COSMETIC PRODUCT SAFETY REPORT –

PARTS 1A AND 1B –

FULL REPORT *

PRODUCT NAME: **CHEEKY PANDA BABY WIPES**

REPORT #: **CPSR 121/23 (8th Jun. 2023)**

STATUS: PASS

PRISTON SAFETY ASSESSMENTS LTD
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COSMETIC PRODUCT SAFETY REPORT * -

CHEEKY PANDA BABY WIPES

1. INTRODUCTION

The subject of this report is Cheeky Panda Baby Wipes. It is a cosmetic product for use by adults for cleansing external intimate hygiene areas of babies from Newborn babies upwards.

It is reviewed for safety and compliance to Regulation (EC) # 1223/2009 on cosmetic products[1] and schedule 34 of the UK cosmetics legislation that came into force on 1st Jan.2021[2]. In addition, ingredients and ingredient names are checked for acceptability under equivalent US FDA legislation [Federal Food, Drug and Cosmetic Act (FD&C Act)].

*: **Aspects reviewed**

- Composition
- Properties of the raw material mixtures and ingredients, including animal testing, impurities and regulatory status
- Reports on product properties, stability, microbial quality and preservation.
- Exposure and margin of safety calculations, taking account of site, frequency of use and intended exposure group(s)
- Primary packaging materials and artwork.

This assessment is conducted in accordance with sound reporting practices such as those outlined in Council Directive 2004/10/EC.

For aspects reviewed, see previous section. This report does not contain study reports.

To comply with EU and UK cosmetic legislation – this report should be stored in the product information file (PIF).

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[1] *Regulation (EC) # 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (article 10 and Annex 1).*

[2] *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Regulations 2019 No. 696, schedule 34.*

ANNEX 1, PART A, SUMMARISED MAIN POINTS

2. QUANTITATIVE & QUALITATIVE COMPOSITION

The table below shows the composition of the formulation with raw material names. If this information is incorrect, please resubmit composition.

Raw Material (RM)	Supplier	Ingredient (INCI) Name	CAS #	RM concentration (%)	RM breakdown (%)	Ingredient (%)	H-phrases*
Water		Water	7732-18-5	97.98	100	97.9800	-
Colalipid C	Univar	Water Cocamidopropyl PG-Dimonium Chloride Glycerin	7732-18-5 83682-78-4 56-81-5	0.90	52.5 45 2.5	0.4700 0.4100 0.0200	H400
Microcare SB	Thor	Potassium Sorbate Sodium Benzoate Aqua	24634-61-5 5320-32-1 7732-18-5	1.00	15 30 55	0.1500 0.3000 0.5500	H315, H319
Citric acid anhydrous	Jungbunzlauer	Citric Acid	7-92-9	0.02	100	0.0200	H319
Geogard Ultra	Arxada	Gluconolactone Sodium Benzoate Calcium Gluconate	90-80-2 532-32-1 299-28-5	0.10	74.5 24.5 1	0.0745 0.0245 0.0010	H319
Total (%):				**100**			

**: Hazard phrases in SDS'.*

The table below lists ingredients in decreasing concentration. These concentrations are used to calculate Margins of Safety (see section 7) and are the concentrations shown in Appendix 2. If incorrect, please resubmit composition.

Ingredient INCI Name	Alternative Name	CAS #	EINECS/ELINCS #	Highest concentration (%)	Controlled EU*
Aqua	Water, Eau	7732-18-5	231-791-2	99.0000	-
Cocamidopropyl PG-Dimonium Chloride		83682-78-4	280-518-3	0.4100	-
Sodium Benzoate		532-32-1	208-534-8	0.3245	YES
Potassium Sorbate		24634-61-5	246-376-1	0.1500	YES
Gluconolactone		90-80-2	202-016-5	0.0745	-
Glycerin		56-81-5	200-289-5	0.0200	-
Citric Acid		7-92-9	201-069-1	0.0200	-
Calcium Gluconate		299-28-5	206-075-8	0.0010	-

*Footnote: *: "YES" = subject to conditions in cosmetic legislation for this application.*

3. ARTWORK

Artwork (see Appendix 1) – content reviewed. For guidance:

It should contain the information below. N.B. reference (Art. 19…) refers to that in EU Regulation 1223/2009. Comments are in **blue**.

i. Name and full contact details of Responsible Person(s) [Art. 19 (a)]: **present.**
ii. Country of origin, if manufactured outside the EU and UK [Art. 19 (a)]: **present.**
iii. Nominal content in weight or volume at time of packaging [Art. 19.1(b)]: **present.**
iv. Expiry date (Period after Opening) [Art. 19.1 (c)]: **1M.**
v. Warnings [Art. 19.1 (d)]. **See section 11.**
vi. Batch number [Art. 19.1 (e)]: **-.**
vii. Function [Art. 19.1 (f)]: **apparent.**
viii. List of ingredients [Art. 19.1(g)]: **Acceptable as reviewed.**

Preface list with **"INGREDIENTS"**
List ingredients at ≥1 % (EU and UK) / >1 % (USA) in decreasing order of concentration. Follow with ingredients at <1 % (EU and UK) / ≤1 % (USA) in any order. Common names (see column 2 in table above) may be included in brackets.

In this case, the following is the correct order:

List ingredients at ≥1%, in the following order: Aqua (Water, Eau).
Follow with those at <1 %, in any order (shown in order of decreasing concentration): Cocamidopropyl PG-Dimonium Chloride, Sodium Benzoate, Potassium Sorbate, Gluconolactone, Glycerin, Citric Acid, Calcium Gluconate.

ix. Claims – **"made from sustainable bamboo"; "99% pure water"; "Dermatologically tested". All supportable and relevant. See Regulation (EU) No 655/2013 and guidance on claims[3] prepared by the sub-working group on claims in the EU (2017).**

4. PHYSICAL-CHEMICAL PROPERTIES & STABILITY

➢ *Product – Physical-Chemical Properties:*

Appearance:	Clear water-like liquid
Odour:	Fragrance-free
pH:	5.0 – 6.0
Fabric type:	100 % viscose
Loading level:	~4.68 g/wipe

➢ *Product – Stability:*

The following measurements have been made to follow the product throughout a short storage period.

Appearance:

[3] file:///C:/Users/bobpr_000/Downloads/technical_document_claims_en%20(2).pdf

		Due Date	Actual
Mix appearance initial	Clear water like liquid		
Mix appearance after 4 weeks	Clear water like liquid, no change	05.10.22	05.10.22
Wipe appearance initial	White/off white nonwoven		
Wipe appearance post stability	No change	28.11.22	28.11.22
Wipe odour post	No change	28.11.22	28.11.22
Film appearance after 4 week dip test	Stable no issues	05.10.22	05.10.22
Film appearance post stability	Good , no visual issues	28.11.22	28.11.22
Label adhesion to film	Good , no visual issues	28.11.22	28.11.22
Label appearance post stability	Good no bubbling/delam	28.11.22	28.11.22

pH:

pH formulation initial	5.94		
pH next day	5.54		
pH after 4 weeks @ RT	5.39	05.10.22	
pH at 12 weeks RT	5.35	28.11.22	16.12.22

Weight loss:

Date	05.09.22	16.12.22		
	Weight pack	Weight pack	Weight Loss (%)	Temperature
Pack Number				
1	218.93	199.26	9	37
2	215.91	198.09	8.25	37
3	207.96	205.98	0.96	RT
4	188.72	tvc		
5	206.68	204.8	0.9	RT

Results & conclusions: there were no significant changes in this product under the storage conditions used.

