

Sakura Blossom Hand Wash 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.

This unique formulation is contained within a PVOH film that dissolves at the point of use. The sachets are dry, compact and light, they reduce storage space and 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) Cosmetic Data Report.



PRODUCT DESCRIPTION

Sakura Blossom Hand Wash is designed to provide a foaming hand wash solution for everyday use. 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
20 * 5g	PVA-OH	CP02:20	Pouch

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

INSTRUCTIONS FOR USE

Place one sachet into the supplied soap dispenser and fill with water. Replace the dispenser head and after making sure the head is fully screwed in place, 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. When the dispenser is ready to be refilled, it is advisable to wash out with warm water before adding clean water and the replenishing sachet.

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: This product is ideally used through the supplied dispenser bottle. If clear bottles are used a slight yellowing of the product will be noted; this is normal.

TECHNICAL DATA SUMMARY

Appearance as supplied	White Powder
Cosmetic Reg No.	UKCP-20144297
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 18 months under normal conditions of dry storage

EMERGENCY DETAILS

For accident, emergency and health & safety information refer to the Safety Data Sheet 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
Product code	: PCP02:20, CP02:20
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
Use of the substance/mixture	: Hand wash soap UK Cosmetic Reg No. UKCP78704148

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.
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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.
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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

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	-	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.

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.

SAKURA BLOSSOM HAND WASH

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	
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

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

SAKURA BLOSSOM HAND WASH

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

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

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

Persistence and degradability	The Surfactants and Chelants used in this mixture are Biodegradable.
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SAKURA BLOSSOM HAND WASH

Safety Data Sheet

According to GB and EU REACH and CLP Regulations

12.3. Bioaccumulative potential

SAKURA BLOSSOM HAND WASH

Bioaccumulative potential	Not expected to Bioaccumulate.
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12.4. Mobility in soil

SAKURA BLOSSOM HAND WASH

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

SAKURA BLOSSOM HAND WASH

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

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According to GB and EU REACH and CLP Regulations

Air transport

Not applicable

Inland waterway transport

Not applicable

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)

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Safety Data Sheet

According to GB and EU REACH and CLP Regulations

Abbreviations and acronyms:	
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
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.

Dr Sara Robb
33 Avondale Road
London, N13 4DX
United Kingdom



COSMETIC PRODUCT SAFETY REPORT

PVA HYGIENE • EVERY DAY HAND WASH WITH VARIATION

REF: PVAHEDHW251121DSR

Issued: 25 NOVEMBER 2021

Modified: 21 MARCH 2022- Variation added
08 SEPTEMBER 2022 Age of user change

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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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

PVA Hygiene Every Day Hand Wash is a rinse-off product that belongs to the "skin care" categories in accordance with the guidelines published by the Scientific Committee on Consumer Safety (SCCS). Supplied in a dry sachet, the packet is dissolved in water to make the cosmetic product, Every Day Hand Wash. This report assesses the safety of the final aqueous cosmetic product- PVA Hygiene Every Day Hand Wash.

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 & qualitative composition of the cosmetic product

Composition of the cosmetic product will be specified using both quantitative and qualitative information. The raw materials contained in the cosmetic product conform to 'The UK Regulation' Schedule 34 of the Product Safety and Metrology Statutory Instrument and "Cosmetics Regulation" Regulation (EC) No. 1223/2009 and its amendments.

Physical characteristics of the cosmetic product

Appearance Liquid

Colour Clear

Odour Characteristic

pH 7.5 – 8.5

INGREDIENTS: AQUA, SODIUM C14-16 OLEFIN SULFONATE, HYDROXYPROPYL GUAR, POLYVINYL ALCOHOL, OLEA EUROPAEA LEAF EXTRACT, SODIUM XYLENESULFONATE, BRONOPOL, MALTODEXTRIN, PARFUM, CAPPARIS SPINOSA FRUIT EXTRACT, OPUNTIA FICUS-INDICA EXTRACT

2 Composition: physical and chemical characteristics

The composition of the cosmetic product is described below. Both quantitative and qualitative composition of the cosmetic product are identified.

