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:**	08 February 2023
Product name:	Melt & Pour 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 Melt & Pour 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 CRYSTAL SLS FREE and CRYSTAL WSLS FREE; Stephenson has removed Pentasodium Pentetate from its formulations. Stephenson has also modified the formulations slightly with the addition of Citric Acid and its sodium salt Sodium Citrate and the removal of Stearic acid and Lauric Acid

Previous formulation:

Trade name	Supplier	INCI name	RM in product %	INCI breakdown of RM %	Total INCI %
May contain CRYSTAL SLS FREE soap base, CRYSTAL WSLES SLS FREE or layering of either soap bases.					
CRYSTAL SLS FREE	Stephenson's	Glycerin	95.600-100.000	Up to 30.800	Up to 30.800
		Aqua		Up to 17.500	Up to 17.500
		Sodium Stearate		Up to 17.500	Up to 17.500
		Propylene Glycol		Up to 7.000	Up to 7.000
		Sorbitol		Up to 7.000	Up to 7.000
		Sodium Laurate		Up to 7.000	Up to 7.000
		Sodium Laureth Sulfate		Up to 7.000	Up to 7.000
		Sodium Chloride		Up to 2.500	Up to 2.500
		Disodium Lauryl Sulfosuccinate		Up to 2.500	Up to 2.500
		Stearic Acid		Up to 0.500	Up to 0.500
		Lauric Acid		Up to 0.500	Up to 0.500
		Pentasodium Pentetate		Up to 0.100	Up to 0.100
		Tetrasodium Etidronate		Up to 0.100	Up to 0.100
CRYSTAL WSLS FREE	Stephenson's	Aqua	95.600-100.000	Up to 31.800	Up to 31.800
		Glycerin		Up to 25.000	Up to 25.000
		Sodium Stearate		Up to 10.000	Up to 10.000
		Sorbitol		Up to 10.000	Up to 10.000
		Propylene Glycol		Up to 7.000	Up to 7.000
		Sodium Laurate		Up to 7.000	Up to 7.000
		Sodium Chloride		Up to 2.500	Up to 2.500
		Sodium Laureth Sulfate		Up to 2.500	Up to 2.500
		Disodium Lauryl Sulfosuccinate		Up to 2.500	Up to 2.500
		CI 77891		Up to 0.500	Up to 0.500
		Stearic Acid		Up to 0.500	Up to 0.500
		Lauric Acid		Up to 0.500	Up to 0.500
		Pentasodium Pentetate		Up to 0.100	Up to 0.100
		Tetrasodium Etidronate		Up to 0.100	Up to 0.100

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Pentasodium Pentetate, Stearic Acid, Lauric Acid (highlighted in pink, above) will be replaced with Tetrasodium Iminodisuccinate, Citric Acid, Sodium Citrate (also highlighted in pink, below).

Revised formulation:

Trade name	Supplier	INCI name	RM in product %	INCI breakdown of RM %	Total INCI %
May contain CRYSTAL SLS FREE soap base, CRYSTAL WSLES SLS FREE or layering of either soap bases.					
CRYSTAL SLS FREE	Stephenson's	Glycerin	95.600-100.000	Up to 30.800	Up to 30.800
		Aqua		Up to 17.500	Up to 17.500
		Sodium Stearate		Up to 17.500	Up to 17.500
		Propylene Glycol		Up to 7.000	Up to 7.000
		Sorbitol		Up to 7.000	Up to 7.000
		Sodium Laurate		Up to 7.000	Up to 7.000
		Sodium Laureth Sulfate		Up to 7.000	Up to 7.000
		Sodium Chloride		Up to 2.500	Up to 2.500
		Disodium Lauryl Sulfosuccinate		Up to 2.500	Up to 2.500
		Citric Acid		Up to 1.000	Up to 1.000
		Sodium Citrate		Up to 0.500	Up to 0.500
		Tetrasodium Iminodisuccinate		Up to 0.100	Up to 0.100
		Tetrasodium Etidronate		Up to 0.100	Up to 0.100
CRYSTAL WSLS FREE	Stephenson's	Aqua	95.600-100.000	Up to 31.800	Up to 31.800
		Glycerin		Up to 25.000	Up to 25.000
		Sodium Stearate		Up to 10.000	Up to 10.000
		Sorbitol		Up to 10.000	Up to 10.000
		Propylene Glycol		Up to 7.000	Up to 7.000
		Sodium Laurate		Up to 7.000	Up to 7.000
		Sodium Chloride		Up to 2.500	Up to 2.500
		Sodium Laureth Sulfate		Up to 2.500	Up to 2.500
		Disodium Lauryl Sulfosuccinate		Up to 2.500	Up to 2.500
		CI 77891		Up to 0.500	Up to 0.500
		Citric Acid		Up to 1.000	Up to 0.500
		Sodium Citrate		Up to 0.500	Up to 0.500
		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: Citric Acid

