

Sakura Blossom Hand Wash 1L Refill Portfolio



PVA Hygiene provides an innovative and sustainable method of cleaning. As the UK's leading manufacturer of water-soluble cleaning products, we cover all areas of commercial cleaning. Over 24 years, we have developed a system using pre-dosed sachets that is straightforward to implement and balances environment diligence with commercial demands. Based in the South West of England, we distribute globally.



This portfolio contains documents relating to PVA Hygiene's SAKURA BLOSSOM HAND WASH 1L REFILL.

This unique formulation is contained within a PVOH or paper film that dissolves at the point of use. The sachets are dry, compact and light, they reduce storage space, transportation costs and heavily reduce the environmental implications often associated with delivering cleaning supplies. The sachets are packed in planet friendly packaging, that can either be composted or recycled, helping you to eliminate single-use plastic from your current cleaning procedure.

CONTENTS:

- 1) Technical Data Sheet.
- 2) Safety Data Document.
- 3) Preservation Study.
- 4) Cosmetic Data Report.



PRODUCT DESCRIPTION

Sakura Blossom Hand Wash 1L Refill is designed to provide a foaming hand wash solution for everyday use through a foaming dispenser. The product utilises PVA Hygiene's unique PD47075/6 technology.

The product is biodegradable, gently perfumed, safe for use on normal unbroken skin, but use by children under the age of three years is not recommended

Sachets are supplied in the following Pack Sizes:-

Pack Size	Sachet Type	Code	Outer Packaging
10 * 10g	PVA - OH	CP03:10	Pouch
10 * 10g	Paper	PCP03:10	Pouch

- Supplied in convenient water soluble sachets within a compostable container.
 - Good soil removal and suspension.
 - Biodegradable.
 - Independent Cosmetic Safety Assessment
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USE INSTRUCTIONS

This product is supplied in a single sachet per 1L of water format (e.g use 4 sachets for a 4L container). Fill the clean jerry can to near the top, leaving room for sachets and agitation. Place the desired number of sachets into the container. Replace the lid and shake the bottle for between thirty seconds and one minute to fully dissolve the sachet, then leave for fifteen minutes for viscosity to fully develop. Fill your dispensers as required.

Note: It is advisable to have a routine for periodic washing out of dispenser reservoirs and cleaning of exterior parts especially around the discharge nozzle.

To use the product, wet hands under clean running warm water, then apply one squirt of soap onto the palm of a hand, work the soap around the hands, nail beds, and around wrists before rinsing under clean water and drying either with a clean soft paper towel or with a suitable air drier.

After regular repeated work place hand washing throughout a day, it is recommended that a suitable end of day moisturising cream is used.

Note: If clear bottles are used for temporary storage of made up solutions a slight yellowing of the product will be noted, this is normal.

Note: When used with dispensers that are not designed to dispense foam, the product will dispense as a viscous liquid.

TECHNICAL DATA SUMMARY

Appearance as supplied	White Powder
Appearance as made up	Clear viscous liquid
Odour	None
Foam	High
pH of use solution	7.5 – 8.5 when diluted
Storage Temperature Range	0°C to +30°C
Shelf Life	Minimum of 12 months under normal conditions of dry storage in the sachet.

EMERGENCY DETAILS

For accident, emergency and health & safety information refer to the Safety Data Document for this product.

This product is registered with the UK National Poisons Information Service.

Office Hours Emergency Number +44 (0) 1934 862859

Outside Office Hours: - +44 (0)7967 149256 (This is for health, safety and environmental emergencies only, it is not for general enquires or ordering.)

DISCLAIMER

Whilst every effort is made to ensure that the information given in this product information sheet is accurate it is given without guarantee, since the conditions of use are beyond our control.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Substance name	: SAKURA BLOSSOM HAND WASH 1L Refill
Product code	: PCP03:10, CP03:10, PD47075
Type of product	: Note: This product is controlled by Cosmetic Regulations and no Safety Data Sheet is required. This document is supplied for information only. A copy of the independent Cosmetic Safety Assessment is available on request

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Professional use, Consumer use

1.2.2. Uses advised against

Restrictions on use : Not for Oral Consumption, Not for Direct Application to Food Stuffs, Not Suitable for Children Under the Age of Three Years.

1.3. Details of the supplier of the safety data sheet

Manufacturer

PVA HYGIENE
UNIT 6 Havyat Business Park Havyat Road
BS40 5PA Bristol – United Kingdom
T +44 (0)1934 862 859
sales@pva-hygiene.co.uk

1.4. Emergency telephone number

Emergency number : 01934 862859 (Office Hours). For Immediate first aid advice in the UK call 111
This product is registered with NPIS in the UK.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] and GB CLP Regulations

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

This product does not contain any substances classified as PBT
This product does not contain any substances classified as vPvB.

SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP] and GB CLP Regulations
SAKURA BLOSSOM HAND WASH 1L Refill	-	100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If medical advice is needed, have product container or label at hand. For immediate First Aid advice in the UK, dial 111. When it is safe to do so, remove the victim immediately from the source of exposure. However, consideration should be given as to whether moving the victim will cause further injury.
First-aid measures after inhalation	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Do not induce vomiting. Rinse mouth thoroughly with water. Get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: Unlikely route of exposure, but inhalation of dilute solution droplets may result in a sore throat.
Symptoms/effects after skin contact	: When used as directed this product is expected to be safe on unbroken skin.
Symptoms/effects after eye contact	: May cause slight temporary irritation.
Symptoms/effects after ingestion	: Unlikely without abuse, likely to cause temporary irritation, a bitter or soapy taste may be reported.

4.3. Indication of any immediate medical attention and special treatment needed

Rinse with plenty of water.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing agent suitable for surrounding fire.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: The product is not flammable.
Hazardous decomposition products in case of fire	: On heating, irritating fumes may be produced.

5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
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SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Normal use volumes can be disposed of to drain.

6.4. Reference to other sections

For further information refer to section 13. See sections 2,8,12,13 &14.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Carefully comply with the instructions for use.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store away from moisture in a closed container. Store above 0 Degrees C.

7.3. Specific end use(s)

Hand wash soap.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

SAKURA BLOSSOM HAND WASH 1L Refill	
United Kingdom - Occupational Exposure Limits	
Remark	No exposure limits known for ingredients.

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

In Normal use eye protection is not required. Consider safety glasses if there is a significant risk of splashing.

8.2.2.2. Skin protection

Hand protection:

After regular use of hand soap in the work place, end of day use of a mositurising cream is recommended.

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Note:- This would be very unusual in normal use.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Colour	: white.
Odour	: Blossom.
Odour threshold	: No data available
pH	: No data available
pH solution	: 7 – 8 @1.6v/v
Relative evaporation rate (butylacetate=1)	: Not applicable.
Melting point	: Not applicable
Freezing point	: Not applicable
Boiling point	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not applicable
Flammability (solid, gas)	: Not Flammable
Vapour pressure	: Not applicable
Relative vapour density at 20°C	: Not applicable
Relative density	: 0.3 – 0.4 g/ml
Solubility	: Completely soluble in water.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong acids. Oxidising agents. Do not mix with Bleach or products containing Sodium Hypochlorite, this could result in dangerous heating of the solution.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: This mixture is not classified as a carcinogen.
Reproductive toxicity	: This mixture has no reproductive/foetal harm classifications and is not expected to be a risk to expectant mothers.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SAKURA BLOSSOM HAND WASH 1L Refill

Viscosity, kinematic	Not applicable
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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Normal use solutions of this product are not classified for environmental harm.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

SAKURA BLOSSOM HAND WASH 1L Refill

Persistence and degradability	The Surfactants and Chelants used in this mixture are Biodegradable.
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12.3. Bioaccumulative potential

SAKURA BLOSSOM HAND WASH 1L Refill

Bioaccumulative potential	Not expected to Bioaccumulate.
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SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

12.4. Mobility in soil

SAKURA BLOSSOM HAND WASH 1L Refill

Additional information	soluble in water
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12.5. Results of PBT and vPvB assessment

SAKURA BLOSSOM HAND WASH 1L Refill

This product does not contain any substances classified as PBT

This product does not contain any substances classified as vPvB.

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal of this product must comply with local and national environmental legislation.
Sewage disposal recommendations	: Small volumes of use solution can be disposed of to sewage drains.
Product/Packaging disposal recommendations	: Cardboard Packaging should be re-cycled or composted.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not applicable.

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Cosmetic regulation

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level

SAKURA BLOSSOM HAND WASH 1L Refill

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

Abbreviations and acronyms:	
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Test Report

Preservative Efficacy Test - ISO 11930:2019

Company Name: PVA Hygiene Ltd
Address: Unit 6, Havyat Business Park
Havyat Road
Wrington, Bristol
BS40 5PA

Contact Name: Jim Taylour
Contact Email:

Purchase Order Ref:
Date of Report: 18/11/2022

Melbec Reference Number: 47075

Test Report

Preservative Efficacy Test - ISO 11930:2019

Sample Details:

Name of Product:	Refill Soap PVA Film
Batch Number:	
Manufacturer / Supplier:	PVA Hygiene Ltd
Product Storage Conditions:	Ambient
Date Product Received:	11/10/2022
Date Testing Commenced:	11/10/2022
Product satisfactory on receipt:	Satisfactory

Preparation Instructions: Dissolve 10g sachet into 1000ml of warm hard water and stir for 5 minutes. Made up liquid is to be tested as the challenge sample.

