29	15.46	2.65	29	15.34	2.71	29	13.51	3.15	29	13.26	3.22
	DAY 2	29	15.85	2.03	29	15.77	2.27	29	15.02	2.44	29	14.86	2.53	29	13.44	3.13	29	13.69	2.95
	DAY 3	29	15.54	1.88	29	15.51	2.11	29	14.95	2.25	29	14.86	2.45	29	13.81	3.34	29	13.77	2.88
	DAY 4	29	15.74	1.94	29	15.44	2.38	29	15.03	2.45	29	15.14	2.30	29	13.86	3.05	29	13.92	2.87
	WC	29	16.64	1.87	29	16.44	2.14	29	15.81	2.34	29	15.85	2.36	29	14.46	3.17	29	14.52	2.92
	Delta E 1H removal	BASELINE ASSESSMENTS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00
Delta E 1H removal	DAY 1- 1 HOUR	29	3.02	2.33	29	2.34	1.71	29	2.63	2.23	29	2.27	1.49	29	2.86	1.49	29	2.82	1.85
	DAY 1- 2 HOURS	29	3.34	1.87	29	2.66	1.64	29	2.44	1.89	29	2.44	1.20	29	3.07	1.24	29	3.03	1.37
	DAY 1- 4 HOURS	29	4.26	3.38	29	3.34	2.46	29	2.99	2.12	29	2.81	1.85	29	3.15	1.61	29	3.26	1.72
	DAY 1- 8 HOURS	29	4.23	2.42	29	4.28	3.59	29	3.46	1.97	29	3.52	2.04	29	4.11	1.58	29	3.82	1.76
	DAY 2	29	4.12	2.84	29	3.47	1.98	29	3.18	1.82	29	3.55	2.13	29	3.66	1.86	29	3.30	1.40
	DAY 3	29	6.32	3.60	29	5.10	3.14	29	4.10	2.48	29	3.84	2.32	29	3.56	1.58	29	3.26	1.21
	DAY 4	29	7.60	3.28	29	6.09	3.00	29	4.75	2.57	29	4.03	2.17	29	2.91	1.61	29	3.13	1.38

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	WC	29	8.67	3.28	29	6.86	2.94	29	5.62	2.72	29	5.16	2.39	29	3.81	1.72	29	4.03	1.65
Delta E 2H removal	BASELINE ASSESSMENTS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 1- 2 HOURS	29	4.55	2.61	29	4.00	2.36	29	2.97	1.79	29	2.82	1.50	29	2.43	1.48	29	2.88	1.52
	DAY 1- 4 HOURS	29	4.60	2.91	29	3.51	2.09	29	2.84	1.85	29	2.95	1.85	29	2.59	1.66	29	2.41	1.57
	DAY 1- 8 HOURS	29	5.05	2.69	29	4.48	2.29	29	3.90	2.10	29	3.65	1.63	29	3.47	1.63	29	3.25	1.54
	DAY 2	29	6.48	3.26	29	5.62	2.98	29	3.98	2.54	29	4.02	2.19	29	3.30	1.48	29	2.76	1.31
	DAY 3	29	8.21	3.50	29	7.31	2.89	29	5.57	2.84	29	4.90	2.56	29	2.60	1.19	29	2.28	1.04
	DAY 4	29	8.73	4.40	29	7.84	3.78	29	4.82	2.47	29	5.40	2.59	29	2.32	1.09	29	2.20	1.15
	WC	29	9.89	3.94	29	8.84	3.38	29	6.68	2.51	29	6.34	2.48	29	3.52	1.83	29	3.21	1.75
Delta E 4H removal	BASELINE ASSESSMENTS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 1- 4 HOURS	29	5.85	3.06	29	4.90	2.57	29	4.42	1.98	29	4.44	2.56	29	3.21	1.81	29	3.02	2.01
	DAY 1- 8 HOURS	29	5.07	2.60	29	4.78	1.96	29	4.11	1.95	29	3.75	1.86	29	2.99	1.54	29	3.62	4.40
	DAY 2	29	7.34	3.70	29	7.28	3.28	29	5.13	2.11	29	5.49	2.26	29	2.57	1.36	29	2.71	1.38
	DAY 3	29	9.65	4.18	29	8.77	3.19	29	7.25	3.00	29	6.81	3.01	29	2.40	1.16	29	2.48	1.19
	DAY 4	29	9.52	4.34	29	8.84	3.99	29	7.19	2.63	29	6.64	2.67	29	2.32	1.70	29	2.40	1.45
	WC	29	10.84	3.97	29	10.09	3.42	29	8.23	2.90	29	7.98	2.95	29	3.58	1.99	29	3.26	1.85
Delta E 8H removal	BASELINE ASSESSMENTS	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00	29	0.00	0.00
	DAY 1- 8 HOURS	29	7.04	2.99	29	6.94	3.16	29	6.09	2.83	29	5.79	1.93	29	4.23	2.32	29	3.85	2.27
	DAY 2	29	7.76	3.67	29	8.06	3.72	29	5.30	2.57	29	5.85	2.89	29	2.81	1.32	29	3.09	1.47
	DAY 3	29	9.27	4.14	29	9.20	3.49	29	7.70	3.34	29	7.92	3.57	29	2.82	1.16	29	3.00	1.43
	DAY 4	29	9.60	4.82	29	9.81	3.98	29	7.01	2.89	29	7.76	3.60	29	2.58	1.58	29	3.58	3.92

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	WC	29	11.36	4.23	29	11.31	3.82	29	8.98	2.88	29	9.76	3.26	29	4.11	2.20	29	3.89	2.01
Temperature Average 1H	BASELINE ASSESSMENTS	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12
removal	DAY 1- 1 HOUR	29	29.31	1.28	29	28.96	1.32	29	28.62	1.26	29	28.45	1.26	29	28.29	1.29	29	28.11	1.32
	DAY 1- 2 HOURS	29	29.69	1.19	29	29.33	1.22	29	28.96	1.26	29	28.84	1.20	29	28.68	1.20	29	28.31	1.29
	DAY 1- 4 HOURS	29	30.33	1.37	29	29.98	1.49	29	29.60	1.38	29	29.53	1.38	29	29.43	1.47	29	28.98	1.46
	DAY 1- 8 HOURS	29	30.58	1.17	29	30.46	1.21	29	30.21	1.18	29	30.02	1.22	29	29.84	1.33	29	29.63	1.46
	DAY 2	29	30.12	1.27	29	30.14	1.36	29	29.89	1.32	29	29.63	1.30	29	29.52	1.39	29	29.26	1.29
	DAY 3	29	30.54	1.28	29	30.51	1.32	29	30.21	1.44	29	30.16	1.38	29	29.80	1.35	29	29.58	1.26
	DAY 4	29	30.37	1.05	29	30.26	1.04	29	29.98	1.17	29	29.73	1.17	29	29.38	1.08	29	29.30	1.21
	WC	29	31.33	1.04	29	31.16	1.06	29	30.82	1.07	29	30.70	1.05	29	30.42	1.10	29	30.24	1.17
Temperature Average 2H	BASELINE ASSESSMENTS	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12
removal	DAY 1- 2 HOURS	29	30.41	1.26	29	29.93	1.20	29	29.68	1.16	29	29.63	1.13	29	29.49	1.16	29	29.38	1.07
	DAY 1- 4 HOURS	29	30.78	1.36	29	30.37	1.23	29	30.22	1.17	29	30.20	1.19	29	30.01	1.14	29	29.85	1.12
	DAY 1- 8 HOURS	29	30.95	1.10	29	30.54	1.15	29	30.28	1.13	29	30.39	1.06	29	30.25	1.15	29	30.18	1.01
	DAY 2	29	30.59	1.17	29	30.45	1.33	29	30.31	1.25	29	30.35	1.13	29	30.26	1.16	29	30.28	1.04
	DAY 3	29	31.08	1.35	29	30.93	1.32	29	30.81	1.37	29	30.84	1.25	29	30.72	1.17	29	30.66	1.00
	DAY 4	29	30.80	1.03	29	30.64	1.09	29	30.50	1.13	29	30.55	1.12	29	30.41	1.06	29	30.41	1.04
	WC	29	31.65	1.07	29	31.38	1.08	29	31.18	1.12	29	31.18	1.06	29	31.11	0.97	29	30.97	0.91
Temperature Average 4H	BASELINE ASSESSMENTS	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12
removal	DAY 1- 4 HOURS	29	31.00	1.52	29	30.55	1.40	29	30.20	1.22	29	30.16	1.13	29	30.23	1.02	29	30.23	1.10
	DAY 1- 8 HOURS	29	31.01	1.26	29	30.58	1.08	29	30.22	1.05	29	30.32	0.99	29	30.37	0.85	29	30.48	0.92

