



COSMETIC PRODUCT SAFETY REPORT

Conforming to
**Regulation (EC) No. 1223/2009 of the European Parliament and of
the Council of 30 November 2009 and SCHEDULE 34 OF THE
PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.)
(EU EXIT) REGULATIONS 2019**

REPORT REFERENCE NUMBER: NB-BL-0322-01BABO

RESPONSIBLE INDIVIDUAL: BECKY LEECH
Becky's Emporium
25 Ash Road
Coningsby
LN4 4FB

PRODUCT BEING ASSESSED: Bath Bombs

CATEGORY OF PRODUCT & INTENDED USE: Bath water additive – rinse off product.

VARIANTS BEING ASSESSED: 1) Rhubarb, 2) Monkey Farts, 3) Coconut, 4) Shark, 5) Rainbow, 6) Thousand Wishes, 7) Apple, 8) Watermelon, 9) Cherry, 10) Avobath, 11) Flowerbomb, 12) Comfort.

REPORT PART A

1. Quantitative and qualitative composition of the cosmetic product(s) (including the chemical identity of substances in the formulation).
2. Physical/chemical characteristics and stability of the cosmetic product(s), including impurities, traces, and packaging material information.
3. Microbiological quality of the product(s).
4. Normal and reasonably foreseeable use of the product(s), target populations and warnings.
5. Product and substance exposure information.
6. Undesirable and serious undesirable effects.
7. Toxicological profile and analysis of substance – including MoS.
8. Information on the cosmetic product(s).

REPORT PART B

9. Assessment conclusions.
10. Labelled warnings and instructions of use.
11. Reasoning.
12. Assessor's credentials and approval of Part B

This report is valid only for the use by the person named as the Responsible Person for the products specified in the assessment. Any deviations from the formulations specified in this report ARE NOT VALID and will not be covered by this assessment.

All manufacture of products must comply with standard of good manufacturing practice as detailed in the relevant legislation.

All raw material specifications and finished product specifications must comply with any restrictions (purity etc.) detailed in REGULATION (EC) No 1223/2009

Any deviation from the prescribed formulation and list of permitted ingredients is NOT covered by this safety report.

MSDS sheets for all materials used must be included by the manufacturer as part of Safety Report Part A – additional information on raw materials (Identification and function) - <http://ec.europa.eu/consumers/cosmetics/cosing/>

MAF Cosmetic Consultants and the assessor named within accept no responsibility or liability for the misuse of this document or for any product produced outside of the specified formulation.

REPORT PART A

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT(S) (INCLUDING THE CHEMICAL IDENTITY OF SUBSTANCES IN THE FORMULATION)

CPNP BANDING

A	>75% - ≤100%
B	>50% - ≤75%
C	>25% - ≤50%
D	>10% - ≤25%
E	>5% - ≤10%
F	>1% - ≤5%
G	>0.1% - ≤1%
H	≤0.1%

BATH BOMBS - BASE FORMULATION				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
SODIUM BICARBONATE	144-55-8	61.12	5000	B
CITRIC ACID	77-92-9	30.56	2500	C
POLYSORBATE 80	9005-65-6	2.69	220	F
BUTYROSPERMUM PARKII BUTTER	194043-92-0	2.20	180	F
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL	8007-69-0 / 90320-37-9	2.20	180	F
KAOLIN	1332-58-7	0.61	50	G
BIO-GLITTER (POLYACTIDE POLYMERS, ALUMINIUM, EPOXY RESIN)	9051-89-2, 7429-90-5	0.37	30	G
COCAMIDOPROPYL BETAINE	97862-59-4	0.24	20	G

BATH BOMBS - VARIANT 1 (RHUBARB)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - RHUBARB FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
ORANGE MICA	77891, 77019, 77492	0.12	10	G
BLUE MICA	77019, 77891, 77007	0.12	10	G
BLACK MICA	77891, 77019, 77499	0.12	10	G
BLUE SOLUBLE COLOUR	42090	0.12	10	G