➢ *Ingredients: Physical properties:*

Raw material documents have been reviewed. All are suitable for this use. For typical ingredient properties, see Appendix 2.

Declared controlled substances possible in raw materials:

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5. MICROBIOLOGY

➢ *Quality:*

Guidance: manufactured product should meet the following microbiological standards (see guidance from the Scientific Committee on Consumer Safety (SCCS) and Cosmetic, Toiletry, and Fragrance Association 2007. “CTFA Microbiology Guidelines"):

- Products specifically intended for babies, the area of the eye or mucosal membranes – total viable count of aerobic mesophylic microorganisms not to exceed 10^2 CFU / gram (ml) (allowing for natural variation of microbial studies, maximum allowed - 5 x 10^2)[4].
- Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans are considered the main potential pathogens in cosmetic products. These must not be detectable in 1 g (ml).

The following summarised information was provided for this assessment.

					Date
TVC initial		pass	Report Number	78612	09.09.22
TVC post stability	37 degrees	pass	Report Number	81751	23.12.22
TVC post stability	RT	pass	Report Number	81754	20.12.22
Challenge test	2.8g.g	Pass	Report Number	23316Asuppl	05.10.22

➢ *Preservation:*

Test: 28-day challenge test conducted according to European Pharmacopoeia, 10th edition. Method: TMPH1-13.

Testing laboratory: MCS Laboratories ltd. Tideswell, Derbyshire, UK.

Product: Cheeky Panda Baby - G.

Results:

	Cfu/g

[4] *COLIPA (Cosmetics Europe): Guidelines on Microbial Quality Management, 1997.*

Time:	Ps. aeruginosa	S. aureus	A. brasiliensis	C. albicans
0	5.4 x 10^5	7.0 x 10^5	5.5 x 10^5	6.2 x 10^5
48 h	4.4 x 103	<10	-	-
7 days	<10	<10	-	-
14 days	-	-	1.6 x 10^2	<10
28 days	<10	<10	<10	<10

Conclusion: Product inhibited growth of microorganisms in accordance with the criteria of the European Pharmacopoeia for topical products.

6. MANUFACTURING AND PACKAGING

This product will be manufactured following Good Manufacturing Procedures (e.g. ISO 22716:2007) and that ingredients used throughout are of a suitable quality. The information provided by the customer indicates that all ingredients are suitable. Full documentation must be held in the Product Information File.

60 wipes per pack of recyclable PE/PE (polyethylene/polyethylene)

Printing will be sandwiched within the laminate.

This type of packaging is typically used for wipe products and is considered to be safe for this application.

Please ensure (1) packaging complies with European Regulation (EC) No 1907/2006 (REACH) and applicable amendments; (2) it does not contain SVHC's (Substances of Very High Concern), (3) it complies with EU Directive 94/62/EC on Packaging and Packaging Waste, and (4) it complies, for this use, with Regulation (EC) No. 1935/2004 on materials and articles in contact with food and the equivalent in the USA.

7. NORMAL & REASONABLY FORESEEABLE USE

For this assessment, skin exposure calculations are presented for a baby wipe as likely worst case.

Directions for use in artwork are: *"peel back re-sealable label. Reseal pack after use to prevent wipes from drying out. Store in a cool, dry place".*

For calculating exposure the product is assumed to be used on the diaper area and whole body at 3 months of age but a Systemic Exposure Dose (SED) is calculated only for the whole body as worst case. SED figures are used to calculate Margins of Safety for the ingredients.

Diaper area skin exposure: The mean surface area of skin covered by a diaper is estimated to be ~260 cm^2. Each wipe contains ~3.82 ml (information from client). From experience, the amount that will be transferred to skin during use is not likely to be more than 5 % but, as a worst case, 10 % is used in this calculation (transfer of fluid per wipe is 0.38 ml). Assumed average use is 8 wipes per day. Thus, transfer is ~3 ml/day over this area.

Whole body skin exposure: Total skin area of a child at 3 months is ~3004 cm^2 (calculated using weight and height figures published by the National Center for Health Statistics [2000]). Usage and transfer of fluid to skin is assumed to be the same as above.

The method of calculation used is that recommended by the SCCS[5]:

Minimum body weight (3 months): 5.6-6.0 kg.

➢ *Exposure to whole product, diaper area and whole body:*

Exposure (cm^2/day) = total amount applied to skin (mg) / skin surface area (cm^2).

Skin exposure (diaper area):		Skin exposure (whole body):	
Surface area (3 months):	260 cm^2	Surface area (3 months):	3004 cm^2
Amount of fluid applied /day:	3 ml (3000 mg)	Amount of fluid applied /day:	3 ml (3000 mg)
Skin exposure:	**11.54 mg/cm^2***	**Skin exposure:**	**1.00 mg/cm^2**

➢ *Systemic exposure (3 months, whole body):*

SED (Systemic Exposure Dose) = total amount applied (mg/kg) x dermal absorption x retention factor / body weight (kg).

	Systemic Exposure Dose (SED): [Exposure/body weight [kg]]*retention factor
Typical Body weight (3 months):	5-6-6.0 kg
Retention factor (leave-on):	1 (100 %)

[5] *SCCS/1628/21, The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 11th revision30-31 March 2021.*

Amount applied:	3 ml (3000 mg)
SED:	**536 mg/kg/day**

➢ ***Exposure to ingredients (3 months):***

There is no evidence that the ingredients in this product react together to a significant extent and so exposure to each is expected to be in proportion to their concentration.

A Margin of Safety is required to be calculated for a cosmetic product although in many cases the value is questionable and, where an absence of dermal penetration can be demonstrated, guidance permits the omission of this. For the calculation, guidance of the Scientific Committee on Consumer Safety (SCCS) is followed using published toxicity information when available such as No (Actual) Effect levels [NO(A)EL]. The approach is described in footnote[5].