		2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
Outcome	Visit	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
	DAY 2	29	30.76	1.13	29	30.75	1.12	29	30.60	1.17	29	30.72	1.01	29	30.68	0.93	29	30.85	0.78
	DAY 3	29	31.20	1.38	29	31.08	1.30	29	30.96	1.38	29	31.13	1.18	29	31.02	0.97	29	31.15	0.92
	DAY 4	29	30.98	1.16	29	30.84	1.14	29	30.68	1.25	29	30.78	1.06	29	30.75	0.92	29	30.85	0.95
	WC	29	31.82	1.15	29	31.65	1.01	29	31.36	1.07	29	31.41	0.95	29	31.36	0.85	29	31.45	0.86
Temperature Average 8H removal	BASELINE ASSESSMENTS	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12	29	30.81	1.12
	DAY 1- 8 HOURS	29	30.92	1.40	29	30.22	1.34	29	29.76	1.38	29	29.45	1.27	29	28.96	1.31	29	28.89	1.44
	DAY 2	29	30.53	1.15	29	30.35	1.14	29	30.04	1.21	29	29.73	1.29	29	29.26	1.29	29	29.15	1.15
	DAY 3	29	30.79	1.44	29	30.58	1.34	29	30.35	1.47	29	30.32	1.46	29	29.70	1.37	29	29.58	1.28
	DAY 4	29	30.76	1.38	29	30.43	1.26	29	30.25	1.42	29	29.92	1.43	29	29.41	1.45	29	29.19	1.34
	WC	29	31.64	1.21	29	31.20	1.10	29	30.92	1.15	29	30.69	1.20	29	30.03	1.26	29	29.92	1.24

Table 8: Adverse Event Overview

		Overall (N=29)		
		n	%	freq
All Adverse Events		2	6.9	2
Pre-Treatment Signs and Symptoms (PTSS)		0	0	0
Treatment Emergent Adverse Events (TEAE)		2	6.9	2
Drug Relationship	Related	0	0	0
	Not Related	2	6.9	2
AE Severity	Mild	2	6.9	2
	Moderate	0	0	0
	Severe	0	0	0
	Life Threatening	0	0	0
	Fatal	0	0	0
AE Outcome	Resolving	1	3.4	1
	Not Resolved	1	3.4	1
SAE		0	0	0

Footnote: n=number of patients; freq=number of events

Table 9: Treatment Emergent Adverse Events Classification by Classification

System Organ Class	Preferred Term	Overall (N=29)		
		n	%	freq
Any TEAE		2	6.9	2
INFECTIONS AND INFESTATIONS		1	3.4	1
	TOOTH INFECTION	1	3.4	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		1	3.4	1
	NECK PAIN	1	3.4	1

NB: Both TEAEs considered unrelated

Footnote 1: n=number of patients; freq=number of events

Footnote 2: TEAE = Adverse Events that occur on or after the date and time of application of the first patch

1 Study name

Short title: Patch-test study of STS01 (dithranol/ProSilic) cream – repeat phase

Full title: A repeat open application patch test (ROAT) using a new controlled release formulation of dithranol (dithranol/ProSilic®) cream in healthy volunteer subjects, preceded by a preliminary safety phase

Study phase: 1 (healthy subjects)

Study number: SOT03 (Repeat Phase)