BATH BOMBS - VARIANT 2 (MONKEY FARTS)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - MONKEY FARTS FRAGRANCE OIL (CRAFTASTIK)	N/A	1.20	100	F
VANILLA STABILISER (FRAGRANCE)	N/A	0.60	50	G
GREEN MICA	77891, 77019, 77288	0.12	10	G
ORANGE MICA	77891, 77019, 77492	0.12	10	G
ORANGE SOLUBLE COLOUR	19140, 16035	0.12	10	G

BATH BOMBS - VARIANT 3 (COCONUT)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - CONONUT FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
VANILLA STABILISER (FRAGRANCE)	N/A	0.60	50	G
GREY MICA	77019, 77499	0.12	10	G
RED SOLUBLE	16035	0.12	10	G
YELLOW SOLUBLE COLOUR	19140	0.12	10	G

BATH BOMBS - VARIANT 4 (SHARK)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - STRAWBERRY FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
BLUE MICA	77019, 77891, 77007	0.12	10	G
PINK MICA	77019, 77891, 77491, 77742	0.12	10	G
RED SOLUBLE COLOUR	16035	0.12	10	G

BATH BOMBS - VARIANT 5 (RAINBOW)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - FANTASY FRAGRANCE OIL (CRAFTASTIK)	N/A	1.20	100	F
RED SOLUBLE COLOUR	16035	0.12	10	G
BLUE SOLUBLE COLOUR	42090	0.12	10	G
YELLOW SOLUBLE COLOUR	19140	0.12	10	G

BATH BOMBS - VARIANT 6 (THOUSAND WISHES)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - THOUSAND WISHES FRAGRANCE OIL (CRAFTASTIK)	N/A	1.19	100	F
VANILLA STABILISER (FRAGRANCE)	N/A	0.60	50	G
GOLD MICA	77019, 77491, 77891	0.36	30	G
YELLOW SOLUBLE COLOUR	19140	0.12	10	G

BATH BOMBS - VARIANT 7 (APPLE)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - APPLE FRAGRANCE OIL (MYSTIC MOMENTS)	N/A	1.20	100	F
BLUE SOLUBLE COLOUR	42090	0.12	10	G
YELLOW SOLUBLE COLOUR	19140	0.12	10	G

BATH BOMBS - VARIANT 8 (WATERMELON)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - WATERMELON FRAGRANCE OIL (MYSTIC MOMENTS)	N/A	1.20	100	F
ORANGE MICA	77891, 77019, 77492	0.12	10	G
BLUE MICA	77019, 77891, 77007	0.12	10	G
ORANGE SOLUBLE COLOUR	19140, 16035	0.12	10	G

BATH BOMBS - VARIANT 9 (CHERRY)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - CHERRY FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
RED SOLUBLE COLOUR	16035	0.12	10	G
PINK MICA	77019, 77891, 77491, 77742	0.12	10	G

BATH BOMBS - VARIANT 10 (AVOBATH)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - AVOBATH FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
RED SOLUBLE COLOUR	16035	0.12	10	G
BLUE SOLUBLE COLOUR	42090	0.12	10	G
PINK MICA	77019, 77891, 77491, 77742	0.12	10	G
BLUE MICA	77019, 77891, 77007	0.12	10	G

BATH BOMBS - VARIANT 11 (FLOWERBOMB)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - FLOWERBOMB FRAGRANCE OIL (PURE SCENTED)	N/A	1.20	100	F
VANILLA STABILISER (FRAGRANCE)	N/A	0.60	50	G
PURPLE SOLUBLE COLOUR	45140/42090	0.12	10	G
GREEN MICA	77891, 77019, 77288	0.12	10	G
BLUE MICA	77019, 77891, 77007	0.12	10	G

BATH BOMBS - VARIANT 12 (COMFORT)				
INGREDIENT NAME / INCI NAME	CAS / CI NUMBER	MAX % IN PRODUCT	MAX IN PRODUCT (G)	CPNP BAND
PARFUM - ULTIMATE COMFORT FRAGRANCE OIL (CRAFTASTIK)	N/A	1.20	100	F
VANILLA STABILISER (FRAGRANCE)	N/A	0.60	50	G
BLUE SOLUBLE COLOUR	42090	0.12	10	G
RED SOLUBLE COLOUR	16035	0.12	10	G
YELLOW SOLUBLE COLOUR	19140	0.12	10	G

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT(S) INCLUDING IMPURITIES, TRACES, AND PACKAGING MATERIAL INFORMATION.