NOAEL values are established from studies with animals (usually rodents). They are dosed orally and daily for several months with an individual chemical substance and the NOAEL is the highest dose that does not cause an effect. Translating this to dermal exposure is not straightforward and factors such as the ability of the substance to penetrate skin, the type of skin and whether it is intact are significant. Extrapolating individual NOAEL' to a mixture of chemicals is even more challenging because, for example, absorption may be influenced by the presence of other chemicals such as organic solvents. Few chemicals used in cosmetics have values for dermal absorption and it is highly unlikely that more than 50 % of any chemical applied to skin will be absorbed. Factors that indicate low absorption include poor solubility (Log Pow ≤1 - ≥4), large molecular weight (>500 daltons), high ionisation, Topological polar surface area >120 Å and a melting point >200 °C.

In spite of the above, Margin of Safety values are expressed for all ingredients in the table below using worst case absorption of 100 % (Oral NOAEL divided by the SED) as advised by the SCCS for when dermal absorption information is unavailable.

Margin of Safety calculation: 1. Calculate SED of each ingredient - SED of product x (ingredient concentration / 100).
2. MoS = NOAEL / (SED x dermal absorption).

INCI Name/CI #	Highest concentration (%)	M Wt.	Log Pow (~20°C)	Water Solubility (~20°C)**	SED	Oral NOAEL (mg/kg/d)	MoS
Aqua	99	18.15	-	1000g/L - Very soluble	530.640	-	-
Cocamidopropyl PG-Dimonium Chloride	0.41	Variable	0	600g/L – Freely soluble	2.198	500	228
Sodium Benzoate	0.3245	144.10	-2.27	556g/L - Freely soluble	1.739	500	287
Potassium Sorbate	0.15	150.22	-1.72	1.95g/L - Slightly soluble	0.804	2500	3109
Gluconolactone	0.0745	178.14	-2.38	Soluble -	0.399	1000	2504
Glycerin	0.02	92.09	-1.75	1000g/L - Very soluble	0.107	2000	18657
Citric Acid	0.02	191	-1.96	600g/L - Freely soluble	0.107	1200	11194
Calcium Gluconate	0.001	430.37	-3.18	33g/L - Soluble	0.005	*No information*	-*

*Footnotes: Variable: ingredient is a UVCB (Substance of Unknown or Variable Composition); N/A: not applicable; SED = Systemic Exposure Dose; NOEL(NOAEL) = No Effect of No Actual Effect Level established by experiment or assumed by read-across to similar ingredients; MoS = Margin of Safety. Calculation assumes 100 % absorption through skin; "-": indicates no information. Ingredients with this are typically insoluble; *: NOAEL not available. From acute properties and those of similar chemicals, a NOAEL of >1000 mg/kg is expected. This will result in a MoS of >100; **: solubility descriptors from ref 5, p 16.*

Conclusion: The Margin of Safety (see above) for all ingredients is expected to be significantly greater than 100. Should the exposure volume be larger than that used in the calculation or the product used more frequently the Margin of Safety is still expected to be significantly greater than 100.

It is generally accepted that a figure of 100 provides adequate protection and it is, therefore, concluded that under the exposure conditions in this example, any exposure to the ingredients will be safe for the intended use and age range.

8. RAW MATERIALS / INGREDIENTS

Sources of information include the client, raw material documents and recognised authoritative sources such as peer reviewed literature, expert group reports such as those of the Cosmetic Ingredient Review Panel[6] and data collections such as COSING and ECHA[7].

All raw materials are permitted for this application as proposed. None is classified as a CMR (Carcinogen, Mutagen or a Reprotoxin), Persistent, Bio-accumulative or Toxic (PBT) or Very Persistent / Very Bio-accumulative (vPvB)]. In addition, none contains nanoparticles as defined by the Scientific Committee on Consumer Safety (SCCS/1484/12) or animal-derived components.

[6] *https://www.cir-safety.org/*
[7] *ECHA: European Chemicals Agency.*

Raw materials do not to contain impurities of significant toxicological concern. Any carried over from manufacturing will be at low concentration and technically unavoidable. Heavy metals present in several raw materials but their content in this product will meet all regional requirements.

Suppliers are understood to have ensured that all ingredients meet requirements of REACH legislation in the EU (Regulation (EC) No 1907/2006) and UK (The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020). Compliance is a pre-requisite for the marketing of this product. Supplier specific status is not addressed in this assessment, REACH status in Appendix 2 refers to information in ECHA (European Chemicals Agency).

Typical properties and regulatory status of all ingredients are in Appendix 2 and the information from suppliers is in line with this. All ingredients are at an acceptable concentration with water accounting for 99 % of the wipe solution. Except where stated (see below), the other ingredients do not have to meet conditions in legislation for this application.

In legislation the following are controlled: Sodium Benzoate to 0.5 % (as acid) and Potassium Sorbate to 0.6% (as acid). As present, they meet requirements.

Whilst most raw materials are single ingredients (or single ingredients with solvents and/or additives) with properties that are summarised in Appendix 2, others are mixtures and for these additional information is given below:

Colalipid C (INCI Name: Cocamidopropyl PG-Dimonium Chloride Phosphate) chemically described as Cocamidopropyl Phosphatidyl PG-Dimonium Chloride, is a coconut oil derived phospholipid composed predominantly of diester and triester phosphatides with multiple chain groups. It has a broad range of functional attributes including gentle cleansing and foaming properties, anti-irritation effects when combined with anionic surfactants, unusually high substantivity, long lasting skin conditioning and broad spectrum antimicrobial activity. Colalipid C is not classified as hazardous to health.

Microcare SB (INCI Names: Aqua (and) Sodium Benzoate (and) Potassium Sorbate) is a blend of organic acids that provide gentle preservation. This activity is best at pH 4.5 – 5.0 where the actives are in their undissociated states as their respective organic acids and they act together by suppressing the growth and spore germination of bacteria and moulds respectively. Both preservatives are in conformance with ECOCERT, BDIH, the Soil Association, Natrue and COSMOS. The supplier classifies this mixture as a skin and eye irritant (H315, H319).

Geogard Ultra (INCI names: Gluconolactone (and) Sodium Benzoate) is a synergistic blend comprised of Gluconolactone and Sodium Benzoate. It has proven broad spectrum and contributes an added skin moisturisation benefit. It has conformance with ECOCERT/COSMOS, NATRUE and the Soil Association.

The gluconolactone in this blend works in conjunction with the sodium benzoate to act as an efficient preservative booster, slowly releasing gluconic acid over time thereby contributing to the broader preservation effect. It is classified as an eye irritant (H319).

This product does not contain a colorant or an added fragrance and none of the ingredients cause skin sensitization.

This product has not been tested for hazards but the ingredients below are classified for physical, health and/or environmental hazards under the Global Harmonised System for Classification, Labelling and Packaging (see Regulation (EC) 1272/2008). The information in the table below is indicative of their classification[8] and, consequently, of their hazards and that of the whole product. Unclassified ingredients are not significantly hazardous.