EudraCT number: 2022-001272-34

REPEAT PHASE Basic Summary Results

Table 1: Disposition

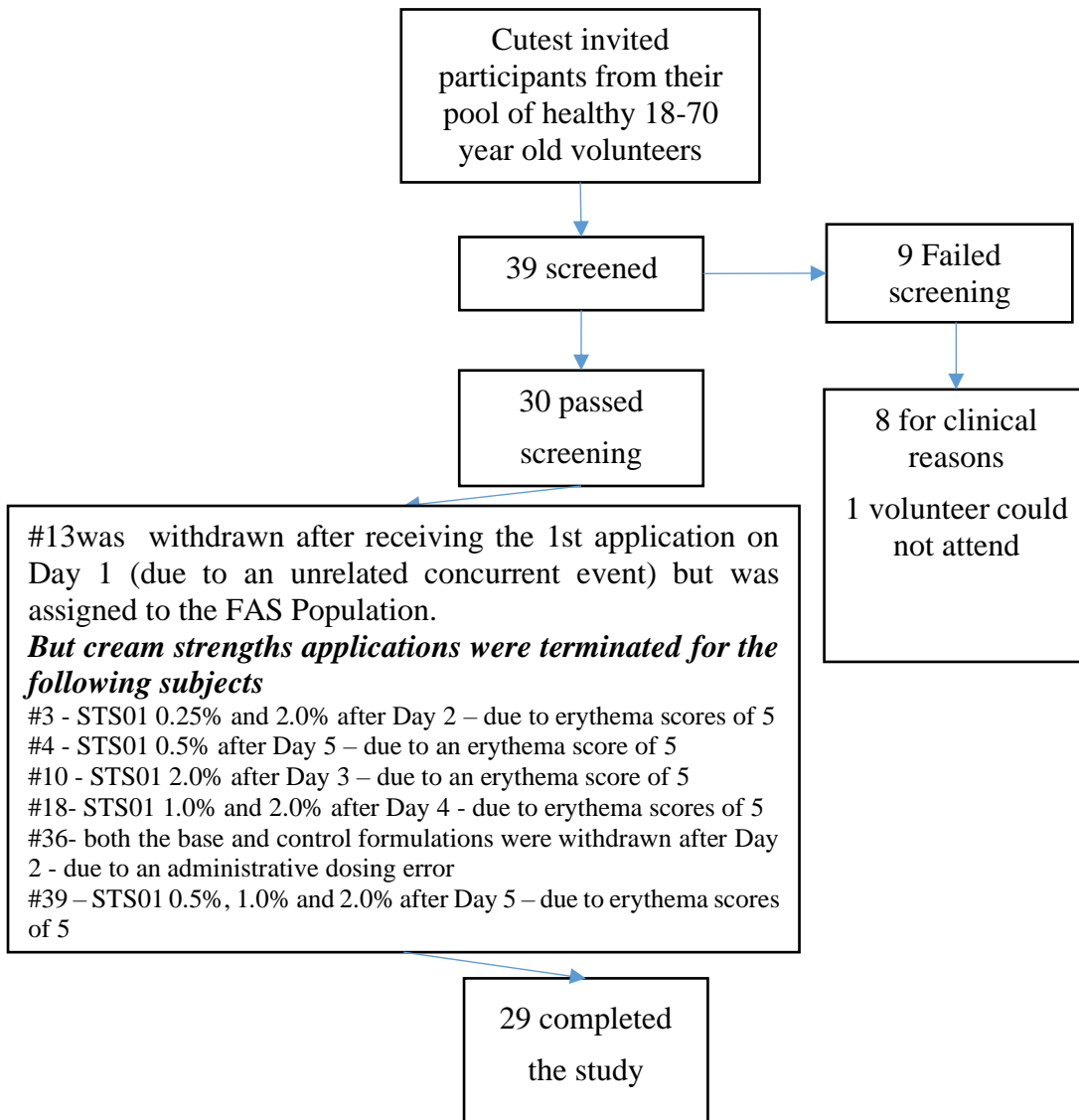


Table 2: Demographics

Observation	Statistic	Overall (N=30)
Age	N	30
	MEAN	42.63
	SD	14.81
	MEDIAN	41.50
	LQ	32.00
	UQ	52.00
	MINIMUM	18.00
	MAXIMUM	70.00
Gender	Female	n (%)
	Male	n (%)
Height (cm)	N	30
	MEAN	167.80
	SD	9.92
	MEDIAN	167.50
	LQ	160.00
	UQ	172.50
	MINIMUM	152.40
	MAXIMUM	201.00
Weight (kg)	N	30
	MEAN	83.24
	SD	21.33
	MEDIAN	79.10
	LQ	66.80
	UQ	94.40
	MINIMUM	52.40
	MAXIMUM	151.00
BMI	N	30
	MEAN	29.66
	SD	7.53
	MEDIAN	29.00
	LQ	23.50
	UQ	31.90
	MINIMUM	17.40
	MAXIMUM	53.50

OUTCOME MEASURES

Table 3: Adhesion - Grade Score Summary

Visit	Grade	2% dithranol/ ProSilic (N=30)	1% dithranol/ ProSilic (N=30)	0.5% dithranol/ ProSilic (N=30)	0.25% dithranol/ ProSilic (N=30)	Placebo (N=30)	E45 Cream (N=30)
DAY 1 IMMEDIATELY POST	0	30 (103.4)	26 (89.7)	30 (103.4)	28 (96.6)	27 (93.1)	28 (96.6)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	1 (3.4)	0 (0)	0 (0)	0 (0)	1 (3.4)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.4)	0 (0)
	4	0 (0)	3 (10.3)	0 (0)	2 (6.9)	2 (6.9)	1 (3.4)
DAY 2 IMMEDIATELY POST	0	26 (89.7)	26 (89.7)	29 (100)	25 (86.2)	25 (86.2)	28 (96.6)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	2 (6.9)	2 (6.9)	0 (0)	4 (13.8)	4 (13.8)	1 (3.4)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	3	1 (3.4)	1 (3.4)	0 (0)	0 (0)	0 (0)	0 (0)
	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DAY 3 IMMEDIATELY POST	0	28 (96.6)	28 (96.6)	27 (93.1)	24 (82.8)	27 (93.1)	26 (89.7)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	0 (0)	1 (3.4)	1 (3.4)	0 (0)	1 (3.4)
	2	0 (0)	1 (3.4)	1 (3.4)	2 (6.9)	0 (0)	0 (0)
	3	0 (0)	0 (0)	0 (0)	1 (3.4)	0 (0)	0 (0)
	4	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.4)	1 (3.4)
DAY 4 IMMEDIATELY POST	0	26 (89.7)	27 (93.1)	24 (82.8)	24 (82.8)	24 (82.8)	25 (86.2)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	1 (3.4)	2 (6.9)	4 (13.8)	4 (13.8)	3 (10.3)	2 (6.9)
	2	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.4)	0 (0)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	4	0 (0)	0 (0)	1 (3.4)	0 (0)	0 (0)	1 (3.4)
DAY 5 IMMEDIATELY POST	0	26 (89.7)	26 (89.7)	26 (89.7)	26 (89.7)	27 (93.1)	28 (96.6)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Grade 0: > 90% adhered (essentially no lifting/detachment of Scanpor « tape).

Grade 1: 75% to < 90% adhered (some edges of Scanpor « tape detached from the skin, chamber not affected).

Grade 2: 50% to < 75% adhered (up to half the Scanpor « tape detached, test site not occluded by Finn chamber).

Grade 3: < 50% adhered (Scanpor « more than half detached).

Grade 4: Test chamber detached.

Soterios Ltd, Study SOT03 Repeat Phase

Visit	Grade	2%	1%	0.5%	0.25%	Placebo	E45 Cream
		dithranol/ ProSilic (N=30)	dithranol/ ProSilic (N=30)	dithranol/ ProSilic (N=30)	dithranol/ ProSilic (N=30)		
DAY 5 IMMEDIATELY POST	1	0 (0)	1 (3.4)	1 (3.4)	2 (6.9)	0 (0)	0 (0)
	2	0 (0)	1 (3.4)	1 (3.4)	0 (0)	1 (3.4)	0 (0)
	3	0 (0)	0 (0)	1 (3.4)	0 (0)	0 (0)	0 (0)
	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DAY 6 IMMEDIATELY POST	0	25 (86.2)	24 (82.8)	26 (89.7)	23 (79.3)	27 (93.1)	25 (86.2)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	2	0 (0)	0 (0)	0 (0)	2 (6.9)	0 (0)	1 (3.4)
	3	0 (0)	2 (6.9)	0 (0)	0 (0)	1 (3.4)	1 (3.4)
4	0 (0)	1 (3.4)	1 (3.4)	3 (10.3)	0 (0)	1 (3.4)	
DAY 7 IMMEDIATELY POST	0	23 (79.3)	27 (93.1)	27 (93.1)	26 (89.7)	24 (82.8)	27 (93.1)
	0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	1	2 (6.9)	0 (0)	0 (0)	0 (0)	3 (10.3)	0 (0)
	2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3.4)
	3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	2 (6.9)	1 (3.4)	0 (0)	

Grade 0: > 90% adhered (essentially no lifting/detachment of Scanpor « tape).

Grade 1: 75% to < 90% adhered (some edges of Scanpor « tape detached from the skin, chamber not affected).

Grade 2: 50% to < 75% adhered (up to half the Scanpor « tape detached, test site not occluded by Finn chamber).

Grade 3: < 50% adhered (Scanpor « more than half detached).

Grade 4: Test chamber detached.

Table/Item 4: Other Clinical Outcomes

A range of 'mixed' types of other clinical signs other than erythema were actually reported.