CAS number: 5949-29-1 / 77-92-9 **EC number:** 201-069-1 (I)

INCI Name: Citric Acid

Pseudonyms: 2-Hydroxy-1,2,3-Propanetricarboxylic Acid, acidum citricum (EP).

Structure:

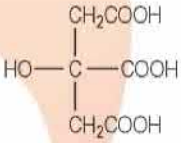

Image:

CLP Hazard classification(s): H319 Causes serious eye irritation

REGULATION (EC) No 1223/2009 Not restricted.

Other regulatory statuses: Food:
USFDA: GRAS, approved indirect and direct food addictive (21CFR178.1010, 21CFR184.1033).
JEFCA: Not restricted.
EU: Approved food additive.

Cosmetics:
Canada Hotlist: (AHAs)
FDA: AHAs
EU: Not restricted

INCI Name	M&P 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 data on all	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/ CEL	Acceptable Exposure Level ug/cm2
Citric Acid	1.000	77-92-9 / 5949-29-1	201-069-1	Buffering, Chelating, Masking	n/a	1.00000	0.00433	1200	276922	☐	100	0.015	No Data	300		

Citric acid is an inorganic acid. It is naturally occurring in fruits with up to 8% of the dry weight of lemons and lime accounting for citric acid[1]. It is used as a chelating agent, fragrance ingredient and pH adjuster in cosmetic products.

Citric acid is an approved in direct and direct food additive by the USFDA (21CFR178.1010, 21CFR184.1033) and is considered to be Generally Recognised As Safe (GRAS). Citric acid was reviewed by JEFCA/WHO as a food additive and is not limited in foods. Citric acid is an approved food additive in the EU (E330).

According to the CIR review citric acid is used up to 35% in bath products (Such as bath salts/bath bombs), up to 10% in rinse off products and up to 4% in leave on products. It is used at up to 3% in products that may be ingested, up to 2% in products used in the eye area and 0.2% in baby products.

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Citric acid when orally administered is well absorbed and metabolised. Citric acid is also produced endogenously as a part of normal metabolism, where is completes the breakdown of pyruvate produced from glucose metabolism. Approximately 2 Kg of citric acid is metabolised every day in humans. Citric acid is freely filterable in the kidney and 65-90% of citric acid is reabsorbed[2]. Therefore as citric acid is present in the diet naturally in addition to synthetic sources, coupled with endogenous production of citric acid, systemic toxicity from cosmetic products containing citric acid is not expected.

Citric acid has a low acute oral toxicity. Citric acid can cause coughing in humans and in animal models when inhaled in high concentrations, the cough reflex is produced by irritation to the larynx and trachea[2]. In animal models citric acid is slightly irritating to the skin and severely irritating to the eyes. In a 48h patch test of 1% citric acid in 133 oral disease patients there were no reactions to citric acid[2], however according to the OECD SIDS report[3] citric acid can cause a stinging sensation at 2% aqueous solutions. This effect was not related to irritation, therefore, although it is not necessarily a safety concern, it is recommended to limit the level of citric acid in aqueous cosmetics as high levels of citric acid topically is not always tolerated by the consumer.

Citric acid has been tested in a HRIPT test. Patches of a cuticle cream containing 4% citric acid were applied 3 times a week for 3 weeks followed by a rest period. There were no reports of irritation or sensitisation[2].

Citric acid is considered an alpha hydroxy acid by the USFDA and Health Canada, at high levels in leave on products it is recommended to place a suncare warning on the labelling.