Experimental Conditions:

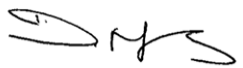
Test/Incubation Temperature: $22.5 \pm 2.5^{\circ}\text{C}$

Test Organisms:	<i>Pseudomonas aeruginosa</i> ATCC 9027
	<i>Escherichia coli</i> ATCC 8739
	<i>Staphylococcus aureus</i> ATCC 6538
	<i>Candida albicans</i> ATCC 10231
	<i>Aspergillus brasiliensis</i> ATCC 16404
Culture Media:	Tryptone Soy Agar ($32.5 \pm 2.5^{\circ}\text{C}$, 48h) for bacteria
	Sabouraud Dextrose Agar for <i>Candida albicans</i> ($32.5 \pm 2.5^{\circ}\text{C}$, 48-72h)
	Potato Dextrose Agar for <i>Aspergillus brasiliensis</i> ($22.5 \pm 2.5^{\circ}\text{C}$, 3-5d)
Enumeration Method:	Pour Plates
Neutralisation Method:	Dilution Neutralisation using Broth for <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>E. coli</i> , <i>Candida albicans</i> , <i>Aspergillus brasiliensis</i> .

Conclusion:

The test product has met the requirements of criteria A as specified in the standard BS EN ISO 11930:2019.

Report Authorised by:



Dawn Mellors
Technical Director

Test Report

Preservative Efficacy Test - ISO 11930:2019

Test Results:**Sterility Check:**

Cfu/g	
Aerobic Mesophilic Bacterial Count	Yeast & Mould Count
<10	<10

Neutraliser Validation:

	Recovery cfu/ml				
	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
NvF	1.71×10^2	1.92×10^2	1.67×10^2	1.08×10^2	8.30×10^1
Inoculum Control	1.42×10^2	1.01×10^2	1.74×10^2	1.10×10^2	8.00×10^1
Control Nvn	1.30×10^2	1.28×10^2	1.63×10^2	1.12×10^2	7.60×10^1

Mf \geq 0.5/Mn: Yes

Mv is equivalent to 0.5/Mn: Yes

Test Organism Inocula:

Test Organism	N	N ₀		lg N ₀	Yes/No
	Organism number in the calibrated suspension	Organism number in the test product at T0			
	cfu/ml	cfu/ml	lg		
<i>Pseudomonas aeruginosa</i>	9.10×10^7	9.10×10^5	5.96	Between 5.00-6.00	Yes
<i>Staphylococcus aureus</i>	5.90×10^7	5.90×10^5	5.77	Between 5.00-6.00	Yes
<i>E. coli</i>	9.10×10^7	9.10×10^5	5.96	Between 5.00-6.00	Yes
<i>Candida albicans</i>	6.20×10^6	6.20×10^4	4.79	Between 4.00-5.00	Yes
<i>Aspergillus brasiliensis</i>	7.90×10^6	7.90×10^4	4.90	Between 4.00-5.00	Yes

Test Report

Preservative Efficacy Test - ISO 11930:2019

Number of surviving micro-organisms in the contaminated formulation at each timepoint (Nx):

Test Organism	7 days		14 days		28 days	
	cfu/ml	lg	cfu/ml	lg	cfu/ml	lg
<i>Pseudomonas aeruginosa</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Staphylococcus aureus</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>E. coli</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Candida albicans</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Aspergillus brasiliensis</i>			<10	<1.00	<10	<1.00

Log Reduction at each timepoint (Rx):

Test Organism	7 days	14 days	28 days	Pass/Fail	Test Criteria Used
<i>Pseudomonas aeruginosa</i>	≥4.96	NI	NI	Pass	A
<i>Staphylococcus aureus</i>	≥4.77	NI	NI	Pass	A
<i>E. coli</i>	≥4.96	NI	NI	Pass	A
<i>Candida albicans</i>	≥3.79	NI	NI	Pass	A
<i>Aspergillus brasiliensis</i>		≥3.90	NI	Pass	A

BS EN ISO 11930:2019 clause 5.7.1 states: *The inherent variability of microbial counts that are used to determine Rx values shall be taken into consideration when comparing the obtained Rx values and the preset criteria A or B. In this document, a deviation of 0.5 log units from the preset criteria is considered acceptable*