Overall, there was little difference in the reporting between the active doses. However, 'Reaction outside the application area' (SO) appeared most commonly although not in an increasing dose fashion. In fact, there were more reports on STS01 0.25% than 0.5% and 1%. There were slightly more reports with STS01 2% than 1% or 0.25% and these appear due to additional: oedema (2 subjects), oedema+outside area (5 subjects), vesiculation+outside area (2 subjects) and oedema+vesiculation+outside area (2 subjects)

Table 5: Outcome Measures - Erythema, Colorimetry and Thermometry WC and LOCF LSMeans (+/-95% CI) (N=30)

Outcome	Treatment Estimates LSMeans (+/-95% CI)						Treatment Differences LSMeans (+/-95% CI)				
	0.25% STS01	0.5% STS01	1% STS01	2% STS01	Placebo	E45 Cream	0.25% STS01 - E45	0.5% STS01 - E45	1% STS01 - E45	2% STS01 -E45	Placebo -E45
Erythema											
WC	3.30 (2.96,3.64)	3.30 (2.96,3.64)	3.50 (3.16,3.84)	3.77 (3.43,4.11)	0.15 (-0.19,0.49)	0.02 (-0.32,0.36)	3.28 (2.80,3.76)	3.28 (2.80,3.76)	3.48 (3.00,3.96)	3.75 (3.27,4.23)	0.13 (-0.35,0.61)
LOCF	1.98 (1.69,2.28)	1.98 (1.69,2.28)	2.18 (1.89,2.48)	2.08 (1.79,2.38)	0.00 (-0.29,0.29)	-0.00 (-0.29,0.29)	1.98 (1.57,2.40)	1.98 (1.57,2.40)	2.18 (1.77,2.60)	2.08 (1.67,2.50)	0.00 (-0.41,0.41)
Colorimetry											
L* Average											
WC	55.83 (53.04,58.62)	56.08 (53.29,58.87)	54.69 (51.90,57.48)	54.46 (51.67,57.25)	61.32 (58.53,64.11)	62.02 (59.23,64.81)	-6.19 (-10.14,-2.25)	-5.95 (-9.89,-2.00)	-7.34 (-11.28,-3.39)	-7.56 (-11.51,-3.62)	-0.70 (-4.65,3.24)
LOCF	57.57 (54.72,60.43)	57.99 (55.13,60.84)	56.77 (53.91,59.62)	56.28 (53.43,59.13)	63.94 (61.09,66.79)	64.38 (61.52,67.23)	-6.81 (-10.84,-2.77)	-6.39 (-10.43,-2.35)	-7.61 (-11.65,-3.57)	-8.10 (-12.13,-4.06)	-0.44 (-4.47,3.60)
a* Average											
WC	15.90 (14.82,16.98)	16.17 (15.10,17.25)	17.22 (16.14,18.30)	16.62 (15.54,17.70)	10.28 (9.20,11.36)	10.70 (9.62,11.78)	5.20 (3.68,6.73)	5.48 (3.95,7.00)	6.52 (5.00,8.05)	5.92 (4.40,7.45)	-0.42 (-1.94,1.11)
LOCF	12.43 (11.51,13.34)	12.89 (11.98,13.81)	13.23 (12.32,14.15)	13.28 (12.36,14.19)	8.95 (8.04,9.86)	9.22 (8.31,10.13)	3.20 (1.91,4.50)	3.67 (2.38,4.96)	4.01 (2.72,5.30)	4.05 (2.76,5.35)	-0.27 (-1.56,1.02)
b* Average											
WC	17.85 (16.63,19.07)	17.69 (16.47,18.91)	17.78 (16.56,19.00)	17.63 (16.41,18.85)	16.86 (15.64,18.08)	16.54 (15.32,17.76)	1.31 (-0.42,3.03)	1.15 (-0.58,2.87)	1.24 (-0.48,2.96)	1.09 (-0.64,2.81)	0.32 (-1.40,2.04)
LOCF	16.33 (15.24,17.42)	16.32 (15.23,17.40)	16.25 (15.17,17.34)	16.22 (15.13,17.31)	15.73 (14.64,16.81)	15.64 (14.55,16.73)	0.69 (-0.85,2.23)	0.68 (-0.86,2.22)	0.61 (-0.92,2.15)	0.58 (-0.96,2.12)	0.09 (-1.45,1.62)
Delta E											
WC	11.25 (9.84,12.66)	11.13 (9.72,12.54)	12.78 (11.37,14.20)	12.66 (11.25,14.08)	3.58 (2.17,4.99)	3.49 (2.07,4.90)	7.76 (5.77,9.76)	7.64 (5.64,9.64)	9.30 (7.30,11.29)	9.18 (7.18,11.17)	0.09 (-1.91,2.09)
LOCF	7.89 (6.68,9.10)	7.60 (6.39,8.81)	8.78 (7.57,10.00)	9.37 (8.16,10.59)	1.83 (0.61,3.04)	2.50 (1.28,3.71)	5.40 (3.68,7.11)	5.10 (3.39,6.82)	6.29 (4.58,8.00)	6.88 (5.16,8.59)	-0.67 (-2.38,1.05)

Outcome	Treatment Estimates LSMeans (+/-95% CI)						Treatment Differences LSMeans (+/-95% CI)				
	0.25% STS01	0.5% STS01	1% STS01	2% STS01	Placebo	E45 Cream	0.25% STS01 - E45	0.5% STS01 - E45	1% STS01 - E45	2% STS01 -E45	Placebo -E45
Thermometry											
Temperature (C)											
WC	31.71 (31.28,32.14)	31.54 (31.11,31.97)	31.35 (30.92,31.78)	31.29 (30.86,31.72)	31.68 (31.25,32.11)	31.30 (30.87,31.73)	0.42 (-0.19,1.02)	0.24 (-0.36,0.85)	0.05 (-0.56,0.66)	-0.01 (-0.62,0.60)	0.38 (-0.23,0.99)
LOCF	30.58 (30.09,31.07)	30.28 (29.79,30.77)	30.10 (29.60,30.59)	30.10 (29.60,30.59)	30.54 (30.05,31.03)	30.18 (29.68,30.67)	0.40 (-0.29,1.10)	0.11 (-0.59,0.80)	-0.08 (-0.78,0.62)	-0.08 (-0.78,0.62)	0.36 (-0.33,1.06)

¹ Erythema best score=0, L*Average best scores are higher numbers and for a*Average, b*Average and Delta E best scores are lower numbers.

² Repeated Mixed Measures Model analysis are also displayed in the main report.

³ WC = Worst Case; LOCF = Last Observation Carried Forward.