INCI Name/CI No	CAS No	Highest (%)	Classification (see Appendix 2)	Har/N Har*
Cocamidopropyl PG-Dimonium Chloride	83682-78-4	0.41	Not classified, Not expected to be hazardous, see summary	N.Har
Sodium Benzoate	532-32-1	0.3245	H319: Causes serious eye irritation, (REACH dossier)	N.Har
Potassium Sorbate	24634-61-5	0.15	H319: Causes serious eye irritation, (REACH dossier)	Har
Citric Acid	77-92-9	0.02	H319: Causes serious eye irritation, (REACH dossier)	Har
Total (%):		**0.9045**		

*Footnote: *: H/N.Har: CLP (GHS) classification, Harmonised at EU level / not harmonised (not harmonised means that this classification is not officially agreed at EU level but that the documentation provided and/or entries on the ECHA website show this classification).*

Based on the properties of the ingredients, their concentration and classification this product is not expected to cause harm on contact with skin and if ingested in small amounts. It is not expected to irritate eyes on contact, although it may cause temporary discomfort, to irritate intact and broken skin or mucosal membranes. It is not expected to cause skin sensitisation.

9. COSMETOVIGILENCE

The brand owner should ensure that any complaint received from the use of this product is reviewed and categorized as either an "Undesirable Effect" or "Serious Undesirable Effect" (Regulation 1223/2009, Article 23 and guidance from Cosmetics

[8] *Classification may vary depending upon supplier. Where sourced from the European Chemicals Agency (ECHA), the classification shown is the most frequent or, or the "harmonized" one (as agreed by experts working under REACH legislation).*

Europe). Serious Undesirable Effects must be reported to authorities within 20 days and additional corrective action may need to be taken, including a revision of this assessment. As a consequence, this assessor must be advised of complaints within a suitable time period.

No adverse reports have been provided for this assessment.

10. OTHER INFORMATION

- ***Animal testing:***

This product and raw materials are understood to comply with the 7th amendment of Cosmetic Directive 76/768/EEC on the use of animals. Evidence should be in the PIF.

- ***96 h hour patch Test for skin irritation.***

Testing facility: PCR Corp. (Chelmsford, UK).

Study: A 96-hour primary irritation patch test in a shared panel of 30 healthy volunteers (male and female aged 21-55) to investigate the skin irritation potential of test articles and two standard controls following cutaneous patch applications (report # SEVMIX18M; date: 31st May 2023).

Test material:

Method: A well conducted single blind, within study comparative study. Test material was tested under occlusive conditions on the back of the subjects. The patches were left in place for four, 23 h periods with assessments being carried out 1 h after patch removal.

Results: This product and the negative control (water) did not cause any level of irritation on any subject. The positive control (0.3 % SLS) caused irritation after each treatment in line with historical findings).

Conclusion: This product was non-irritant under the conditions of this test and is unlikely to cause skin irritation under conditions of everyday use.

Comments: Study was approved by a consultant dermatologist. The report claims that the conclusions support the claims: “dermatologically tested”, “clinically tested”, “clinically proven”, “kind to skin”, “mild to skin” and “safe to skin”.

ANNEX I, PART B — COSMETIC PRODUCT SAFETY ASSESSMENT

11. REASONING

The subject of this report is Cheeky Panda Baby Wipes. It is a cosmetic product for use by adults for cleansing external intimate hygiene areas of babies from Newborn babies upwards.

It has been reviewed for safety and compliance to Regulation (EC) # 1223/2009 on cosmetic products[9] and schedule 34 of the UK cosmetics legislation that came into force on 1st Jan.2021[10]. In addition, ingredients and ingredient names have been checked for acceptability under equivalent US FDA legislation [Federal Food, Drug and Cosmetic Act (FD&C Act)].

***: Aspects reviewed**

- Composition
- Properties of the raw material mixtures and ingredients, including animal testing, impurities and regulatory status
- Reports on product properties, stability, microbial quality and preservation.
- Exposure and margin of safety calculations, taking account of site, frequency of use and intended exposure group(s)
- Primary packaging materials and artwork.

All raw materials are permitted for this application as proposed. None is classified as a CMR (Carcinogen, Mutagen or a Reprotoxin), Persistent, Bio-accumulative or Toxic (PBT) or Very Persistent / Very Bio-accumulative (vPvB)]. In addition, none contains nanoparticles as defined by the Scientific Committee on Consumer Safety (SCCS/1484/12) or animal-derived components.

Suppliers of all ingredients are understood to have met requirements of REACH legislation (Regulation (EC) No 1907/2006) and UK[1]. Compliance is a pre-requisite for the marketing of this product.

Based on the properties of the ingredients, their concentration and Classification, Labelling and Packaging legislation (see section 8) this product is not expected to cause harm on contact with skin and if ingested in small amounts. It is not expected to irritate eyes on contact, although it may cause temporary discomfort, to irritate intact and broken skin or mucosal membranes. It is not expected to cause skin sensitisation.

Dermal absorption is expected to be low for all ingredients and all margins and safety (MoS), calculated for predicted use, exceed 100 (see section 7). On this understanding all ingredients are judged to be acceptable for use as intended.

From stability and microbiological studies, this product is expected to be stable under intended use, storage and transport conditions and to not support the growth of microorganisms (see sections 4 & 5).

Based on the outcome of a 96-h patch test (see section 10), the following claims are suitable for this product:
"dermatologically tested", "clinically tested", "clinically proven", "kind to skin", "mild to skin" and "safe to skin".

It is understood that this product will be manufactured according to international manufacturing practices and that the product will comply with animal testing requirements of the 7th Amendment of Directive 76/768/EEC.

Artwork (see Appendix 1) contains all required information and the ingredient list is correct.

CONCLUSION:

From a review of the information available on the product, the ingredients and intended use, this product is judged to be safe to be used by adults for cleansing external intimate hygiene areas of babies from Newborn babies upwards[11]. It is not expected to cause harm on contact with skin and if ingested in small amounts. It is not expected to irritate eyes on contact, although it may cause temporary discomfort, to irritate intact and broken skin or mucosal membranes. It is not expected to cause skin sensitisation.

The information reviewed is sufficient to support the marketing of this product in the regions covered by this report.

OTHER COMMENTS:

Warnings:

Required by legislation: None.

Consider: Keep out of the reach of babies; for external use only; if irritation occurs, stop using and wash affected area with

[9] *Regulation (EC) # 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (article 10 and Annex 1).*
[10] *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Regulations 2019 No. 696, schedule 34.*
[11] *NB. This conclusion is valid only when, on-going, the same or equivalent ingredients are used.*
If this formulation is reported to cause significant adverse reaction amongst consumers the undersigned should be informed.

water; if it continues, seek medical advice.

R.A.J.Priston*[12]

B.Sc. Ph.D. C.Biol. C.Sci. UK & European Registered Toxicologist (ERT)
Toxicologist / Safety Assessor – meeting academic and professional requirements for the assessment of chemical ingredients and mixtures, including cosmetics, biocides and toys, for safety.

Report date: 8th Jun. 2023.

