**NAME: Hand Foam Sanitiser** 

CODE: B3009/02

PDP REF:

PDP-B3009 v03



DOCUMENT ISSUE					
ROLE	NAME	JOB TITLE	SIGN & DATE		
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QUALITY APPROVER	Polly Smith	Quality Manager	Polly Smith	22-May-2023	
ISSUE DATE	22 MAY 2023	REVIEW DATE	22 MAY 2025		

	PRODUCT INFORMATION				
PRODUCT NAME	Hand Foam Sanitiser				
PRODUCT CODE	B3009/02				
FORMULATION VARIANTS	N/A				
SDS REFERENCE	B3009/02				
<b>NOTE:</b> ACTIVE INGREDIENTS AN	D SAFETY INFORMATION DETAILED IN SDS				
DIRECTIONS FOR USE	On to dry hands dispense as many pumps necessary to give good coverage. Rub hands together, especially between fingers and around nails, until product has dried. Do not rinse off. Repeat as necessary.				
APPLICATION AREAS	Hands (in accordance with BPR PT1)				
STORAGE CONDITIONS	Keep containers upright. Store in tightly closed, original container in a dry, cool and well-ventilated place. Protect from freezing and direct sunlight. Avoid contact with oxidising agents. Store at temperatures not exceeding 35°C.				
SHELF-LIFE	2 years under recommended storage conditions.  Established following criteria for accelerated storage test in section 3.4.1.1 of ECHA guidance on the BPR: Volume I. Part A. Chapter III: Requirements for Biocidal Products. Version 1.1 November 2014				

PRODUCT SPECIFICATION			
APPEARANCE	Clear liquid		
COLOUR	plourless		
ODOUR	Characteristic		
рН	5.00 – 7.00 (20°C)		
SPECIFIC GRAVITY	0.990 – 1.020 (20°C)		
VISCOSITY	Water thin; 0 – 20cps		

TEMPLATE: T001 – SOPRAD001 V01	Page 1 of 4
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**NAME: Hand Foam Sanitiser** 

CODE: B3009/02

PDP REF: PDP-B3009 v03



BACTERICIDAL EFFICACY					
TEST REF	TEST ORGANISMS	TEST CONDITIONS	TEST RESULT	REPORT REF	COMMENTS
EN1276	E. coli	1 min, low soil	>5 log reduction	TR 423	None
EN1276	E. hirae	1 min, low soil	>5 log reduction	TR 423	None
EN1276	P. aeruginosa	1 min, low soil	>5 log reduction	TR 423	None
EN1276	S. aureus	1 min, low soil	>5 log reduction	TR 423	None
EN1276	L. monocytogenes	1 min, low soil	>5 log reduction	TR 423	None
EN1276	S. typhimurium	1 min, low soil	>5 log reduction	TR 423	None
EN1276	S. pyogenes	1 min, low soil	>5 log reduction	TR 423	None
EN1276	C. jejuni	1 min, low soil	>5 log reduction	TR 424	None
EN1276	B. bronchiseptica	1 min, low soil	>5 log reduction	TR 436	None
EN1276	MRSA	30 sec, low soil	>5 log reduction	TR 583	None
EN1276	K. pneumoniae (CRE)	30 sec, low soil	>5 log reduction	TR 583	None
EN1276	A. baumanii	30 sec, low soil	>5 log reduction	TR 584	None
EN1276	E. cloacae	30 sec, low soil	>5 log reduction	TR 584	None
EN1276	E. faecalis (VRE)	30 sec, low soil	>5 log reduction	TR 585	None
EN1276	P. aeruginosa	30 sec, low soil	>5 log reduction	TR 585	None
EN13727	E. coli	30 sec, high soil	>5 log reduction	TR 528	None
EN13727	E. hirae	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	P. aeruginosa	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	S. aureus	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	K. pneumoniae (CRE)	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	E. faecalis (VRE)	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	S. pyogenes	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	MRSA	30 sec, high soil	>5 log reduction	TR 529	None
EN13727	E. coli K12	30 sec, high soil	>5 log reduction	TR 530	None
EN13727	A. baumanii	30 sec, high soil	>5 log reduction	TR 531	None
EN13727	S. typhimurium	30 sec, high soil	>5 log reduction	TR 531	None
EN13727	L. monocytogenes	30 sec, high soil	>5 log reduction	TR 531	None
EN13727	C. jejuni	30 sec, high soil	>5 log reduction	TR 532	None