Table 6: Repeat Phase - Summaries of Outcomes – Actual Scores

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Erythema																		
Day 1 Immediately Post	30	0.17	0.24	30	0.18	0.25	29	0.16	0.24	30	0.15	0.23	29	0.26	0.29	29	0.02	0.09
Day 1 1h Post	30	0.02	0.09	30	0.02	0.09	30	0.03	0.13	30	0.00	0.00	30	0.02	0.09	30	0.02	0.09
Day 2 Pre Application	29	0.19	0.43	29	0.07	0.18	29	0.03	0.13	29	0.05	0.15	29	0.00	0.00	29	0.00	0.00
Day 2 Immediately Post	29	0.33	0.31	29	0.38	0.34	29	0.36	0.40	29	0.34	0.36	29	0.31	0.31	29	0.02	0.09
Day 2 1h Post	29	0.21	0.28	29	0.28	0.37	29	0.17	0.24	29	0.12	0.26	29	0.00	0.00	29	0.00	0.00
Day 3 Pre Application	29	1.19	1.24	29	1.12	1.15	29	0.95	0.88	29	0.91	0.97	29	0.02	0.09	29	0.00	0.00
Day 3 Immediately Post	29	1.33	1.23	29	1.05	0.88	29	0.84	0.67	29	0.95	1.00	28	0.13	0.22	28	0.04	0.13
Day 3 1h Post	29	1.38	1.05	29	1.19	1.01	29	1.10	0.76	29	1.07	1.01	28	0.02	0.09	28	0.00	0.00
Day 4 Pre Application	29	2.34	1.25	29	2.09	1.30	29	1.78	0.98	29	1.60	1.22	28	0.02	0.09	28	0.00	0.00
Day 4 Immediately Post	29	2.10	1.17	29	1.74	1.22	29	1.76	1.01	29	1.57	1.20	28	0.16	0.31	28	0.00	0.00
Day 4 1h Post	29	2.48	1.39	29	1.97	1.25	29	2.05	1.04	29	1.79	1.21	28	0.00	0.00	28	0.00	0.00
Day 5 Pre Application	29	2.59	1.24	29	2.31	1.16	29	2.28	0.99	29	1.90	1.00	28	0.02	0.09	28	0.00	0.00
Day 5 Immediately Post	29	2.93	1.10	29	2.48	1.15	29	2.24	1.18	29	1.91	1.04	28	0.11	0.25	28	0.04	0.13
Day 5 1h Post	29	3.07	1.13	29	2.74	1.12	29	2.52	1.24	29	2.07	0.99	28	0.02	0.09	28	0.00	0.00
Day 6 Pre Application	29	2.64	1.17	29	2.33	1.25	29	2.10	1.21	29	1.88	1.18	28	0.00	0.00	28	0.00	0.00
Day 6 Immediately Post	29	3.05	1.10	29	2.74	1.15	29	2.53	1.21	29	2.34	1.13	28	0.04	0.13	28	0.04	0.13
Day 6 1h Post	29	2.76	1.24	29	2.59	1.26	29	2.43	1.18	29	1.97	1.04	28	0.00	0.00	28	0.00	0.00
Day 7 Pre Application	29	3.05	1.17	29	2.81	1.25	29	2.79	1.11	29	2.48	1.08	28	0.00	0.00	28	0.00	0.00
Day 7 Immediately Post	29	3.05	1.26	29	2.90	1.11	29	2.71	1.25	29	2.59	1.23	28	0.02	0.09	28	0.00	0.00
Day 7 1h Post	29	3.26	1.23	29	2.98	1.23	29	2.90	1.11	29	2.88	1.24	28	0.11	0.57	28	0.00	0.00
Day 8	29	3.12	1.13	29	2.88	1.18	29	2.36	1.03	29	2.48	1.01	28	0.00	0.00	28	0.00	0.00
Day 9	29	3.12	1.00	29	2.76	0.87	29	2.60	0.98	29	2.55	1.01	28	0.00	0.00	28	0.00	0.00
Day 10	29	3.09	1.05	29	2.69	0.76	29	2.60	0.94	29	2.50	0.87	28	0.00	0.00	28	0.00	0.00

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 11	29	2.64	1.08	29	2.57	1.08	29	2.19	0.97	29	2.29	0.99	28	0.00	0.00	28	0.00	0.00
Day 12	29	2.40	1.21	29	2.33	0.93	29	2.12	0.94	29	2.16	1.05	28	0.00	0.00	28	0.00	0.00
Day 13	29	2.40	0.94	29	2.34	0.96	29	2.19	0.97	29	2.31	1.06	28	0.00	0.00	28	0.00	0.00
Day 16	29	2.16	0.88	29	2.26	0.91	29	2.05	0.95	29	2.05	0.99	28	0.00	0.00	28	0.00	0.00
WC	30	3.77	1.14	30	3.50	1.04	30	3.30	1.09	30	3.30	1.21	30	0.15	0.56	30	0.02	0.09
LOCF	30	2.08	0.95	30	2.18	0.99	30	1.98	1.00	30	1.98	1.04	30	0.00	0.00	30	0.00	0.00
L* Average																		
Baseline	30	64.15	8.12	30	64.15	8.12	30	64.15	8.12	30	64.15	8.12	30	64.15	8.12	30	64.15	8.12
Day 1 Immediately Post	30	62.02	8.05	30	62.23	7.28	30	62.67	7.66	30	62.30	7.48	30	62.38	8.25	30	63.64	7.32
Day 1 1h Post	30	62.50	8.41	30	62.78	7.55	30	63.14	7.54	30	62.92	7.93	30	63.36	8.38	30	64.05	7.48
Day 2 Pre Application	29	62.15	8.13	29	62.39	7.37	29	62.90	8.00	29	62.59	7.77	29	63.41	8.45	29	63.67	7.33
Day 2 Immediately Post	29	60.82	7.91	29	61.08	7.40	29	61.53	6.99	29	61.16	7.81	29	62.08	8.10	29	62.83	7.43
Day 2 1h Post	29	61.73	7.68	29	61.72	7.32	29	62.13	7.43	29	61.90	7.90	29	62.84	8.48	29	63.51	7.60
Day 3 Pre Application	29	59.87	7.56	29	60.70	6.54	29	61.48	7.13	29	61.03	7.63	29	63.53	8.55	29	64.02	7.39
Day 3 Immediately Post	28	59.29	7.29	29	60.10	6.41	29	60.65	7.11	28	60.16	7.38	28	62.49	8.09	28	63.55	7.08
Day 3 1h Post	28	59.30	7.20	29	59.93	6.37	29	60.51	6.80	28	60.26	7.45	28	63.25	8.23	28	63.92	7.33
Day 4 Pre Application	28	57.93	7.36	29	58.93	5.83	29	59.54	6.40	28	59.87	7.13	28	63.54	8.70	28	63.81	7.89
Day 4 Immediately Post	27	56.69	7.18	28	57.50	6.04	29	58.54	6.44	28	58.54	6.93	28	61.87	8.44	28	63.12	7.37
Day 4 1h Post	26	56.80	7.53	28	57.83	5.97	29	59.07	6.50	28	58.75	6.77	28	62.58	8.74	28	63.48	7.69
Day 5 Pre Application	26	56.35	7.51	28	58.06	6.12	29	58.50	6.76	28	58.52	7.11	28	63.49	8.77	28	63.81	7.64
Day 5 Immediately Post	25	55.16	7.12	27	56.59	5.81	29	57.18	6.27	28	57.40	6.64	28	61.91	8.04	28	63.30	7.05
Day 5 1h Post	25	54.94	7.53	27	56.33	5.62	28	57.71	6.39	28	57.89	7.17	28	62.59	8.92	28	63.55	7.75
Day 6 Pre Application	25	55.02	7.44	27	56.59	5.84	28	57.92	6.52	28	58.04	6.86	28	63.11	8.18	28	63.86	7.04
Day 6 Immediately Post	25	54.24	7.04	27	55.89	5.53	27	56.96	6.71	28	56.94	6.66	28	62.16	7.96	28	63.62	6.87
Day 6 1h Post	25	54.46	7.27	27	55.93	5.93	27	57.37	6.64	28	57.24	6.72	28	62.83	8.25	28	63.83	7.29
Day 7 Pre Application	25	54.84	7.26	27	56.39	5.64	27	58.08	6.60	28	58.18	6.70	28	63.25	8.30	28	63.72	7.38
Day 7 Immediately Post	24	54.46	6.86	27	55.23	5.78	26	56.85	6.58	27	56.80	6.79	28	61.65	7.91	28	62.82	7.09