[12] *For qualifications, see section 12.*

12. ASSESSOR'S CREDENTIALS

Overview:

- An experienced scientist with proven record in research, product safety and regulatory.
- More than 40 years the chemical sector, Oil, Chemicals and Consumer Products.
- Technically strong in chemical hazard/risk assessment, test methodologies, programme planning and execution.
- Strong communication skills.
- Recognised in Law as a qualified safety assessor.
- Working knowledge of global chemical requirements, particularly in Cosmetics and chemicals.
- Experienced in Trade Association activities.

Education/Accreditation:

B.Sc. Double Honours, Zoology & Botany with Chemistry (EQF 6; Irish NFQ 8).
Diploma in Microbiology, London University, UK
Ph.D. London University, UK. Coverage: virology, genetics, cell biology, immunology, biochemistry (EQF 8; Irish NFQ 10).
UK & EUROTOX Registered Toxicologist (ERT).
Chartered Biologist (C.Biol): 2013 – present; membership # 106097*; Chartered Scientist (C.Sci): 2021 -.

Associations:

Royal Society of Biology (RSB); Society of Cosmetic Scientists (SCS); International Federation of Societies of Cosmetic Chemists (IFSCC); British Toxicology Society (BTS); Cosmetic, Toiletry & Perfumery Assoc. (CTPA); International Fragrance Assoc. (IFRA).

Current committees:

CTPA - (1) CTPA-BSCA, (2) Cosmetovigilance (3) Toxicology.

Employment:

Priston Safety Assessments Ltd (Jan. 2013 - present) - co-owner.

Services: Consumer product safety reports, product labelling and claims; Customers worldwide.
Toxicology reviews for individual chemicals and mixtures, hazard and risk advice.
Support and management of studies, including alternative approaches and clinical.

UL-STR (Sep. 2011-Aug 2012)

Role: Team leader & technical expert, Toxicology Services, Europe and USA.
Technical responsibilities - consumer product safety reports for Europe and the USA (cosmetics, toys, general mixtures); provision of expertise in legislation for consumer products, classification and labelling and REACH (chemicals).

Kimberly-Clark Europe (Jul. 2006 – Aug. 2011)

Role: Global Product Safety and Toxicology Manager, consumer products. Teams in the UK and USA; responsibilities included management of research programs, safety testing, product safety reporting and cosmetovigilance.

Technical committees: EUCOMED (Medical Devices), EDANA (Disposables & Nonwovens), IIVS (In-Vitro Sciences, USA) and CAAT (Alternative testing, USA).

Royal Dutch Shell - Shell International (1989 - 2006)

Principal Toxicologist - Speciality and agrochemicals, lower olefins, EO/Glycols, PO/Glycols, solvents, surfactants and higher olefins, elastomers, fine chemicals, oil products and gas.
Hazard and risk assessments - new and existing chemicals.
Global network of company and third party experts, timely networking and good communication skills.

Membership/chairman of technical committees: CONCAWE (Oils HSE), ECETOC, CEFIC & UK CIA (Chemicals HSE), III (Isocyanates HSE), ISOPA (Diisocyanates & Polyols), HSE (UK), EPAA & FRAME (Alternative Testing).

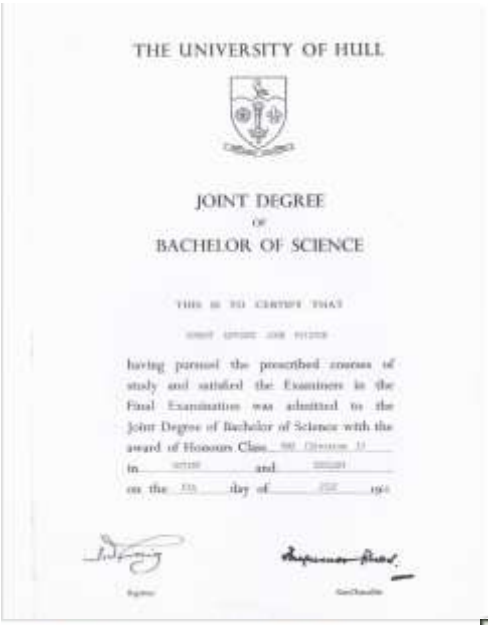
Royal Dutch Shell - Shell Research Limited (1974 - 1989)

Business liaison manager: Laboratory/Business interface for technical, programme management and budgeting.
Leader, Genetic toxicology Section, responsible for chemical test programmes, internal and collaborative. Leader, cancer research.
Virologist, pest control agents – Studies into safety, characterisation and growth of insect viruses as alternatives to chemical pesticides.

Animal Virus Research Institute (1968 - 1974)

Genetics department - Scientific/senior Scientific Officer, completion of PhD on genetic, biochemical and structural properties of picornaviruses, principally Foot-and-Mouth-Disease Virus. Progressed to acting head of department by 1972.

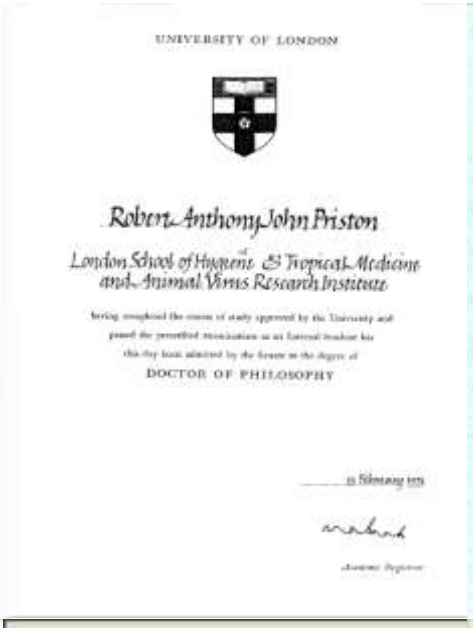
Publication list available on request.



THE UNIVERSITY OF HULL

JOINT DEGREE
OF
BACHELOR OF SCIENCE

having pursued the prescribed courses of study and satisfied the Examiners in the Final Examination was admitted to the Joint Degree of Bachelor of Science with the award of Honours Class ... in ... and ... on the ... day of ... 19..