TEMPLATE: T001 – SOPRAD001 V01	Page 2 of 4
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**NAME: Hand Foam Sanitiser** 

CODE: B3009/02

PDP REF:

PDP-B3009 v03



BACTERICIDAL EFFICACY						
TEST REF	TEST ORGANISMS	TEST CONDITIONS	TEST RESULT	REPORT REF	COMMENTS	
EN1500	E. coli K12	2 x application of test product over 1 min.	Test product was non- inferior to 60% propan- 2-ol and therefore satisfies the requirements of EN1500	TR 421	None	
Residual antimicrobial efficacy on VitroSkin	E. coli K12	n/a	>3log reduction of E. coli K12 in 5 mins, 8- hour post application to VitroSkin	TR 416v2	None	

YEASTICIDAL/FUNGICIDAL EFFICACY					
TEST REF	TEST ORGANISMS	TEST CONDITIONS	TEST RESULT	REPORT REF	COMMENTS
EN1650	C. albicans	1 min, low soil	>4 log reduction	TR 425	None
EN13624	C. albicans	30 sec, high soil	>4 log reduction	TR 533	None

VIRUCIDAL EFFICACY					
TEST REF	TEST ORGANISMS	TEST CONDITIONS	TEST RESULT	REPORT REF	COMMENTS
EN14476	Human Rotavirus (strain Wa)	30 sec, low soil	>4 log reduction	TR 414	None
EN14476	Influenza A Virus (H1N1, Swine)	30 sec, low soil	>4 log reduction	TR 415	None
EN14476	Vaccinia Virus	30 sec, low soil	>4 log reduction	TR 438	None
EN14476	Feline Coronavirus	1 min, low soil	>4 log reduction	TR 452	None
Residual antiviral efficacy on VitroSkin	Vaccinia Virus	n/a	>4 log reduction of Vaccinia virus in 5 mins, 8-hour post product application to VitroSkin	TR 569	None

TEMPLATE: T001 - SOPRAD001 V01

**Page** 3 **of** 4

**NAME: Hand Foam Sanitiser** 

CODE: B3009/02

PDP REF:

PDP-B3009 v03



ADDITIONAL DATA					
TEST METHOD	RESULT	TEST REPORT REF			
96-hour patch test	"Based on the data, the test article can be considered as safe for use and claims such as, 'Dermatologically tested', 'Clinically proven', 'Kind to skin', 'Mild for skin' and 'Safe for skin' are all substantiated".	TRC 320			
Potential Taint from Direct Contact with Test Materials	"The statistical test results show that the control and test chocolate samples (test sample treated with the Hand Foam Sanitiser) were statistically similar at the selected levels (10% Beta (b) and 30% Pd). Furthermore, no taint descriptors were used (by the panel) to describe the treated chocolate sample. We have therefore concluded that the test results indicate, the test product: RTU Hand Foam Sanitiser: B3009 does not have the potential to taint when tested as above."	TRC 319			
Trans epidermal water loss (TEWL) test	"When compared to the positive control, the TEWL values (p<0.05) indicate the product does not compromise the skin barrier as harshly as the positive control (70% v/v ethanol). Based on this, the claims of, "Kind to skin", "Maintains skins natural moisture levels", "Maintains skins natural hydration" and "Does not compromise the skin as harshly as ethanol" are substantiated for the test article".	TRC 297			
Challenge Testing	"When assessed against the European Pharmacopoeia criteria for topical products, this sample complies."				

	CHANGE HISTORY					
PREVIOUS VERSION/REF	CHANGE REFERENCE	CHANGE TYPE	REASON FOR CHANGE			
02	DCC23.173	UPDATE	Change to shelf life (3 years to 2 years)			
01	DCC23.064	UPDATE	Change to formulation blend code (B3009 to B3009/02)			
N/A	DCC22.258	NEW	New PDP for new formulation			