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 7 1h Post	24	54.89	7.19	27	55.34	5.79	26	57.12	6.53	27	57.14	6.82	28	62.47	8.32	28	63.62	7.60
Day 8	24	54.53	7.03	27	55.43	5.41	26	57.19	6.75	27	57.05	6.76	28	63.49	8.06	28	64.07	7.38
Day 9	24	54.34	7.36	27	55.29	5.76	26	57.73	6.71	27	57.27	7.16	28	63.65	8.44	28	63.95	7.58
Day 10	24	55.20	7.70	27	55.76	6.20	26	57.33	7.03	27	57.20	7.08	28	63.41	8.85	28	64.12	7.21
Day 11	24	55.09	7.57	27	55.50	6.50	26	57.20	7.15	27	57.07	7.19	28	63.80	8.29	28	64.26	6.97
Day 12	24	54.94	7.51	27	55.60	6.68	26	56.94	7.29	27	56.92	7.63	28	63.51	8.43	28	64.18	7.42
Day 13	24	54.79	7.33	27	55.44	6.56	26	57.02	7.37	27	57.08	7.12	28	63.57	7.91	28	63.71	7.18
Day 16	24	55.20	8.26	27	55.91	6.62	26	57.41	7.88	27	57.04	8.07	28	63.87	8.60	28	64.21	7.30
WC	30	54.46	8.56	30	54.69	6.81	30	56.08	7.27	30	55.83	7.74	30	61.32	8.47	30	62.02	7.48
LOCF	30	56.28	8.59	30	56.77	6.97	30	57.99	7.86	30	57.57	8.23	30	63.94	8.50	30	64.38	7.24
a* Average																		
Baseline	30	9.06	2.41	30	9.06	2.41	30	9.06	2.41	30	9.06	2.41	30	9.06	2.41	30	9.06	2.41
Day 1 Immediately Post	30	10.66	3.10	30	10.55	2.88	30	10.28	3.28	30	10.45	2.18	30	10.59	2.75	30	9.97	2.45
Day 1 1h Post	30	9.42	2.51	30	9.37	2.27	30	9.30	2.44	30	9.36	2.12	30	9.04	2.32	30	9.15	2.02
Day 2 Pre Application	29	10.17	2.37	29	10.22	2.34	29	9.92	2.57	29	9.80	2.16	29	9.11	2.32	29	9.42	2.30
Day 2 Immediately Post	29	11.39	2.87	29	11.44	2.43	29	11.27	2.70	29	10.99	2.01	29	10.65	2.32	29	10.20	2.24
Day 2 1h Post	29	10.22	2.16	29	10.47	2.26	29	9.94	2.39	29	10.03	2.08	29	9.27	2.23	29	9.45	2.28
Day 3 Pre Application	29	12.94	2.69	29	12.62	1.91	29	11.97	2.66	29	11.59	2.88	29	9.02	2.36	29	9.29	2.43
Day 3 Immediately Post	28	13.17	2.76	29	13.22	2.34	29	12.14	3.10	28	12.23	2.16	28	10.07	2.31	28	9.92	2.42
Day 3 1h Post	28	13.32	2.70	29	13.13	2.09	29	12.51	2.58	28	12.21	2.28	28	9.00	2.32	28	9.22	2.27
Day 4 Pre Application	28	15.22	2.40	29	15.03	2.44	29	14.50	2.67	28	13.88	2.24	28	9.23	2.26	28	9.54	2.23
Day 4 Immediately Post	27	15.77	2.60	28	15.12	2.26	29	15.04	2.76	28	14.29	2.25	28	10.82	2.46	28	10.30	2.44
Day 4 1h Post	26	15.33	2.57	28	14.94	2.25	29	14.31	3.03	28	14.15	2.12	28	9.41	2.20	28	9.45	2.16
Day 5 Pre Application	26	15.23	2.54	28	14.81	2.24	29	14.60	2.52	28	14.32	2.39	28	8.88	2.64	28	9.32	2.43
Day 5 Immediately Post	25	16.18	2.80	27	15.50	2.68	29	15.65	2.43	28	14.75	2.42	28	10.21	2.33	28	9.99	2.42
Day 5 1h Post	25	16.15	2.73	27	15.81	2.40	28	15.15	2.47	28	14.35	2.46	28	9.14	2.45	28	9.50	2.51
Day 6 Pre Application	25	15.69	3.12	27	15.36	2.62	28	14.69	2.70	28	14.38	2.41	28	9.31	2.32	28	9.43	2.19

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 6 Immediately Post	25	16.52	3.24	27	15.80	2.87	27	15.34	2.95	28	15.12	2.55	28	10.28	2.10	28	10.06	2.38
Day 6 1h Post	25	15.97	3.18	27	15.60	2.49	27	14.98	2.75	28	14.87	2.33	28	9.30	2.18	28	9.43	2.12
Day 7 Pre Application	25	15.45	2.82	27	15.09	2.15	27	14.34	2.91	28	13.61	3.51	28	9.15	2.17	28	9.38	2.54
Day 7 Immediately Post	24	16.70	3.27	27	16.34	2.65	26	15.32	2.76	27	15.04	2.68	28	10.66	2.06	28	10.64	2.43
Day 7 1h Post	24	15.93	3.23	27	15.94	2.52	26	15.00	2.68	27	14.69	2.32	28	9.52	2.39	28	9.50	2.21
Day 8	24	16.21	3.06	27	16.29	2.20	26	14.96	2.68	27	15.07	2.35	28	9.00	2.33	28	9.22	2.47
Day 9	24	15.45	3.05	27	15.84	2.49	26	14.46	2.72	27	14.66	2.51	28	9.08	2.34	28	9.53	2.47
Day 10	24	14.97	3.17	27	15.27	2.45	26	14.47	2.98	27	14.34	2.20	28	9.09	2.48	28	9.35	2.34
Day 11	24	14.95	3.30	27	15.26	2.72	26	14.53	2.88	27	14.35	2.54	28	9.08	2.26	28	9.41	2.24
Day 12	24	14.45	3.29	27	14.40	2.55	26	14.14	3.08	27	13.87	2.43	28	8.99	2.32	28	9.08	2.09
Day 13	24	14.31	2.50	27	14.28	2.41	26	13.93	3.13	27	13.57	2.20	28	8.84	2.08	28	9.20	2.77
Day 16	24	13.25	2.46	27	13.28	2.00	26	12.78	2.62	27	12.44	1.80	28	8.94	2.28	28	9.25	2.18
WC	30	16.62	3.62	30	17.22	3.00	30	16.17	3.23	30	15.90	3.14	30	10.28	2.26	30	10.70	2.50
LOCF	30	13.28	2.82	30	13.23	2.34	30	12.89	2.98	30	12.43	2.49	30	8.95	2.27	30	9.22	2.21
b* Average																		
Baseline	30	15.76	3.73	30	15.76	3.73	30	15.76	3.73	30	15.76	3.73	30	15.76	3.73	30	15.76	3.73
Day 1 Immediately Post	30	16.38	3.55	30	16.39	3.69	30	16.35	3.41	30	16.11	3.53	30	15.65	3.66	30	15.48	3.70
Day 1 1h Post	30	16.21	3.70	30	16.35	3.97	30	16.06	3.89	30	16.04	3.76	30	15.72	3.96	30	15.53	3.80
Day 2 Pre Application	29	15.93	3.71	29	15.94	3.66	29	16.08	3.82	29	16.04	3.65	29	15.48	3.87	29	15.75	3.89
Day 2 Immediately Post	29	16.57	3.49	29	16.49	3.78	29	16.50	3.30	29	16.26	3.51	29	15.57	3.69	29	15.11	3.77
Day 2 1h Post	29	16.54	3.66	29	16.39	3.58	29	16.45	3.45	29	16.42	3.50	29	15.53	3.75	29	15.24	3.91
Day 3 Pre Application	29	16.23	3.78	29	16.17	3.53	29	16.29	3.42	29	16.39	3.49	29	15.55	3.69	29	15.69	3.90
Day 3 Immediately Post	28	16.64	3.18	29	16.58	3.21	29	16.60	3.47	28	16.33	3.30	28	15.56	3.64	28	15.43	3.62
Day 3 1h Post	28	16.85	3.23	29	16.72	3.08	29	16.66	3.28	28	16.76	3.64	28	15.72	3.81	28	15.50	3.74
Day 4 Pre Application	28	16.13	2.78	29	16.15	2.80	29	16.35	2.91	28	16.36	3.19	28	15.52	3.71	28	15.67	3.73
Day 4 Immediately Post	27	16.72	2.71	28	16.74	2.90	29	16.31	2.95	28	16.67	3.30	28	15.75	3.59	28	15.48	3.77
Day 4 1h Post	26	16.88	2.79	28	16.78	2.81	29	16.63	3.00	28	16.80	3.29	28	15.52	3.65	28	15.27	3.80