NI - No increase in the viable count (cfu/g)

NT - Not tested

BS EN ISO 11930:2019 Test Criteria:

Criteria A:

Organism:	7 day	14 day	28 day
<i>Pseudomonas aeruginosa</i>	≥3	NI	NI
<i>Staphylococcus aureus</i>	≥3	NI	NI
<i>Escherichia coli</i>	≥3	NI	NI
<i>Candida albicans</i>	≥1	NI	NI
<i>Aspergillus brasiliensis</i>	-	≥0	≥1

Test Report
Preservative Efficacy Test - ISO 11930:2019

Criteria B:

Organism:	7 day	14 day	28 day
<i>Pseudomonas aeruginosa</i>	Not performed	≥3	NI
<i>Staphylococcus aureus</i>		≥3	NI
<i>Escherichia coli</i>		≥3	NI
<i>Candida albicans</i>		≥1	NI
<i>Aspergillus brasiliensis</i>		≥0	NI

The sample detailed in this report will be retained for 1 month after report date, unless otherwise requested. The results on this report refer to the items tested only. Sample description and batch references stated are as provided by the customer. This report shall not be reproduced in part or full without written permission from Melbec Microbiology Limited.

****End of test report****

Test Report

Preservative Efficacy Test - ISO 11930:2019

Company Name: PVA Hygiene Ltd
Address: Unit 6, Havyat Business Park
Havyat Road
Wrington, Bristol
BS40 5PA

Contact Name: Jim Taylour
Contact Email:

Purchase Order Ref:
Date of Report: 18/11/2022

Melbec Reference Number: 47076

Test Report

Preservative Efficacy Test - ISO 11930:2019

Sample Details:

Name of Product:	Refill Soap Paper Film
Batch Number:	
Manufacturer / Supplier:	PVA Hygiene Ltd
Product Storage Conditions:	Ambient
Date Product Received:	11/10/2022
Date Testing Commenced:	11/10/2022
Product satisfactory on receipt:	Satisfactory

Preparation Instruction: Dissolve 5g sachet into 500ml of warm water and stir for 5 minutes. Made up liquid to be tested as the challenge sample.

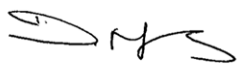
Experimental Conditions:

Test/Incubation Temperature:	22.5 ± 2.5°C
Test Organisms:	<i>Pseudomonas aeruginosa</i> ATCC 9027 <i>Escherichia coli</i> ATCC 8739 <i>Staphylococcus aureus</i> ATCC 6538 <i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> ATCC 16404
Culture Media:	Tryptone Soy Agar (32.5 ± 2.5°C, 48h) for bacteria Sabouraud Dextrose Agar for <i>Candida albicans</i> (32.5 ± 2.5°C, 48-72h) Potato Dextrose Agar for <i>Aspergillus brasiliensis</i> (22.5 ± 2.5°C, 3-5d)
Enumeration Method:	Pour Plates
Neutralisation Method:	Dilution Neutralisation using Broth for <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>E. coli</i> , <i>Candida albicans</i> , <i>Aspergillus brasiliensis</i> .

Conclusion:

The test product has met the requirements of criteria A as specified in the standard BS EN ISO 11930:2019.

Report Authorised by:



Dawn Mellors
Technical Director

Test Report

Preservative Efficacy Test - ISO 11930:2019

Test Results:**Sterility Check:**

Cfu/g	
Aerobic Mesophilic Bacterial Count	Yeast & Mould Count
<10	<10

Neutraliser Validation:

	Recovery cfu/ml				
	<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Candida albicans</i>	<i>Aspergillus brasiliensis</i>
NvF	1.59x10 ²	1.81x10 ²	1.55x10 ²	8.80x10 ¹	1.12x10 ²
Inoculum Control	1.42x10 ²	1.01x10 ²	1.74x10 ²	1.10x10 ²	8.00x10 ¹
Control Nvn	1.30x10 ²	1.28x10 ²	1.63x10 ²	1.12x10 ²	7.60x10 ¹

Mf ≥ 0.5Mn: Yes

Mv is equivalent to 0.5Mn: Yes

Test Organism Inocula:

Test Organism	N Organism number in the calibrated suspension	N ₀ Organism number in the test product at T ₀		lg N ₀	Yes/No
	cfu/ml	cfu/ml	lg		
<i>Pseudomonas aeruginosa</i>	9.10x10 ⁷	9.10x10 ⁵	5.96	Between 5.00-6.00	Yes
<i>Staphylococcus aureus</i>	5.90x10 ⁷	5.90x10 ⁵	5.77	Between 5.00-6.00	Yes
<i>E. coli</i>	9.10x10 ⁷	9.10x10 ⁵	5.96	Between 5.00-6.00	Yes
<i>Candida albicans</i>	6.20x10 ⁶	6.20x10 ⁴	4.79	Between 4.00-5.00	Yes
<i>Aspergillus brasiliensis</i>	7.90x10 ⁶	7.90x10 ⁴	4.90	Between 4.00-5.00	Yes