PHYSICAL AND CHEMICAL PROPERTIES: The product is a solid blend of fixed and volatile oils and other compounds. The colour and fragrance are characteristic of the fragrance and colourants used in the formulation (if any). *For detailed information regarding the physical and chemical characteristics of the raw materials please refer to the MSDS in the product information file (PIF).*

The pH is expected to be around 9-10.

STABILITY AND REACTIVITY: The product is expected to be nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made. No major interactions are expected - possible interaction between labile components of fragrance materials (esters, alcohols) - no resulting components that are likely to alter the toxicity profile of the initial ingredients. A shelf life of greater than 12 months and a PAO of 6 months is expected with this product. The manufacturer is responsible to undertake further testing on the shelf life and stability of the product and amend these limits if necessary. The product will dissolve fully when added to water.

INGREDIENT PURITY: Specific purity criteria do not apply. The purity of the ingredients in the formulation(s) is specified – where appropriate – in the MSDS documents in PIF. Pharmaceutical, food or cosmetic grade ingredients are used in the manufacture of the product(s). The manufacturer is responsible for ensuring the purity of the ingredients used and the quality of the raw materials.

PACKAGING MATERIAL: No specific requirements. Inert cosmetic/food grade packaging must be used. The manufacturer is responsible for ensuring the suitability and quality of the packaging material.

3. MICROBIOLOGICAL QUALITY OF THE PRODUCT(S).

The product(s) are anhydrous and have a low activity of water, and – under normal conditions of storage and/or use – does not support microbial growth. Product(s) is a Category 2 product:

For any cosmetic product classified as a “Category 2 Product”, the total viable count (TVC) the TVC for aerobic mesophilic microorganisms should not exceed 1000cfu/g or mL of product. In addition, the pathogens Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans should not be detectable in 1g or 1mL of the product.

Microbiological testing of the raw materials has been performed by the primary manufacturer. Further specific microbiological testing is not required, nor recommended for this product(s).

4. NORMAL AND REASONABLY FORESEEABLE USE OF THE PRODUCT(S), TARGET POPULATIONS AND WARNINGS.

The product is a bath water additive – bath bomb. It is intended to be occasionally added to bath water. It is a rinse off product.

It is intended to be used by the general population and is not intended for, nor is marketed for use on babies, infants, or children under 3 years of age. The product(s) is not intended to be used on mucous membranes or on the eye area. There is no other reasonable or foreseeable use for this product(s).

There is no specific requirement for warnings required for the product labelling, however a general statement that these products are for external use only, should not be applied to the eye area, mucous membranes, broken or irritated skin is recommended. It is also recommended that a statement advising to discontinue use in the case of irritation should also be included.

5. PRODUCT AND SUBSTANCE EXPOSURE INFORMATION.

EXPOSURE OF PRODUCT: WHOLE BODY							
PRODUCT AMOUNT PER APPLICATION ¹ (G)	POTENTIAL FREQUENCY OF USE ¹ (PER DAY)	MAXIMUM DAILY PRODUCT USE (G)	RETENTION FACTOR ²	MAXIMUM DAILY PRODUCT EXPOSURE (MG)	DAILY SYSTEMIC EXPOSURE DOSE (SED) [†] (MG/KG/DAY)	SURFACE AREA EXPOSED (CM ²)	LOCAL EXPOSURE DOSE (LED) (MG/CM ²)
25	0.2849	7.12	0.01	71.2329	1.1678	16340	0.0044