UNIVERSITY OF LONDON

Robert Anthony John Priston

London School of Hygiene & Tropical Medicine and Animal Virus Research Institute

having completed the course of study approved by the University and passed the prescribed examination as an External Student has this day been admitted by the Senate to the degree of

DOCTOR OF PHILOSOPHY

EUROTOX

This is to Certify that

R. A. PRISTON

may use the title

EUROTOX REGISTERED TOXICOLOGIST

naric

QQI

Advice on Academic Recognition of a Foreign Qualification

Comparability Statement

bts the british toxicology society

Royal Society of Biology

This is to certify that

Robert Anthony John Priston

has been included within the

UK Register of Toxicologists

and is bound by the codes of conduct of the

Royal Society of Biology

and

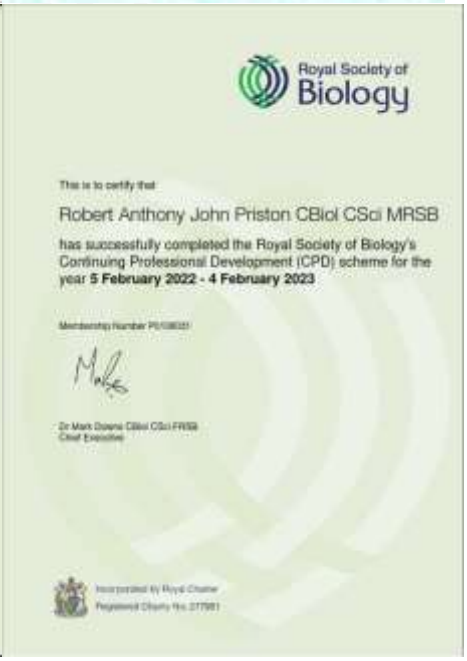
British Toxicology Society

for the period

5 October 2021 to **4 October 2026**

Mr Colin Davies, RRT
(Panel Chair)

Incorporated by Royal Charter
Registered Charity No. 277981



Royal Society of Biology

This is to certify that

Robert Anthony John Priston CBiol CSci MRSB

has successfully completed the Royal Society of Biology's Continuing Professional Development (CPD) scheme for the year **5 February 2022 - 4 February 2023**

Membership Number [redacted]

Dr Mark Downs CBiol CSci FRSB
Chief Executive

Incorporated by Royal Charter
Registered Charity No. 277981

Science Council

Royal Society of Biology

Awards this certificate to

Robert Anthony John Priston

in recognition of the award of

Chartered Scientist

Signed this day
7 January 2022

Registration number
[redacted]

Helen Gordon
Chief Executive
Science Council

Dr Mark Downs CBiol CSci FRSB
Chief Executive
Royal Society of Biology

APPENDIX 1: ARTWORK

Report no CPSR 121/23

Product name: CHEEKY PANDA BABY WIPES

AQUA

Last review: 29/06/2020

CAS #:	Other Name:	EC #:	Highest conc (%):
7732-18-5	Water, Eau	231-791-2	99
Function -	Solvent, Diluent		

PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Liquid	H2O	18.15	0°C	100°C	-

Log.P	Solubility:	
-	1000g/L	Very soluble

SUMMARY:

Water is a clear liquid used as a universal solvent. The quality of water should be monitored according to Good Manufacturing Procedures (GMP) and/or should meet international Pharmacopeia standards for water purity used in drugs, devices and diagnostics.
Oral LD50 (rat) >90ml/kg. Not an irritant or skin sensitiser. It presents no significant toxicological hazard in this application.

References: SDS, Univar, Bradford, UK.

Oral NOAEL (mg/kg/day): Jecfa ADI mg/kg/d (other): -

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED
GHS (EU CLP)**:	Not classified
UK, Cosmetics:	As EU
REACH:	Exempt [Annex IV, article 2 (7)(a)]
US, CIR/FDA:	CIR: -; FDA: no exclusions
US, TSCA:	Listed, Water

N.Har

Prop 65: Not listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

COCAMIDOPROPYL PG-DIMONIUM CHLORIDE

Last review: 08/06/2023

CAS #:	Other Name:	EC #:	Highest conc (%):
83682-78-4		280-518-3	0.41

Function - Antistatic, Hair conditioning

PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Liquid	UVCB, organic	Variable	-	246°C	

Log.P	Solubility:	
0	600g/L	Freely soluble

SUMMARY:

Cocamidopropyl PG-Dimonium Chloride is fully registered under REACH legislation at ≥ 100 to < 1 000 tonnes per year. The majority of notifiers (222 at time of writing) do not classify it as hazardous with less than 20 classifying it according to "very toxic to aquatic life, toxic to aquatic life with long lasting effects and causes serious eye damage".
According to the REACH dossier (1) Cocamidopropyl PG-Dimonium Chloride, a liquid is a UVCB. In tests for toxicity oral and dermal LD50 values were>2g/kg, it was not irritation at 45% in a human skin model but in a BCOP it was irritating at 4% (and predicted to be severely irritating if tested neat). Modern in-vitro and historical human studies do not indicate any imune response or potential sensitisation and it was not genotoxic in Ames and in vivo.
Repeat dose toxicity results are reported on a similar substance and by read-across the NOAEL is expected to be ~1000mg/kg with the principle effect being irritation.
Cocamidopropyl PG-Dimonium Chloride is a frequent component of cosmetic products and as proposed it is expected to be safe.

References (1) REACH dossier on Cas # 83682-78-4; (2)

Oral NOAEL (mg/kg/day): 500 Jecfa ADI mg/kg/d (other): -

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED		
GHS (EU CLP)**:	Not classified, Not expected to be hazardous, see summary		
UK, Cosmetics:	As EU		
REACH:	Registered, ≥ 100 to < 1 000 tonnes per year; 01-2120763938-35-xxxx		N.Har
US, CIR/FDA:	CIR: Not reviewed; FDA: -		
US, TSCA:	Listed	Prop 65:	Not listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

SODIUM BENZOATE

Last review: 25/03/2021

CAS #:	Other Name:	EC #:	Highest conc (%):
532-32-1		208-534-8	0.3245

Function - Anti-Corrosive, Preservative, Masking,

PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Solid	C7H6O2.Na	144.10	>300°C	465°C	Not flamm

Log.P	Solubility:	
-2.27	556g/L	Freely soluble

SUMMARY:

Sodium Benzoate, the sodium salt of Benzoic Acid, is a widely used preservative. WHO-JECFA has set the ADI at 5mg/kg and the FDA concluded that it is "GRAS".
It was non-toxic when ingested and only a mild irritant to skin. It was not genotoxic (2,3), carcinogenic or toxic to reproduction. It is not a skin sensitiser or photo-sensitiser but there is some evidence of contact dermatitis at high concentrations and asthma in compromised patients.
In establishing a NOAEL, the SCCP (3) used that obtained in a 4-generation study (500 mg/kg bw/d).
They concluded that Benzoic Acid and Sodium Benzoate are safe for use for preservative and non-preservative purposes in cosmetic rinse-off products at a maximum concentration of 2.5%, in cosmetic oral-care products at up to 1.7%, and in leave-on products up to 0.5% (in each as, as acid).

References (1) REACH dossier; (2) Ishidate et al,.A. Primary mutagenicity screening of food additives currently used in Japan. Food Chem Toxicol 22(8):623-636, 1984; (3) Prival, M.J., Simmon, V.F. and Mortelmans, K.E. (1991). Bacterial mutagenicity testing of 49 food ingredients gives very few positive results. Mutat. Res., 260, 321-329; (3) Opinion on Benzoic Acid and Sodium Benzoate, SCCP/0891/05; (4) CIR report IJT 36(Suppl. 3):5-30, 2017.