2.1 Physical and chemical characteristics of the raw materials

Raw materials and the constituents of the final product are described by percentage. The substances are identified below by INCI. Each ingredient's CAS, and EINECS is provided when available. Intended function(s) are also described

Aqua

Max % (w/w): 97.732000

Cas Number(s): 7732-18-5

EINECS: 231-791-2

Function(s): SOLVENT

Restriction: None

Sodium C14-16 Olefin Sulfonate

Max % (w/w): 1.130000

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): 0.255000

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

Polyvinyl Alcohol

Max % (w/w): 0.166000

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

EINECS:

Function(s): FILM FORMING, VISCOSITY CONTROLLING

Restriction: None

Parfum

Max % (w/w): 0.016600

Cas Number(s):

EINECS:

Function(s): FRAGRANCE, PERFUMING

Restriction: None

Olea Europaea Leaf Extract

Max % (w/w): 0.136800

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

EINECS: 232-277-0

Function(s): PERFUMING, SKIN CONDITIONING

Restriction: None

Sodium Xylenesulfonate

Max % (w/w): 0.120000

Cas Number(s): 1300-72-7

EINECS: 215-090-9

Function(s): SURFACTANT - HYDROTROPE

Restriction: None

Bronopol

Max % (w/w): 0.092000

Cas Number(s): 52-51-7

EINECS: 200-143-0

Function(s): PRESERVATIVE

Restriction: V/21

Maltodextrin

Max % (w/w): 0.041040

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): 0.015200

Cas Number(s): 89958-23-6

EINECS: 289-646-4

Function(s): SKIN CONDITIONING

Restriction: None

Opuntia Ficus-indica Extract

Max % (w/w): 0.011400

Cas Number(s): 90082-21-6

EINECS: 290-109-1

Function(s): SKIN CONDITIONING

Restriction: None

2.2 Cosmetic product variations

The cosmetic product, PVA Hygiene Every Day Hand Wash, is supplied in the following variations.

PVA HYGIENE EVERY DAY HAND WASH

INGREDIENTS: AQUA, SODIUM C14-16 OLEFIN SULFONATE, HYDROXYPROPYL GUAR, POLYVINYL ALCOHOL, OLEA EUROPAEA LEAF EXTRACT, SODIUM XYLENESULFONATE, BRONOPOL, MALTODEXTRIN, CAPPARIS SPINOSA FRUIT EXTRACT, OPUNTIA FICUS-INDICA EXTRACT

PVA HYGIENE EVERY DAY BLOSSOM HAND WASH

INGREDIENTS: AQUA, SODIUM C14-16 OLEFIN SULFONATE, HYDROXYPROPYL GUAR, POLYVINYL ALCOHOL, OLEA EUROPAEA LEAF EXTRACT, SODIUM XYLENESULFONATE, BRONOPOL, MALTODEXTRIN, PARFUM, CAPPARIS SPINOSA FRUIT EXTRACT, OPUNTIA FICUS-INDICA EXTRACT

2.3 Physical and chemical properties of the raw materials

The chemical dossiers for the raw materials are included in the Product Information File (PIF). These sheets describe the physical and chemical properties of each ingredient.

2.4 Stability of the cosmetic product

PVA Hygiene Every Day Hand Wash will be stored at ambient temperature. Relevant stability tests were undertaken. The durability for the sachet is 30 months with the durability of the aqueous cosmetic indicated as 12 months.

3 Microbiological quality

PVA Hygiene Every Day Hand Wash meets the microbial requirements set out for products that are under 3 years old. The cosmetic product will remain free of microbial contamination through the period of minimum durability when stored under appropriate conditions.

3.1 Raw materials

The microbiological quality of the raw materials, if available, are included in the PIF.

3.2 The cosmetic product

A cosmetic product's susceptibility to contamination is related directly to its composition, the preservative content, good manufacturing practice, the packaging material and storage conditions. Cosmetic products susceptible to microbial contamination, including aqueous formulations, should employ a preservative.

3.3 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. PVA Hygiene Every Day Hand Wash is an aqueous product that required PET. The cosmetic product met standard requirements to pass PET. The results are included in the PIF.

4 Impurities and prohibited substances

A small, unintended quantity of prohibited substances may result from impurities in the ingredients. For further details see the attached dossier for each raw material.

Additionally, impurities and prohibited substances may be produced in the manufacturing process or entering the cosmetic product through packaging. The product packaging meets necessary standards as demonstrated by the attached documents. Any impurities in the cosmetic product, do not affect the safety of the product.

4.1 Impurities in the raw materials

Any impurities present in the raw materials were determined to be minimal and are found in only trace amounts in the finished product.

4.2 Prohibited substances

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

PVA Hygiene Every Day Hand Wash is intended to be applied to the skin (hands). Expected usage is 5 time(s) daily. Instructions for use can be found in the PIF.

6 Exposure to the cosmetic product

PVA Hygiene Every Day Hand Wash is a rinse-off product.

6.1 Normal and reasonably foreseeable exposure route(s)

The exposure route for the cosmetic product is dermal.

6.2 Exposure levels to the cosmetic product

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

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: 100.0%

Body weight: 60.0 kg

Grams of cosmetic product applied, and frequency of application are described in the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) Cosmetic Fact Sheet and listed in Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation.