Test Report

Preservative Efficacy Test - ISO 11930:2019

Number of surviving micro-organisms in the contaminated formulation at each timepoint (Nx):

Test Organism	7 days		14 days		28 days	
	cfu/ml	lg	cfu/ml	lg	cfu/ml	lg
<i>Pseudomonas aeruginosa</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Staphylococcus aureus</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>E. coli</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Candida albicans</i>	<10	<1.00	<10	<1.00	<10	<1.00
<i>Aspergillus brasiliensis</i>			<10	<1.00	<10	<1.00

Log Reduction at each timepoint (Rx):

Test Organism	7 days	14 days	28 days	Pass/Fail	Test Criteria Used
<i>Pseudomonas aeruginosa</i>	≥4.96	NI	NI	Pass	A
<i>Staphylococcus aureus</i>	≥4.77	NI	NI	Pass	A
<i>E. coli</i>	≥4.96	NI	NI	Pass	A
<i>Candida albicans</i>	≥3.79	NI	NI	Pass	A
<i>Aspergillus brasiliensis</i>		≥3.90	NI	Pass	A

BS EN ISO 11930:2019 clause 5.7.1 states: *The inherent variability of microbial counts that are used to determine Rx values shall be taken into consideration when comparing the obtained Rx values and the preset criteria A or B. In this document, a deviation of 0.5 log units from the preset criteria is considered acceptable*

NI - No increase in the viable count (cfu/g)

NT - Not tested

BS EN ISO 11930:2019 Test Criteria:

Criteria A:

Organism:	7 day	14 day	28 day
<i>Pseudomonas aeruginosa</i>	≥3	NI	NI
<i>Staphylococcus aureus</i>	≥3	NI	NI
<i>Escherichia coli</i>	≥3	NI	NI
<i>Candida albicans</i>	≥1	NI	NI
<i>Aspergillus brasiliensis</i>	-	≥0	≥1

Test Report
Preservative Efficacy Test - ISO 11930:2019

Criteria B:

Organism:	7 day	14 day	28 day
<i>Pseudomonas aeruginosa</i>	Not performed	≥3	NI
<i>Staphylococcus aureus</i>		≥3	NI
<i>Escherichia coli</i>		≥3	NI
<i>Candida albicans</i>		≥1	NI
<i>Aspergillus brasiliensis</i>		≥0	NI

The sample detailed in this report will be retained for 1 month after report date, unless otherwise requested. The results on this report refer to the items tested only. Sample description and batch references stated are as provided by the customer. This report shall not be reproduced in part or full without written permission from Melbec Microbiology Limited.

****End of test report****

Dr Sara Robb
33 Avondale Road
London, N13 4DX
UK



COSMETIC PRODUCT SAFETY REPORT

ECO REFILL HANDWASH WITH VARIATIONS

REF: ERHWV260123DSR

Issued: 26 JANUARY 2023

Prepared in accordance with 'The UK Regulation' Schedule 34 of the Product Safety and Metrology Statutory Instrument and "Cosmetics Regulation" Regulation (EC) No. 1223/2009

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REFERENCES

INTRODUCTION

1 Validity of the Cosmetic Product Safety Report

This report remains valid until any of the following occur:

Amendments or changes to the regulatory requirements concerning cosmetic products

Reassignment of the Responsible Person

Alteration of the cosmetic product's quantitative and qualitative formulation

Amendment or changes to the format or contents without the permission of the author

2 Name and description of the cosmetic product

Eco Refill Handwash with Variations (PD47075 & PD47076) is a cosmetic product that belongs to the "rinse-off product" category. Supplied as dry 10 gram sheets of cellulose (PD47075) or PVA (PD47076), which is dissolved into one liter of water to make the cosmetic product, Eco Refill Handwash. **This report assesses the safety of the final aqueous cosmetic product.**

3 Responsible Person(s)

European Union (EU)

Responsible Person: Clenli Direct

Address: Unit 14A, Stadium Business Park, Ballycoolin Road, Dublin 11, Ireland

United Kingdom (UK)

Responsible Person: PVA Hygiene Ltd

Address: Unit 6, Havyat Business Park, Havyat Road, Wrington, Bristol, BS40 5PA, UK

PART A COSMETIC PRODUCT SAFETY INFORMATION

Part A of the Cosmetic Product Safety Report (CPSR) outlines the data necessary to demonstrate that the cosmetic product is safe.