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 5 Pre Application	26	15.78	2.67	28	16.06	3.01	29	16.05	2.93	28	16.02	3.03	28	14.95	3.75	28	15.30	3.53
Day 5 Immediately Post	25	16.52	2.61	27	16.35	2.67	29	16.13	2.78	28	16.27	2.93	28	15.16	3.83	28	15.01	3.68
Day 5 1h Post	25	16.54	2.53	27	16.55	2.78	28	16.28	2.78	28	16.54	3.18	28	15.24	3.89	28	15.19	3.72
Day 6 Pre Application	25	16.08	2.69	27	16.10	2.80	28	16.07	3.00	28	16.02	2.89	28	15.25	3.81	28	15.40	3.73
Day 6 Immediately Post	25	16.55	2.34	27	16.48	2.56	27	16.20	2.58	28	16.18	2.69	28	15.35	3.65	28	15.39	3.54
Day 6 1h Post	25	16.58	2.57	27	16.46	2.70	27	16.23	2.74	28	16.42	2.76	28	15.37	3.78	28	15.31	3.69
Day 7 Pre Application	25	16.68	2.77	27	16.48	2.55	27	16.38	3.00	28	16.52	2.72	28	15.50	3.83	28	15.76	3.76
Day 7 Immediately Post	24	17.00	2.30	27	16.89	2.55	26	16.83	2.61	27	16.79	2.79	28	15.81	3.87	28	15.39	3.58
Day 7 1h Post	24	16.86	2.55	27	16.96	2.48	26	16.95	2.69	27	16.78	2.81	28	15.60	3.80	28	15.69	3.89
Day 8	24	16.45	2.49	27	16.44	2.83	26	16.49	2.80	27	16.32	2.88	28	15.40	4.10	28	15.58	3.92
Day 9	24	16.31	2.65	27	16.32	2.59	26	16.57	2.62	27	16.31	2.77	28	15.62	3.85	28	15.71	3.85
Day 10	24	16.41	2.72	27	16.76	2.91	26	16.68	3.06	27	16.53	2.77	28	15.70	3.77	28	15.60	3.82
Day 11	24	16.22	2.63	27	16.43	2.54	26	16.50	2.64	27	16.44	2.71	28	15.61	3.80	28	15.57	3.67
Day 12	24	16.23	2.48	27	16.31	2.71	26	16.24	2.64	27	16.15	2.53	28	15.46	3.93	28	15.46	3.57
Day 13	24	16.61	2.61	27	16.54	2.61	26	16.77	2.89	27	16.63	2.61	28	15.74	3.87	28	15.73	3.59
Day 16	24	16.36	2.50	27	16.44	2.74	26	16.52	2.77	27	16.30	2.70	28	15.84	3.78	28	15.83	3.82
WC	30	17.63	3.13	30	17.78	3.02	30	17.69	3.34	30	17.85	3.22	30	16.86	3.71	30	16.54	3.80
LOCF	30	16.22	2.41	30	16.25	2.66	30	16.32	2.71	30	16.33	2.61	30	15.73	3.67	30	15.64	3.77
Delta E																		
Day 1 Immediately Post	30	3.29	1.93	30	3.17	1.86	30	3.06	2.27	30	3.04	2.03	30	2.91	1.75	30	2.41	1.34
Day 1 1h Post	30	2.32	1.34	30	2.44	1.38	30	2.18	1.32	30	2.15	1.34	30	1.89	1.11	30	2.23	1.31
Day 2 Pre Application	29	2.58	1.73	29	2.72	1.43	29	2.24	1.29	29	2.47	1.52	29	2.00	0.81	29	2.21	1.45
Day 2 Immediately Post	29	4.35	2.26	29	4.12	1.75	29	3.75	2.22	29	3.81	1.76	29	3.01	1.52	29	2.79	1.20
Day 2 1h Post	29	3.17	2.16	29	3.51	2.00	29	2.60	1.45	29	2.93	1.83	29	2.23	1.31	29	2.42	0.99
Day 3 Pre Application	29	6.16	2.89	29	5.24	3.17	29	4.33	2.37	29	4.83	2.34	29	2.29	1.36	29	2.40	1.62
Day 3 Immediately Post	28	6.59	3.52	29	6.04	3.42	29	5.22	2.51	28	5.32	2.81	28	2.90	1.30	28	2.82	1.06
Day 3 1h Post	28	6.56	3.52	29	6.18	3.52	29	5.22	2.58	28	5.26	2.44	28	2.25	1.32	28	2.52	1.01

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 4 Pre Application	28	8.83	3.93	29	8.06	4.79	29	7.26	3.93	28	6.64	2.86	28	2.10	1.06	28	2.10	1.00
Day 4 Immediately Post	27	9.99	4.50	28	8.82	4.36	29	8.25	3.96	28	7.91	3.49	28	3.73	1.66	28	3.05	1.48
Day 4 1h Post	26	9.27	4.12	28	8.42	4.28	29	7.44	4.15	28	7.64	3.50	28	2.56	1.21	28	2.54	1.00
Day 5 Pre Application	26	9.55	4.11	28	8.26	3.86	29	8.11	3.68	28	7.98	3.54	28	2.35	1.24	28	2.23	0.88
Day 5 Immediately Post	25	10.69	4.39	27	9.37	4.47	29	9.61	4.39	28	9.05	3.95	28	3.25	2.13	28	2.94	1.20
Day 5 1h Post	25	10.80	3.95	27	9.72	4.38	28	8.54	3.45	28	8.29	3.37	28	2.73	1.41	28	2.37	0.99
Day 6 Pre Application	25	10.46	4.27	27	9.25	4.18	28	8.05	3.70	28	8.24	4.03	28	2.34	1.61	28	2.49	1.35
Day 6 Immediately Post	25	11.60	4.07	27	10.09	4.76	27	9.32	4.13	28	9.50	4.14	28	3.05	2.07	28	2.85	1.50
Day 6 1h Post	25	11.06	3.99	27	9.85	4.27	27	8.78	3.43	28	9.07	4.02	28	2.43	1.43	28	2.41	1.22
Day 7 Pre Application	25	10.47	3.84	27	9.24	4.02	27	7.86	4.16	28	8.21	4.15	28	2.13	1.14	28	2.56	2.22
Day 7 Immediately Post	24	11.94	4.32	27	10.88	4.57	26	9.24	3.83	27	9.78	4.21	28	3.26	1.75	28	3.33	1.42
Day 7 1h Post	24	11.06	4.47	27	10.51	4.64	26	8.84	3.80	27	9.28	4.29	28	2.40	1.19	28	2.23	1.17
Day 8	24	11.45	4.00	27	10.74	4.41	26	8.77	3.54	27	9.49	4.44	28	2.19	0.91	28	2.54	1.14
Day 9	24	11.29	3.48	27	10.53	4.55	26	8.06	3.20	27	9.11	3.82	28	2.06	0.74	28	2.15	1.20
Day 10	24	10.33	2.76	27	9.73	4.45	26	8.42	3.83	27	9.03	4.04	28	2.16	1.23	28	2.47	1.11
Day 11	24	10.37	2.81	27	9.95	3.96	26	8.48	3.67	27	9.10	4.24	28	1.75	0.99	28	2.39	1.33
Day 12	24	10.21	3.14	27	9.42	3.43	26	8.43	3.36	27	8.94	4.21	28	2.20	1.09	28	2.33	0.94
Day 13	24	10.21	2.79	27	9.46	4.00	26	8.28	3.41	27	8.67	3.96	28	2.38	1.09	28	2.56	1.95
Day 16	24	9.33	2.56	27	8.56	3.81	26	7.28	3.28	27	8.16	3.71	28	1.89	0.81	28	2.50	1.54
WC	30	12.66	4.59	30	12.78	4.83	30	11.13	4.25	30	11.25	4.84	30	3.58	1.67	30	3.49	1.90
LOCF	30	9.37	3.87	30	8.78	4.40	30	7.60	3.84	30	7.89	3.99	30	1.83	0.82	30	2.50	1.50
Temperature (C)																		
Baseline	30	30.36	1.24	30	30.36	1.24	30	30.36	1.24	30	30.36	1.24	30	30.36	1.24	30	30.36	1.24
Day 1 Immediately Post	30	30.10	1.37	30	29.96	1.61	30	30.27	1.27	30	30.45	1.36	30	30.51	1.36	30	29.99	1.58
Day 1 1h Post	30	29.73	1.41	30	29.59	1.59	30	29.88	1.27	30	29.99	1.42	30	30.20	1.39	30	29.69	1.45
Day 2 Pre Application	29	30.46	1.40	29	30.46	1.80	29	30.68	1.40	29	30.84	1.24	29	30.87	1.41	29	30.47	1.61
Day 2 Immediately Post	29	30.07	1.44	29	30.06	1.56	29	30.39	1.27	29	30.45	1.26	29	30.58	1.14	29	30.11	1.34