Oral NOAEL (mg/kg/day): 500 Jecfa ADI mg/kg/d (other): 0-5 (1996)

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	APPROVED PRESERVATIVE (V/1). AS ACID, RINSE-OFF EXCEPT ORAL CARE: ≤2.5%; ORAL CARE:≤1.7%; LEAVE-ON: ≤0.5%
GHS (EU CLP)**:	H319: Causes serious eye irritation, (REACH dossier)
UK, Cosmetics:	As EU
REACH:	Registered, 01-2119460683-35-xxxx N.Har
US, CIR/FDA:	CIR (2017): Safe as used ≤1%; FDA: -
US, TSCA:	Listed Prop 65: Not listed

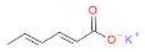
N.B.: Inventory information is based on a CAS # search unless stated otherwise.

POTASSIUM SORBATE

Last review: 25/03/2021

CAS #:	Other Name:	EC #:	Highest conc (%):
24634-61-5, 590-00-1		246-376-1, -	0.15

Function - Fragrance ingredient, Preservative



PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Solid	C6H7O2K	150.22	~250°C	-	-

Log.P	Solubility:	
-1.72	1.95g/L	Slightly soluble

SUMMARY:

Potassium Sorbate is a potassium salt of sorbic acid, a naturally occurring antimicrobial compound. It is used as a preservative. In tests it was not acutely toxic and was well tolerated in repeat-dose studies. It may be a moderate irritant but not a skin irritant, sensitiser or photo-sensitiser. It was not carcinogenic, mutagenic, or a reproductive toxin.
In a 2 yr study the NOAEL was 750mg/kg bw/d. It was without effect in several human repeat insult patch tests. The highest induction concentration used was 20%.
It is an approved food additive (E202) and is listed by the U.S. FDA as GRAS for direct addition to food. In Regulation 1223/2009 Annex V/4 it is limited to 0.6% (acid).
In 1988, the CIR Expert Panel (1) concluded that in cosmetic applications it was safe at the maximum used (5%). JECFA identified an oral NOAEL of 2500mg/kg/day from studies in rodents. EFSA agreed an ADI for sorbates of 25mg/kg bw based on a NOAEL of 2500mg/kg/day for sorbic acid (4). .

References (1) Final Report on the Safety Assessment of Sorbic Acid and Potassium Sorbate, JACT 7(6):837-880, 1988; (2) Annual Review of Cosmetic Ingredient Safety Assessments: 2005/20061, IJT 27(Suppl. 1):77-142, 2008; (3) JECFA, 1974; REACH dossier; WHO Food Additive series 67.29; (4) Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives, EFSA Journal 2015;13(6):4144; REACH dossier.

Oral NOAEL (mg/kg/day): 2500 Jecfa ADI mg/kg/d (other): 0-25 (1973)

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	APPROVED PRESERVATIVE (V/4) ≤0.6% (AS ACID)
GHS (EU CLP)**:	H319: Causes serious eye irritation, (REACH dossier)
UK, Cosmetics:	As EU
REACH:	Registered, (24634-61-5) 01-2119950315-41-xxxx
US, CIR/FDA:	CIR(1988): Acceptable as reviewed (≤7%); FDA: -
US, TSCA:	Listed, 2,4-Hexadienoic acid, potassium salt (1:1), (2E,4E)-

Har

Prop 65: Not listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

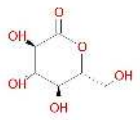
Product name: CHEEKY PANDA BABY WIPES

GLUCONOLACTONE

Last review: 29/01/2021

CAS #:	Other Name:	EC #:	Highest conc (%):
90-80-2		202-016-5	0.0745

Function - Chelating, Conditioning



PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Solid	C6H10O6	178.14	-	155°C	-

Log.P	Solubility:
-2.38	Soluble

SUMMARY:

Gluconolactone (D-glucono-1,5-lactone) is a PHA (polyhydroxy acid). PHA are similar in function as alpha-hydroxy Acids (AHA) but because of their larger structure, do not penetrate as deeply into the skin. They are less irritating than other chemical exfoliants and are used as agents for exfoliating, skin smoothing, moisturising and anti-aging benefits. They may be a good alternative in patients with sensitive skin, including those with rosacea and eczema, who cannot tolerate AHA and BHA.
The properties of Gluconolactone have been reviewed by the CIR Expert Panel (3) and they reported availability of products for use around the eye (eye lotions, eye makeup removers and other eye makeup preparations [up to 0.075%]) and use on mucous membranes(feminine wipes (up to 0.56%) and in baby products. In terms of concentration in products, they have been reported to be used in leave-on products at up to 15% and rinse-off at up to 0.3 % with the highest exposures being from skin products.
Gluconolactone may be derived from fermentation of glucose syrup (2). It is a crystalline, white powder with a meting point of 160°C (Sigma-aldrich SDS). Few toxicity data are available on this specific chemical but (SIDS) addressed the class of gluconates which can be considered to have a low order of acute toxicity and to be at most mildly irritating. Gluconalactone was not mutagenic and, in a 28-day feeding study, potassium gluconate, a metabolite, had a NOAEL >1000mg/kg/day. This value is used to calculate a MoS for this ingredient.
There are no restrictions in legislation and, as proposed, the concentration of Gluconolactone is acceptable.

References: (1) REACH dossier (09Jan15); SIDS Gluconates; JECFA Monograph 1 (2006); (2) Glucono-delta-Lactone (100%) from Jungbunzlauer S.A, France; (3) Safety Assessment of Glycolactones as Used in Cosmetics, Jan 26, 2021.

Oral NOAEL (mg/kg/day): 1000 Jecfa ADI mg/kg/d (other): Group ADI not specified (

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED
GHS (EU CLP)**:	Not classified, (REACH dossier)
UK, Cosmetics:	As EU
REACH:	Registered, 01-2119451153-49-xxxx
US, CIR/FDA:	CIR (2015): used in LO: ≤15% and RO: ≤0.3%; FDA: -
US, TSCA:	Listed, .delta.-Gluconolactone

N.Har

Prop 65: Not listed

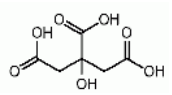
N.B.: Inventory information is based on a CAS # search unless stated otherwise.