EXPOSURE OF SUBSTANCE: WHOLE BODY								
SUBSTANCE (INCI)	MAX CONTENT (%)	DAILY AMOUNT OF PRODUCT USED (G)	MAXIMUM DAILY SUBSTANCE USE (G)	RETENTION FACTOR ²	MAXIMUM DAILY PRODUCT EXPOSURE (MG)	DAILY SYSTEMIC EXPOSURE DOSE (SED) [†] (MG/KG/DAY)	SURFACE AREA EXPOSED (CM ²)	LOCAL EXPOSURE DOSE (LED) (MG/CM ²)
BIO-GLITTER (POLYACTIDE POLYMERS, ALUMINIUM, EPOXY RESIN)	0.37	7.12	0.026112	0.01	0.261125	0.004281	16340	0.0000
BLACK MICA	0.12	7.12	0.008558	0.01	0.085577	0.001403	16340	0.0000
BLUE MICA	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
BLUE SOLUBLE COLOUR	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
BUTYROSPERMUM PARKII BUTTER	2.20	7.12	0.156675	0.01	1.566748	0.025684	16340	0.0001
CITRIC ACID	30.56	7.12	2.176039	0.01	21.76039	0.356728	16340	0.0013
COCAMIDOPROPYL BETAINE	0.24	7.12	0.017408	0.01	0.174083	0.002854	16340	0.0000
GOLD MICA	0.36	7.12	0.02552	0.01	0.255197	0.004184	16340	0.0000
GREEN MICA	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
GREY MICA	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
KAOLIN	0.61	7.12	0.043521	0.01	0.435208	0.007135	16340	0.0000
ORANGE MICA	0.12	7.12	0.008568	0.01	0.08568	0.001405	16340	0.0000
ORANGE MICA	0.12	7.12	0.008558	0.01	0.085577	0.001403	16340	0.0000
ORANGE SOLUBLE COLOUR	0.12	7.12	0.008568	0.01	0.08568	0.001405	16340	0.0000
PARFUM - APPLE FRAGRANCE OIL (MYSTIC MOMENTS)	1.20	7.12	0.085783	0.01	0.857831	0.014063	16340	0.0001

PARFUM - AVOBATH FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.085577	0.01	0.855769	0.014029	16340	0.0001
PARFUM - CHERRY FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.085783	0.01	0.857831	0.014063	16340	0.0001
PARFUM - CONONUT FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.085167	0.01	0.851675	0.013962	16340	0.0001
PARFUM - FANTASY FRAGRANCE OIL (CRAFTASTIK)	1.20	7.12	0.08568	0.01	0.856799	0.014046	16340	0.0001
PARFUM - FLOWERBOMB FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.085167	0.01	0.851675	0.013962	16340	0.0001
PARFUM - MONKEY FARTS FRAGRANCE OIL (CRAFTASTIK)	1.20	7.12	0.085167	0.01	0.851675	0.013962	16340	0.0001
PARFUM - RHUBARB FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.085577	0.01	0.855769	0.014029	16340	0.0001
PARFUM - STRAWBERRY FRAGRANCE OIL (PURE SCENTED)	1.20	7.12	0.08568	0.01	0.856799	0.014046	16340	0.0001
PARFUM - THOUSAND WISHES FRAGRANCE OIL (CRAFTASTIK)	1.19	7.12	0.085066	0.01	0.850657	0.013945	16340	0.0001
PARFUM - ULTIMATE COMFORT FRAGRANCE OIL (CRAFTASTIK)	1.20	7.12	0.085167	0.01	0.851675	0.013962	16340	0.0001
PARFUM - WATERMELON FRAGRANCE OIL (MYSTIC MOMENTS)	1.20	7.12	0.08568	0.01	0.856799	0.014046	16340	0.0001
PINK MICA	0.12	7.12	0.008558	0.01	0.085577	0.001403	16340	0.0000
POLYSORBATE 80	2.69	7.12	0.191491	0.01	1.914914	0.031392	16340	0.0001
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL	2.20	7.12	0.156675	0.01	1.566748	0.025684	16340	0.0001
PURPLE SOLUBLE COLOUR	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
RED SOLUBLE	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
RED SOLUBLE COLOUR	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000
SODIUM BICARBONATE	61.12	7.12	4.352078	0.01	43.52078	0.713455	16340	0.0027
VANILLA STABILISER (FRAGRANCE)	0.60	7.12	0.042584	0.01	0.425837	0.006981	16340	0.0000
YELLOW SOLUBLE COLOUR	0.12	7.12	0.008517	0.01	0.085167	0.001396	16340	0.0000

1: Product amount per application, frequency of use and surface area exposed RIVM report 320104001/2006, H. J., Bremmer.