1 Quantitative formulation and qualitative composition of the cosmetic product

The composition of the cosmetic product is described below. Both quantitative and qualitative composition of the cosmetic product are identified. Raw materials and the constituents of the final product are described by maximum percentage (w/w). Each ingredient's CAS Number, and EINECS is provided when available. Intended function(s) are also described and restrictions are noted.

MSDSs for raw materials are included in the PIF. These provide toxicological details for each ingredient. Specific suppliers are not specified, however ingredients used to manufacture the cosmetic product must have identical CAS numbers and INCI names, as well as meet all purity standards for each ingredient.

Fragrance and perfuming ingredient documentation (essential oil, parfum and aroma) must be provided in the PIF, including supplier's identification, IFRA documents and allergen declarations. Labelling must declare cosmetic allergens as specified by Article 19(1)(g) when its concentration exceeds: — 0.001 % in leave-on products and — 0.01 % in rinse-off products.

Aqua

Max % (w/w): 99.000000
Cas Number(s): 7732-18-5
EINECS: 231-791-2
Function(s): SOLVENT
Restriction: None

Sodium C14-16 Olefin Sulfonate

Max % (w/w): 0.779200
Cas Number(s): 68439-57-6
EINECS: 270-407-8/931-534-0
Function(s): CLEANSING, FOAMING, SURFACTANT - CLEANSING
Restriction: None

Hydroxypropyl Guar

Max % (w/w): 0.099000
Cas Number(s): 68442-94-4 / 39421-75-5
EINECS: 270-497-9 / -
Function(s): ANTISTATIC, BINDING, EMULSION STABILISING, FILM FORMING, SURFACTANT - CLEANSING, VISCOSITY CONTROLLING
Restriction: None

Bronopol

Max % (w/w): 0.079200
Cas Number(s): 52-51-7
EINECS: 200-143-0
Function(s): PRESERVATIVE
Restriction: V/21 Maximum 0.1%

Maltodextrin

Max % (w/w): 0.030331

Cas Number(s): 9050-36-6

EINECS: 232-940-4

Function(s): ABSORBENT, BINDING, EMULSION STABILISING, FILM FORMING, HAIR CONDITIONING, SKIN CONDITIONING

Restriction: None

Capparis Spinosa Fruit Extract

Max % (w/w): 0.011234

Cas Number(s): 89958-23-6

EINECS: 289-646-4

Function(s): SKIN CONDITIONING

Restriction: None

Olea Europaea Leaf Extract

Max % (w/w): 0.010110

Cas Number(s): 8001-25-0 / 84012-27-1

EINECS: 232-277-0

Function(s): PERFUMING, SKIN CONDITIONING

Restriction: None

Polyvinyl Alcohol

Max % (w/w): 0.009900

Cas Number(s): 9002-89-5 / 25213-24-5

EINECS:

Function(s): FILM FORMING, VISCOSITY CONTROLLING

Restriction: None

Cellulose

Max % (w/w): 0.009900

Cas Number(s): 9004-34-6

EINECS: 232-674-9

Function(s): ABSORBENT, BULKING, OPACIFYING, VISCOSITY CONTROLLING

Restriction: None

Parfum (Carvansons SAKURA FN0010377)

Max % (w/w): 0.009000

Cas Number(s):

EINECS:

Function(s): FRAGRANCE, PERFUMING

Restriction: None

Opuntia Ficus-Indica Extract

Max % (w/w): 0.008425

Cas Number(s): 90082-21-6

EINECS: 290-109-1

Function(s): SKIN CONDITIONING

Restriction: None

2 Physical/ chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the cosmetic product are described below. The stability of the cosmetics product under reasonably foreseeable storage conditions.

Name: Eco Refill Handwash with Variations (PD47075 & PD47076)

Appearance: Liquid

Colour: Clear

Odour: Characteristic

pH: 7.5 – 8.5

Variations: 1) PD47075 & 2) PD47076

Storage conditions: Ambient conditions

Stability of the cosmetic product: The minimum durability for the cosmetic is 30 months, with a Period After Opening (PAO) of 12 months.

3 Microbiological quality and Preservative Efficacy Test (PET)

Following the guidelines set in ISO 29621 on the risk assessment and identification of microbial risk to cosmetic products, the cosmetic product, Eco Refill Handwash with Variations (PD47075 & PD47076) is an aqueous product that required PET. The cosmetic product is expected to remain free of microbial contamination through the period of minimum durability when stored under appropriate conditions.