CITRIC ACID

Last review: 27/01/2021

CAS #:	Other Name:	EC #:	Highest conc (%):
77-92-9; 5949-29-1		201-069-1, -	0.02

Function - Buffering, Chelating



PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Solid	C6H8O7	191	153°C	-	-

Log.P	Solubility:	
-1.96	600g/L	Freely soluble

SUMMARY:

Citric Acid is a natural substance produced by citrus fruits. It is an alpha-hydroxy acid (AHA), similar is structure to lactic and glycolic acids but less widely used in cosmetic products. It is also a food ingredient (E330).
In cosmetic products, such as shampoos and conditioners, it is principally a buffering (pH adjusting) and chelating agent but, as with the other AHA, it is a defoliating agent at high concentrations breaking down the bonds between live and dead cells. As such it is useful in skin creams to reduce wrinkles etc.
In tests, citric acid had low acute toxicity and the NOAEL for repeated dose toxicity was 1200mg/kg/day (rat) with effects limited to changes in blood chemistry and excretion (1). It was not a carcinogen or mutagen and the NOAEL for reproductive effects was 2500mg/kg/day. It was irritating to skin, eyes and the respiratory system but not a skin sensitiser or photo-sensitiser (1).
In the EU and USA there are no restrictions or labelling requirements. In Canada (4) they are:
1. All skin products containing AHAs at concentrations ≥3%: Warnings: "Use only as directed.", "Avoid contact with the eyes.", "If irritation persists, discontinue use and consult a physician.", "It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied with sunscreen.", "Contact of the product with the skin must be of limited frequency or duration."
2. Products intended for consumer use: Manufacturer must provide Health Canada with pH levels at 10% and a pH ≥3.5.
3. Products for professional use: Manufacturer must provide Health Canada with evidence of safety including: pH levels, AHA concentrations, Directions for use, Clinical studies demonstrating minimal skin irritation..
4. Products intended to be diluted in bath water may contain levels of citric acid exceeding 10%.

References: (1): SIDS, 11th SIAM, 11 Jan,2001; (2) IJT 33(Suppl.2):16-46, 2014; (3) REACH dossier; (4) Canada Cosmetic Ingredient Hotlist.

Oral NOAEL (mg/kg/day): 1200 Jecfa ADI mg/kg/d (other): Not limited

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED
GHS (EU CLP)**:	H319: Causes serious eye irritation, (REACH dossier)
UK, Cosmetics:	As EU
REACH:	Registered, 01-2119457026-42-xxxx
US, CIR/FDA:	CIR (2014): Safe at 39%. See general position on AHA; FDA: See position on AHA (summary)
US, TSCA:	Listed, 1,2,3-Propanetricarboxylic acid, 2-hydroxy-; -

Har

Prop 65: Not listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

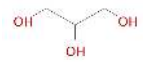
GLYCERIN

Last review: 25/03/2021

CAS #:	Other Name:	EC #:	Highest conc (%):
56-81-5		200-289-5	0.02

Function - Humectant, Moisturiser

PHYSICAL PROPERTIES:



Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Liquid	C3H8O3	92.09	18.2°C	182-290°C	177°C

Log.P	Solubility:	
-1.75	1000g/L	Very soluble

SUMMARY:

Glycerin (Glycerol) is a sugar alcohol derived from animal products, plants or petroleum. In cosmetic products it provides moisturisation and acts as a humectant by absorbing and retaining moisture to improve feel, resilience and youthful look. It is fully soluble in water with a neutral pH.
In tests it had a low order of acute toxicity, was not a skin or eye irritant, skin sensitiser or photo-sensitiser and there are no structural alerts for genotoxicity.
The LD Lo in humans was 1428mg/kg. When given orally to rats at 20% in diet for 2 years there were no adverse effects (1) (NOAEL: 10,000 mg/kg/d) (2). There were no effects on fertility and reproductive performance in a two generation gavage study (NOAEL 2,000mg/kg bw/day) and no maternal toxicity or teratogenic effects in the rat, mouse and rabbit at the highest dose (NOEL 1180mg/kg bw/day) (2).
For calculating a MoS a NOAEL of 2000mg/kg/day is used.
The REACH dossier contains information on inhalation. Based on a 1h inhalation study, the calculated 4h LC50 value was >2.75mg/L. In a sub-chronic toxicity study following aerosol exposure the NOAEL was 167mg/m3 based on local irritant effects on the upper respiratory tract (3). Glycerol is a permitted food additive and a natural constituent of foods in the form of triglycerides with an ADI of "not specified".
It is concluded that Glycerin is safe to use.

References: (1) REACH dossier; (2) OECD SIDS Initial Assessment Report for SIAM 14 (2002); (3) Safety Assessment of Glycerin as Used in Cosmetics, 12/09/2014.

Oral NOAEL (mg/kg/day): 2000 Jecfa ADI mg/kg/d (other): Not specified (1976)

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED
GHS (EU CLP)**:	Not classified, (REACH dossier)
UK, Cosmetics:	As EU
REACH:	Exempt [Annex IV, article 2 (7)(a)] - Registered, 01-2119471987-18-xxxx N.Har
US, CIR/FDA:	CIR:Reviewed, 2014. LO - ≤79%; RO - ≤99%; FDA: No exclusions
US, TSCA:	Listed, 1,2,3-Propanetriol Prop 65: Not Listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

CALCIUM GLUCONATE

Last review: 18/11/2019

CAS #:	Other Name:	EC #:	Highest conc (%):
299-28-5		206-075-8	0.001

Function - Humectant, Skin conditioning

PHYSICAL PROPERTIES:

Appearance:	Formula:	M.Wt.:	M.pt. °C:	B.pt °C:	F.pt. °C:
Solid	C12H22CaO14	430.37	120-195°C	-	-

Log.P	Solubility:	
-3.18	33g/L	Soluble

SUMMARY:

Calcium D-gluconate is a mineral supplement manufactured by the neutralization of gluconic acid with lime or calcium carbonate.
According to ECHA, this ingredient is not classified as hazardous to heath but some suppliers do classify it e.g. R20/21/22, R36/37/38 due to potential activity. Other uses of Calium gluconate dilutions are as: medical supplements, as an antidote to certain snake bites and in treatment of hydrofluoric acid eye burns.

References: (1) Wikipedia; (2) SDS Sigma Aldrich; (3) Hazardous substance Database.

Oral NOAEL (mg/kg/day): Jecfa ADI mg/kg/d (other): Not specified (1998)

REGULATORY INFORMATION (based on CAS #):

Regulat. 1223-2009:	NOT CONTROLLED		
GHS (EU CLP)**:	Not classified		
UK, Cosmetics:	As EU		
REACH:	Pre-registered, calcium gluconate		N.Har
US, CIR/FDA:	Not restricted		
US, TSCA:	Listed, D-Gluconic acid, calcium salt (2:1)	Prop 65:	Not listed

N.B.: Inventory information is based on a CAS # search unless stated otherwise.

Abreviations: US, CIR/FDA: Cosmetic Ingredient Expert Panel/ Food Drug, USA; ADI: Acceptable Daily Intake agreed by WHO JECFA (US or Canada); NOAEL: No Observable Actual Effect Level; EU CLP; Harmonised: Classification agreed at EU level; "Yes" = listed; "No" = Not listed.; "Har" = Harmonized CLP classification in the EU; "NHar"= CLP classification Not harmonized, subject to variation; "REACH Dossier" = REACH compliant dossier available on ECHA website. Unless mentioned otherwise, regional regulatory listing refers to presence or absence of CAS #.