Summary:

The concentration and use of citric acid 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 such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. Journal of Endourology. 22 (3): 567–570
2. IJT 33(Suppl.2):16-46, 2014
3. OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001

Specification data:

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

Appearance:	White crystalline powder of crystals
Lead:	<0.5 mg/kg
Arsenic:	<3 mg/kg
Mercury:	<1 mg/kg

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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	Not to GLP	Mouse LD_{50}: 5400 mg/kg	Secondary source: SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1981
Dermal irritation	OECD 404, not to GLP	Rabbit: Slightly irritating	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1991.
Eye irritation	Draize, not to GLP	Rabbit: At 10%, 30% citric acid was mildly to moderately irritating.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1984
Reproductive/developmental toxicity	Pre-guideline test data.	Rats NOAEL: 2500 mg/kg bw/day	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1976.
***In vitro* Bacterial Reverse Mutation Test**	OECD 471	Not mutagenic up to 5000 µg/plate ±S9	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: Non animal test method.
Chronic systemic toxicity	Pre-guideline test data.	NOAEL rat: 1200 mg/kg bw/day fed 3 and 5% citric acid in the diet for 2 years.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1957
Chronic systemic toxicity	Pre-guideline test data.	NOAEL dog: 1380 mg/kg bw/day fed in the diet for up to 120 days.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1946
Supporting data	N/A	In humans a 2% aqueous solution of citric acid can cause a stinging sensation that is not related to irritation.	SIDS Initial Assessment Report for 11th SIAM, 2001
Supporting data	N/A	HRIPT of 60 ezcema patients with 2.5% citric acid in petrolatum did not cause any irritant reactions	SIDS Initial Assessment Report for 11th SIAM, 2001

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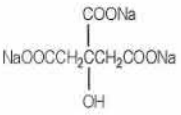
Ingredient Profile: Sodium Citrate

CAS number:	994-36-5 / 6132-04-3 (dihydrate) / 68-04-2 (anhydrous)	**EC number:**	213-618-2 (I) / 200-675-3 (I)
INCI Name:	Sodium Citrate		
Pseudonyms:	Citric Acid, Trisodium Salt		
Structure:	$C_6H_5O_7 \cdot 3Na$	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	M&P 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	penceration data? (Tick applies skin penceration data on all	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/ CEL	Acceptable Exposure Level ug/cm2
Sodium Citrate	0.500	68 04 2 / 6132 04 3	200 675 3	Buffering, Chelating, Masking	N/A	0.50000	0.0021 / No Data				100	0.001 / No Data		100		

Sodium Citrate is the sodium salt of citric acid. Sodium Citrate is used as a buffering agent, chelating agent, pH adjuster and fragrance ingredients in cosmetic products.

According to the CIR review[1] Sodium Citrate is typically used at up to 10% in leave on products and up to 10% in rinse off products, up to 2% in products used in the eye area, up to 0.4% in products which may be ingested, up to 4% in hair products, up to 0.5% in nail products and up to 1% in products which may be used on the mucous membrane. In a human irritation study Sodium Citrate was not irritating to the skin at 10%[1]. Citric acid and its salts have not reported to be a sensitiser in human studies[1]. Sodium Citrate was not genotoxic in an *in vitro* Ames study.

Upon ingestion it is expected that Sodium Citrate will dissociate into Citric acid and sodium. When orally administered is well absorbed and metabolised. Citric acid is also produced endogenously as a part of normal metabolism, where is completes the breakdown of pyruvate produced from glucose metabolism. Approximately 2 Kg of citric acid is metabolised every day in humans. Citric acid is freely filterable in the kidney and 65-90% of citric acid is reabsorbed[2]. Therefore, as citric acid is present in the diet naturally in addition to synthetic sources, coupled with endogenous production of citric acid, systemic toxicity from cosmetic products containing citric acid/ sodium citrate is not expected.

Summary:

The concentration and use of Sodium Citrate 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.

References:

1. IJT 33(Suppl.2):16-46, 2014

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Specification data:

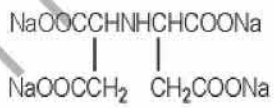
No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

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
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: IJT 33(Suppl.2):16-46, 2014 Non animal test data.

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	M&P 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 <1/hr small	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/ CEL	Acceptable Exposure Level ug/cm2
Tetrasodium Iminodisuccinate	0.100	144538-83-0	N/A	Chelating	N/A	0.10000	0.00043	No Data			100	0.001	No Data	300		

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:

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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.

Stephenson has also modified the formulations slightly with the addition of Citric Acid and its sodium salt Sodium Citrate and the removal of Stearic acid and Lauric Acid. These modifications are minor and are not a safety nor regulatory concern. The modification is not expected to affect stability.

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).

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Chartered Biologist (CBiol RSB).

Member of the Royal Society of Biology (MRSB).