4 Impurities and prohibited substances

Any impurities present in the raw materials were determined to be minimal and are found in only trace amounts in the finished product. Based on the available information, no traces of prohibited substances are expected to be present in the finished product.

5 Normal and reasonably foreseeable use

Eco Refill Handwash with Variations (PD47075 & PD47076) is intended to be applied to the skin (hands). Expected usage is by those 3 years and above in age. Instructions for use can be found in the PIF.

6 Exposure to the cosmetic product

The calculation of the exposure for the cosmetic product considers the amount applied, applications per day and body weight.

Exposure type: Rinse-off

Normal and reasonably foreseeable exposure route(s): Dermal

Values used for the cosmetic product

Amount of cosmetic product applied per use: 2.0 g

Frequency of application: 5.0 time/day

Amount of cosmetic product applied per day: 10.0 g

Retention factor: 1.0%

Body weight: 60.0 kg

7 Exposure to the ingredients and calculation of Systemic Exposure Dose (SED)

The Systemic Exposure Dose (SED) of a cosmetic substance estimates the amount expected to be systemically available, reported as milligram per kilogram body weight per day. The SED is determined using dermal absorption, which is reported as a percentage of the amount of cosmetic product applied. Additionally, the quantity applied and frequency of application of the cosmetic product are considered.

The following equation is used to calculate SED (mg/kg bw/day)

$$\text{SED} = A \text{ (mg/kg bw/day)} \times C \text{ (\%)/100} \times \text{Fret (\%)/100}$$

A (mg/kg bw/day) - mg applied per kg body weight per day

C (%) - Maximum percentage concentration of the substance in the cosmetic product

Fret - Retention Factor of the cosmetic product. When reference values are unavailable a retention factor of 100% is used for leave-on products and 1% for rinse-off products. For cosmetics products with reduced surface area exposure (liquid-saturated masks, waxing products...) 10% is used.

The SED for each ingredient in the cosmetic product is shown below.

INCI- Ingredient name

Max %- Maximum percentage of the ingredient (w/w)

g App- grams per application of cosmetic product

RF- Retention Factor of the cosmetic product.

E mg/d- Exposure to the cosmetic product mg per day (mg/d)

SED of the Ingredients in the Cosmetic Product

INCI	Max % (w/w)	g/app	RF	SED
AQUA	99.000000	9.900000	1%	1.650000
SODIUM C14-16 OLEFIN SULFONATE	0.779200	0.077920	1%	0.012987
HYDROXYPROPYL GUAR	0.099000	0.009900	1%	0.001650
BRONOPOL	0.079200	0.007920	1%	0.001320
MALTODEXTRIN	0.030331	0.003033	1%	0.000506
CAPPARIS SPINOSA FRUIT EXTRACT	0.011234	0.001123	1%	0.000187
OLEA EUROPAEA LEAF EXTRACT	0.010110	0.001011	1%	0.000169
CELLULOSE	0.009900	0.000990	1%	0.000165
POLYVINYL ALCOHOL	0.009900	0.000990	1%	0.000165
PARFUM	0.009000	0.000900	1%	0.000150
OPUNTIA FICUS-INDICA EXTRACT	0.008425	0.000843	1%	0.000140

8 Toxicological profiles of the substances

To evaluate the safety of the finished cosmetic product, the available toxicological data for all substances was considered by the safety assessor. Scientific literature was used to assess the toxicological profile of each ingredient, including the No Observable Adverse Effects Level (NOAEL). Exposure to the raw materials and cosmetic product were also considered and used to determine a Margin of Safety (MoS) for each component. Combined, this data led the safety assessor to the conclusion that the ingredients pose insignificant risk.

Calculation of the Margin of Safety (MoS)

The Margin of Safety (MoS) is a measure of the probability a substance will cause harm to the human body. The Margins of Safety were calculated for each ingredient in the cosmetic product using following equation:

$$\text{MoS} = \frac{\text{NOAEL}}{\text{SED}}$$

where SED represents the Systemic Exposure Dosage

The Margin of Safety (MoS) is calculated using the Systemic Effect Dose (SED) and the No Observable Adverse Effects Level (NOAEL). An ingredient is considered safe if the MoS is greater than 100 (>100).

In some cases, the MoS could not be calculated because the ingredient did not have a NOAEL. When NOAEL was unavailable for an ingredient, Cosmetic Ingredient Review (CIR) of ingredients was consulted.

In cases where the ingredient does not have a determined NOAEL and has not been evaluated for safety by the Cosmetic Ingredient Review, the safety assessor has consulted the available scientific literature to make a judgement about the ingredient's suitability for the ingredient to be used in cosmetics and safety.