2: Retention factor THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 10TH REVISION.

‡: Mean body weight used 60kg.

‡: Based on the product amount per application.

Exposure (under foreseeable conditional use) is by dermal absorption only. The retention factor of 1% has been applied (as per The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th Revision), and all calculations have been based on typical exposure values (as per RIVM Report 320104001/2006). Exposure of this product is dermal only. There is no likely exposure by consumption, inhalation and – under normal conditions of use – no exposure to the eye or the eye area. This product will not be applied to the mucous membranes.

6. UNDESIRABLE AND SERIOUS UNDESIRABLE EFFECTS

There were no undesirable or serious undesirable effects reported at the time this report was prepared. A record must be kept of any reported undesirable effects, and they must be notified to the relevant competent authority.

7. TOXICOLOGICAL PROFILE AND ANALYSIS OF SUBSTANCE – INCLUDING MOS.

The NOAEL values for each ingredient in the products assessed within this report were obtained. The margin of safety (MoS) value was determined for each ingredient using the following formula (as defined by the SCCS):

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

For the purposes of this toxicological assessment, a MoS of >100 is considered acceptable. Any ingredients with a MoS of less than 100 will have specific justification for their approval (if such approval is granted).

NOAEL values were obtained from published, repeat dose toxicity studies.

The following table details the NOAEL and MoS values for each relevant substance included in the formulations.

In addition to calculating the MoS, the TTC (threshold of toxicological concern) was determined where relevant. The following TTC apply to compounds, where relevant:

Cramer Class I	30ug/kg/day
Cramer Class II	9ug/kg/day
Cramer Class III	1.5ug/kg/day

Where the TTC is exceeded for a specific substance, justification for deeming it “safe” will be provided.

MoS OF SUBSTANCES ASSESSED IN THIS REPORT.

The MoS was calculated for each substance used in each of the formulations covered in this assessment; the MoS for each substance was >100; the assessment determined that each of the substances was satisfactorily safe when used as specified by each of the formulations detailed in this report. When the MoS is greater than 1000 the ingredient can be considered safe and “non-toxic”.

TOXICOLOGICAL PROFILE OF INGREDIENTS							
INCI NAME	CAS / CI NUMBER	FUNCTION (COSING)	DESCRIPTION (COSING)	TOXICITY PROFILE ^[1]	TOX. RISK CATEGORY	SED	MoS
CI 77000	CI 77000	COLORANT	CI 77000 is classed chemically as an inorganic colour. It consists of finely powdered aluminium.	Permitted to be used in rinse off products without further restriction Reg EC 1223/2009 Annex IV/117. NOAEL data not available.	1	0.004281	N/A
POLYLACTIC ACID	9051-89-2	ABRASIVE	Polymer of lactic acid	Considered safe as a cosmetic ingredient: https://www.cir-safety.org/sites/default/files/ahas.pdf No toxicological significance.	1	0.004281	N/A
EPOXY RESIN-1	N/A	FILM FORMING	Epoxy Resin-1 is a copolymer formed by first reacting diethylenetriamine with 3 moles of glycidyl neodecanoate. This compound is further reacted with isopropylidenebisphenol diglycidyl ether, Dimethylaminopropylamine, and Diethanolamine. The resulting polymer is capped with Oleic Acid, partially neutralized with Lactic Acid, and dispersed into water.	No toxicological significance.	1	0.004281	N/A
BUTYROSPERMUM PARKII BUTTER	194043-92-0	SKIN CONDITIONING VISCOSITY CONTROLLING	Butyrospermum Parkii Butter is the fat obtained from the fruit of the Shea Tree, Butyrospermum parkii, Sapotaceae	Considered safe as cosmetic ingredient (CIR, 2017, https://doi.org/10.1177%2F1091581817740569). No toxicological significance.	1	0.025684	N/A
CITRIC ACID	77-92-9	BUFFERING CHELATING FRAGRANCE	Citric Acid is an organic acid.	Considered safe as a cosmetic ingredient: (https://journals.sagepub.com/doi/pdf/10.1177/1091581814526891) NOAEL (rat, 28 day study) = 1200mg/kg: (https://hvpchemicals.oecd.org/Ui/handler.axd?id=e19d2799-0c16-496d-a607-b09330dd28a7)	1	0.356728	3363.91
COCAMIDOPROPYL BETAINE	97862-59-4	ANTISTATIC CLEANSING HAIR CONDITIONING SURFACTANT - CLEANSING SURFACTANT - FOAM BOOSTING VISCOSITY CONTROLLING	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts	Considered safe as a cosmetic ingredient: (https://doi.org/10.3109/10915819109078621) No restriction for rinse-off products. NOAEL (http://webnet.oecd.org/Hpv/ui/handler.axd?id=1415a0a7-54dd-4be8-bb55-fbf7ec8eab50) = 330mg/kg	3	0.002854	115634.4
KAOLIN	1332-58-7	ABRASIVE ABSORBENT ANTICAKING BULKING COLORANT OPACIFYING	Naturally occurring substances, kaolin (CI 77004)	Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/sites/default/files/alkcly122015Rev%20Tent.pdf) Limited toxicological concern for kaolin used in topical applications due to the large molecule size (i.e., dermal absorption will be negligible). Read across data for stearylalkonium bentonite: NOAEL(oral): 1000mg/kg/day (limit of dose, no observed adverse effects at this level).	1	0.007135	140162.9
PARFUM - APPLE FRAGRANCE OIL (MYSTIC MOMENTS)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014063	N/A
PARFUM - AVOBATH FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014029	N/A
PARFUM - CHERRY FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014063	N/A
PARFUM - CONONUT FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.013962	N/A
PARFUM - FANTASY FRAGRANCE OIL (CRAFTASTIK)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014046	N/A

