Swift Fox Consultancy Ltd
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ADDENDUM TO

COSMETIC PRODUCT SAFETY REPORT

In accordance with Annex I, EC 1223/2009 and The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Report Number	See accompanying report	**Date:**	26 August 2022
Product name:	Jelly Soap	**Company contact:**	See accompanying report
Product code:	N/A	**Company address:**	See accompanying report
Product category:	Soap – Rinse Off	**Email:**	See accompanying report

SUMMARY

The product(s) have been reviewed and according to the information submitted in this report the product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date. The product(s) have been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date. The ingredients in this product are used at levels that are consistent with industry norms.

It is my opinion that these cosmetic formulation(s) are considered safe to use under normal or reasonably foreseeable conditions of use. The assessment is conditional on the items outlined in section B.

Signed:

Laura Turnham, ERT, RSB CBiol, MSc

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COSMETIC PRODUCT SAFETY INFORMATION

Quantitative and qualitative composition of the cosmetic product(s)

This Addendum to the Cosmetic Product Safety Report is dependent on the manufacturer making the product in accordance to the instructions and recipe as supplied by Stansfield's. This addendum is reliant on having the Jelly Soap CPSR. This addendum may not be used in other products or on its own.

Any deviation from listed suppliers, trade names would invalidate the report/addendum. Any deviations from the recipe and instructions would validate the report. The product must be sold and manufactured in accordance to Cosmetic Regulations EC 1223/2009 and The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019. The product must be manufactured in accordance to Good Manufacturing Practice.

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Outline of changes:

The recently published 18th ATP (EU/2022/692) to the EU CLP Regulation (EC/1272/2008), includes a reclassification of Pentasodium Pentetate (CAS 140-01-2) as a Reprotoxic CMR 1B.

As the EU cosmetic's industry are not defending the materials continued use, as a CMR the material will be added to Annex II (prohibited substances) of the Cosmetic Product Regulation (EC/1223/2009).

In response to this regulatory change, the supplier of the Jelly Soap Base; Stephenson has removed Pentasodium Pentetate from its formulations.

Previous formulation:

Trade name	Supplier	INCI name	RM in product %	INCI breakdown of RM %	Total INCI %
CRYSTAL JELLY SOAP	Stephenson's	Glycerin	97.000-100.000	Up to 41.900	Up to 41.900
		Aqua		Up to 41.900	Up to 41.900
		Sodium Laureth Sulfate		Up to 10.000	Up to 10.000
		Chondrus Crispus Powder		Up to 5.000	Up to 5.000
		Phenoxyethanol		Up to 1.000	Up to 1.000
		Pentasodium Pentetate		Up to 0.100	Up to 0.100
		Tetrasodium Etidronate		Up to 0.100	Up to 0.100

Pentasodium Pentetate (highlighted in pink) will be replaced with Tetrasodium Iminodisuccinate (also highlighted in pink, below).

Revised formulation:

Trade name	Supplier	INCI name	RM in product %	INCI breakdown of RM %	Total INCI %
CRYSTAL JELLY SOAP	Stephenson's	Glycerin	97.000-100.000	Up to 41.900	Up to 41.900
		Aqua		Up to 41.900	Up to 41.900
		Sodium Laureth Sulfate		Up to 10.000	Up to 10.000
		Chondrus Crispus Powder		Up to 5.000	Up to 5.000
		Phenoxyethanol		Up to 1.000	Up to 1.000
		Tetrasodium Iminodisuccinate		Up to 0.100	Up to 0.100
		Tetrasodium Etidronate		Up to 0.100	Up to 0.100

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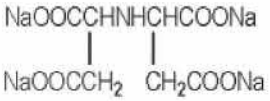
The following section has been amended:

Annex I – Toxicological Ingredient Profiles

Ingredient Profile: Tetrasodium Iminodisuccinate

CAS number:	144538-83-0	**EC number:**	N/A
INCI Name:	Tetrasodium Iminodisuccinate		
Pseudonyms:	N/A		
Structure:	$C_8H_7NO_8 \cdot 4Na$	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Jelly Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	penetration data? (Tick applies skin penetration	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Tetrasodium Iminodisuccinate	0.10000	144538 83 0	N/A	Chelating	N/A	0.10000	0.00043	No Data			100	0.001	No Data	500		

Tetrasodium Iminodisuccinate is an organic compound. Tetrasodium Iminodisuccinate is used as a chelating agent in cosmetic products.

Tetrasodium Iminodisuccinate is not toxic via the oral or dermal route. Tetrasodium Iminodisuccinate is not irritating to the eyes and skin in animal models. In a guinea pig Maximisation test Tetrasodium Iminodisuccinate was not a sensitiser when tested at 25%. Tetrasodium Iminodisuccinate was tested in a 28 day oral study in rats, the NOAEL was 200 mg/kg bw/day. Tetrasodium Iminodisuccinate was not genotoxic *in vitro* and *in vivo*.

Summary:

The concentration and use of Tetrasodium Iminodisuccinate is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

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Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 423	Rat LD_{50}: >2000 mg/kg	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1996
Acute dermal toxicity	OECD 402	Rat LD_{50}: >2000 mg/kg	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1997
Skin irritation	OECD 404	Rabbit: Non irritating at up to 100%	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1998
Eye irritation	OECD 405	Rabbit: Non irritating at up to 100%	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1998
Skin sensitisation	OECD 406	Not sensitising at up to 25% in guinea pigs	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1997
Repeated dose 28-day oral toxicity study in rodents	OECD 407	NOAEL Rat: 200 mg/kg bw/day	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1997
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: NICNAS STD/1018 Animal test date: Non animal test data.
***In vivo* mammalian erythrocyte micronucleus test**	OECD 474	Not genotoxic at up to 1500 mg/kg bw/day	Secondary source: NICNAS STD/1018 Animal test date: Prior to 1997.

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Assessor's credentials and approval

The re-classification of Pentasodium Pentetate as Reprotoxic CMR 1B has necessitated the substitution of Tetrasodium Iminodisuccinate.

Tetrasodium Iminodisuccinate has been reviewed by National Industrial Chemicals Notification and Assessment Scheme (NICNAS Australia) which concluded that Tetrasodium Iminodisuccinate was not expected to pose a risk to the environment, is a negligible for public health and safety and low risk occupational health and safety.

Tetrasodium Iminodisuccinate has a long history of safe use in household and cosmetic product formulations. Tetrasodium Iminodisuccinate is not expected to affect the stability of the formulation. Tetrasodium Iminodisuccinate is not expected to affect the products microbial efficacy.

Therefore, the substitution of Pentasodium Pentetate with Tetrasodium Iminodisuccinate has been reviewed as acceptable.

The product has been reviewed and according to the information submitted in this amendment and the attached report. The product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date.

The product has been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date

The ingredients in these products are used at levels that are consistent with industry norms.

It is my opinion that the amendment to this cosmetic formulation is considered safe to use under normal or reasonably foreseeable conditions of use.

Signed:

Laura Turnham, ERT, RSB CBiol, MSc

Qualifications:

Safety assessment of cosmetics in the EU, VUB (University of Brussels), 2015, Pass

MSc Molecular Pathology and Toxicology, Leicester University (UK), 2011. Distinction.

BSc Biochemistry (Toxicology), University of Surrey, 2008, 2:1 (Hons).

Eurotox registered toxicologist (ERT).

UK Registered Toxicologist (UKRT).

Chartered Biologist (CBiol RSB).

Member of the Royal Society of Biology (MRSB).