Exposure to water (INCI Aqua) poses little risk and is thereby considered safe to use as a cosmetic ingredient. Noted as SAFE.

None of the assessed raw materials are classified as Carcinogenic, Mutagenic or Genotoxic (CMG) ingredients.

In conclusion, there are no reported adverse toxicological issues relating to the ingredients used to make the cosmetic.

Safety of the Ingredients in the Cosmetic Product

INCI	Max % (w/w)	SED	MoS/Assessment
AQUA	99.000000	1.650000	SAFE
SODIUM C14-16 OLEFIN SULFONATE	0.779200	0.012987	CIR SAFE
HYDROXYPROPYL GUAR	0.099000	0.001650	CIR SAFE
BRNOPOL	0.079200	0.001320	>100
MALTODEXTRIN	0.030331	0.000506	CIR SAFE
CAPPARIS SPINOSA FRUIT EXTRACT	0.011234	0.000187	>100
OLEA EUROPAEA LEAF EXTRACT	0.010110	0.000169	>100
CELLULOSE	0.009900	0.000165	CIR SAFE
POLYVINYL ALCOHOL	0.009900	0.000165	>100
PARFUM	0.009000	0.000150	-
OPUNTIA FICUS-INDICA EXTRACT	0.008425	0.000140	>100

9 Undesirable effects and serious undesirable effects

No undesirable effects or serious undesirable effects have been reported resulting from the application of the cosmetic product, under normal and reasonably foreseeable use.

10 Information on the cosmetic product and packaging

Eco Refill Handwash with Variations (PD47075 & PD47076) is supplied in cosmetic or food grade packaging. The cosmetic product's formulation, packaging material, and environmental exposure are expected to have no significant effect of the safety of the finished product.

PART B COSMETIC PRODUCT SAFETY ASSESSMENT

Part B of Annex I describes the reasoning used to assess the safety of the product and provides the conclusions made by the qualified safety assessor.

1 Assessment conclusions

Eco Refill Handwash with Variations (PD47075 & PD47076) meets the safety criteria specified in the 'The UK Regulation' Schedule 34 of the Product Safety and Metrology Statutory Instrument and "Cosmetics Regulation" Regulation (EC) No. 1223/2009.

2 Instructions for use and product warnings

Instructions for use and product warnings are detailed in the PIF.

3 Reasoning

The product's safety assessment was based on the evaluation of the individual safety profile of each ingredient present in the formulation and the final composition of the cosmetic products. Eco Refill Handwash with Variations (PD47075 & PD47076) is manufactured using safe ingredients that are unlikely to cause adverse effects under normal and foreseeable use.

4 Safety assessor credentials

Dr Sara Robb, the author of this report has the qualifications required in the pharmaceutical and toxicological areas, according to the defined in Regulation (EC) 1223/2009.

Qualifications:

B.A. Iowa State University USA

M.A. University of South Dakota, USA

Ph.D. The Pennsylvania State University, USA

Winner of the Marian Kies Award

Post-doctorate Research Fellow

University of Dundee, UK

University College London, UK

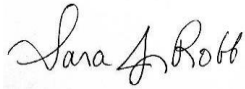


Member of the Society for Cosmetic Scientists & the Cosmetic, Toiletry and Perfumery Association

VUB Certificate for completing the European Registered Toxicologist- accredited course "Safety Assessment of Cosmetics in the EU" offered by Vrije Universiteit Brussel.

CPSR APPROVED on 26 January 2023

Eco Refill Handwash with Variations (PD47075 & PD47076) is safe for human health when used under normal or reasonably foreseeable conditions of use as set out in 'The UK Regulation' Schedule 34 of the Product Safety and Metrology Statutory Instrument and Article 3 of "Cosmetics Regulation" Regulation (EC) No. 1223/2009.



Dr Sara J Robb (VUB)

European Credit Transfer and Accumulation System ECTS: 6 credit points
ERT-accredited course: taken into consideration for the recognition as European Registered Toxicologist

CERTIFICATE

The Undersigned declare that

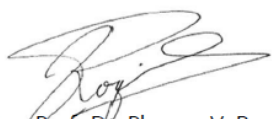
Sara Robb

has followed the lessons and has successfully passed the exam of the

"Online Safety Assessment of Cosmetics in the EU – Training Course 2022"

organized by the Vrije Universiteit Brussel

Brussels, 23 May 2022



Em. Prof. Dr. Pharm. V. Rogiers
Course organizer



Prof. Dr. Caroline Pauwels
Rector of Vrije Universiteit Brussel



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