Outcome	2% STS01			1% STS01			0.5% STS01			0.25% STS01			Base Formulation			E45 Cream		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Day 2 1h Post	29	29.61	1.47	29	29.69	1.51	29	29.94	1.33	29	29.94	1.34	29	30.21	1.36	29	29.67	1.48
Day 3 Pre Application	29	30.40	1.67	29	30.29	1.79	29	30.53	1.67	29	30.63	1.35	29	30.62	1.33	29	30.35	1.61
Day 3 Immediately Post	28	30.17	1.42	29	30.21	1.69	29	30.37	1.36	28	30.39	1.33	28	30.45	1.23	28	30.11	1.46
Day 3 1h Post	28	29.70	1.50	29	29.75	1.68	29	29.93	1.52	28	29.97	1.39	28	30.18	1.48	28	29.75	1.61
Day 4 Pre Application	28	30.74	1.36	29	30.73	1.76	29	30.84	1.49	28	31.10	1.38	28	30.98	1.12	28	30.71	1.25
Day 4 Immediately Post	27	30.64	1.24	28	30.69	1.53	29	30.78	1.09	28	30.85	1.26	28	30.87	0.98	28	30.38	1.27
Day 4 1h Post	26	30.07	1.20	28	30.01	1.73	28	30.13	1.34	28	30.14	1.45	28	30.22	1.28	28	29.76	1.44
Day 5 Pre Application	26	30.19	1.60	28	30.11	1.95	29	30.59	1.42	28	30.54	1.44	28	30.47	1.28	28	30.17	1.31
Day 5 Immediately Post	25	30.26	1.19	27	30.27	1.46	29	30.42	1.11	28	30.45	1.37	28	30.56	1.10	28	30.05	1.32
Day 5 1h Post	25	30.18	1.22	27	29.97	1.66	28	30.12	1.17	28	29.99	1.40	28	30.37	1.21	28	29.87	1.34
Day 6 Pre Application	25	30.32	1.35	27	30.11	1.91	28	30.28	1.57	28	30.80	1.27	28	30.74	1.13	28	30.28	1.51
Day 6 Immediately Post	25	30.33	1.23	27	30.15	1.49	27	30.19	1.24	28	30.43	1.26	28	30.53	0.96	28	30.21	1.26
Day 6 1h Post	25	29.92	1.24	27	29.76	1.60	27	30.00	1.31	28	30.16	1.43	28	30.39	1.14	28	29.97	1.43
Day 7 Pre Application	25	30.86	1.87	27	30.65	2.15	27	30.82	1.81	28	31.17	1.64	28	31.01	1.60	28	30.75	1.62
Day 7 Immediately Post	24	31.02	0.98	27	30.71	1.62	26	30.93	1.22	27	31.07	1.40	28	31.16	1.10	28	30.75	1.25
Day 7 1h Post	24	30.45	1.24	27	30.30	1.65	26	30.58	1.08	27	30.68	1.36	28	30.80	1.38	28	30.44	1.45
Day 8	24	30.30	1.18	27	30.47	1.47	26	30.39	1.51	27	30.78	1.19	28	30.78	1.10	28	30.27	1.24
Day 9	24	31.02	1.07	27	30.76	1.42	26	30.77	1.20	27	31.17	1.04	28	31.06	0.94	28	30.68	1.08
Day 10	24	30.68	1.45	27	30.60	1.60	26	30.50	1.66	27	31.12	1.29	28	30.89	1.29	28	30.35	1.52
Day 11	24	30.50	1.09	27	30.44	1.51	26	30.51	1.22	27	30.90	0.96	28	30.79	1.09	28	30.51	1.25
Day 12	24	30.37	1.28	27	30.23	1.77	26	30.40	1.34	27	30.86	1.23	28	30.74	1.11	28	30.53	1.17
Day 13	24	30.70	1.22	27	30.39	1.63	26	30.75	1.20	27	30.99	1.31	28	30.91	1.23	28	30.60	1.32
Day 16	24	30.18	1.42	27	30.15	1.69	26	30.33	1.42	27	30.69	1.20	28	30.62	1.07	28	30.29	1.26
WC	30	31.29	1.19	30	31.35	1.41	30	31.54	1.00	30	31.71	1.13	30	31.68	1.17	30	31.30	1.23
LOCF	30	30.10	1.35	30	30.10	1.69	30	30.28	1.39	30	30.58	1.21	30	30.54	1.16	30	30.18	1.34

Table 7: Adverse Event Overview

		Overall (N=30)		
		n	%	freq
All Adverse Events		4	13.3	5
Pre-Treatment Signs and Symptoms (PTSS)				
Treatment Emergent Adverse Events (TEAE)		4	13.3	5
Drug Relationship	Related			
	Not Related	4	13.3	5
AE Severity	Mild	4	13.3	5
	Moderate			
	Severe			
	Life Threatening			
	Fatal			
AE Outcome	Resolved	1	3.3	1
	Resolving			
	Not Resolved	3	10.0	4
SAE				

Footnote: n=number of patients; freq=number of events

Table 8: Treatment Emergent Adverse Events Classification by Classification

System Organ Class	Preferred Term	Overall (N=30)		
		n	%	freq
Any TEAE		4	13.3	5
GASTROINTESTINAL DISORDERS		1	3.3	2
	DIARRHOEA	1	3.3	1
	VOMITING	1	3.3	1
INFECTIONS AND INFESTATIONS		1	3.3	1
	CONJUNCTIVITIS	1	3.3	1
INVESTIGATIONS		1	3.3	1
	URINE ANALYSIS ABNORMAL	1	3.3	1
PSYCHIATRIC DISORDERS		1	3.3	1
	ANXIETY	1	3.3	1

NB: None of the 5 TEAEs were considered related to the study drug

Footnote 1: n=number of patients; freq=number of events

Footnote 2: TEAE = Adverse Events that occur on or after the date and time of application of the first patch