6.3 Target population

The cosmetic product is formulated to be used by those 2 years and older.

7 Exposure to the ingredients

Exposure per use is 2.0 g, applied to the hair/skin (hands) with subsequent washing to remove the cosmetic product. The retention factor (RF) for rinse-off products is 1%.

7.1 Calculation of Systemic Exposure Dose

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)

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

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

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

DAp (%) – Dermal Absorption percentage. When reference values are unavailable a retention factor of 100% is used for leave-on products and 1% for rinse-off products.

The SED for each ingredient in PVA Hygiene Every Day Hand Wash is shown in section 7.2, 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)

7.2 SED of the ingredients in the cosmetic product

INCI	Max % (w/w)	g/app	RF	SED
AQUA	97.732000	9.773200	1%	1.628867
SODIUM C14-16 OLEFIN SULFONATE	1.130000	0.113000	1%	0.018833
HYDROXYPROPYL GUAR	0.255000	0.025500	1%	0.004250
POLYVINYL ALCOHOL	0.166000	0.016600	1%	0.002767
OLEA EUROPAEA LEAF EXTRACT	0.136800	0.013680	1%	0.002280
SODIUM XYLENESULFONATE	0.120000	0.012000	1%	0.002000
BRONOPOL	0.092000	0.009200	1%	0.001533
MALTODEXTRIN	0.041040	0.004104	1%	0.000684
PARFUM	0.016600	0.001660	1%	0.000277
CAPPARIS SPINOSA FRUIT EXTRACT	0.015200	0.001520	1%	0.000253
OPUNTIA FICUS-INDICA EXTRACT	0.011400	0.001140	1%	0.000190

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.

8.1 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 on tables 7.2 and 8.2, respectively.

None of the assessed raw materials are classified as toxic, specifically no Carcinogenic, Mutagenic or Genotoxic (CMG) ingredients. In conclusion, the respective ingredients are harmless in the concentration contained in the cosmetic product.

8.2 Safety of the ingredients in the cosmetic product

INCI	Max % (w/w)	SED	MoS/Assessment
AQUA	97.732000	1.628867	SAFE
SODIUM C14-16 OLEFIN SULFONATE	1.130000	0.018833	CIR SAFE
HYDROXYPROPYL GUAR	0.255000	0.004250	CIR SAFE
POLYVINYL ALCOHOL	0.166000	0.002767	>100
OLEA EUROPAEA LEAF EXTRACT	0.136800	0.002280	>100
SODIUM XYLENESULFONATE	0.120000	0.002000	CIR SAFE
BRONOPOL	0.092000	0.001533	>100
MALTODEXTRIN	0.041040	0.000684	CIR SAFE
PARFUM	0.016600	0.000277	-
CAPPARIS SPINOSA FRUIT EXTRACT	0.015200	0.000253	>100
OPUNTIA FICUS-INDICA EXTRACT	0.011400	0.000190	>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 foreseeable use.

10 Information on the cosmetic product

The ingredients used in the formulation for the cosmetic product comply with 'The UK Regulation' Schedule 34 of the Product Safety and Metrology Statutory Instrument and "Cosmetics Regulation" Regulation (EC) No. 1223/2009 and its amendments.

10.1 Description of the product packaging

PVA Hygiene Every Day Hand Wash is supplied in cosmetic packaging. The packaging material, cosmetic product's formulation, and environmental exposure are expected to have no significant effect of the safety of the finished product. The packaging is not expected to react with the cosmetic product.

PART B COSMETIC PRODUCT SAFETY ASSESSMENT

Part B of Annex I to Regulation (EC) No 1223/2009, describes the reasoning used to assess the safety of the product and provides the conclusions made by the qualified safety assessor.

1 Assessment conclusions

PVA Hygiene Every Day Hand Wash 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. PVA Hygiene Every Day Hand Wash is manufactured using safe ingredients that are unlikely to cause adverse effects under normal and foreseeable use.

4 Safety assessor credentials and Approval

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



Experience:

Formulating for nearly 20 years, Sara's recipes are available in books (Dr Sara's Honey Potions, Beauty & the Bees, Making and Selling Cosmetics: Honeycomb Cleansing Cream) and numerous journal articles (British Beekeeping Journal, Bee Craft, BBKA News, Bees for Development Journal). Dr Robb has a keen interest in teaching others to formulate cosmetics (running workshops at the British Beekeepers Association Spring Convention and The National Honey Show) and helping small producers by providing Cosmetic Product Safety Reports.

CPSR APPROVED on 25 November 2021 (modified on 21 March 2022)

PVA Hygiene Every Day Hand Wash is safe when used under normal or reasonably foreseeable conditions.



Dr Sara J Robb

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contain except subject to the restrictions laid down

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