PARFUM - FLOWERBOMB FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.013962	N/A
PARFUM - MONKEY FARTS FRAGRANCE OIL (CRAFTASTIK)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.013962	N/A
PARFUM - RHUBARB FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014029	N/A
PARFUM - STRAWBERRY FRAGRANCE OIL (PURE SCENTED)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014046	N/A
PARFUM - THOUSAND WISHES FRAGRANCE OIL (CRAFTASTIK)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.013945	N/A
PARFUM - ULTIMATE COMFORT FRAGRANCE OIL (CRAFTASTIK)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.013962	N/A
PARFUM - WATERMELON FRAGRANCE OIL (MYSTIC MOMENTS)	N/A	N/A	N/A	Used within IFRA permitted limits.	3	0.014046	N/A
POLYSORBATE 80	9005-65-6	DENATURANT SURFACTANT - CLEANSING SURFACTANT - EMULSIFYING	Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)-	Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/sites/default/files/polysorbates_0.pdf) NOAEL (28 day rat study) = 2500mg/kg (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4152)	1	0.031392	79638.02
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL	8007-69-0 / 90320-37-9	SKIN CONDITIONING	Prunus Amygdalus Dulcis Oil is the fixed oil obtained from the ripe seed kernel of the Sweet Almond Tree, Prunus amygdalus var. dulcis, Rosaceae	Density: 0.91 g/mL at room temp. Refractive Index: n20/D1.471 Insoluble in water, slightly soluble in ethanol. Clear, colourless or pale yellow coloured oil with a nutty fragrance and aroma. Considered safe as a cosmetic ingredient: (https://doi.org/10.1177/1091581817740569) Similar plant-derived fatty acid oils are not known to be photosensitising, phototoxic, dermal or ocular irritants or sensitisers (MCII <0.25). LD50 = >5000mg/kg (ECHA, unnamed study report, 2014) Prunus amygdalus dulcis oil was not found to be genotoxic (ECHA, unnamed study report, 2014, OECD 471). Considered a non-toxic ingredient - no repeat-dose toxicity data available	1	0.025684	N/A
SODIUM BICARBONATE	144-55-8	ABRASIVE BUFFERING DEODORANT ORAL CARE SKIN PROTECTING	N/A	Considered safe as a cosmetic ingredient: (https://doi.org/10.3109/10915818709095491) Slight irritating to the skin when used in isolation. Not an ocular irritant. NOAEL (repeat dose, 28 day in mouse. Developmental toxicity, no other data available) = 580mg/kg (OECD SIDS)	2	0.713455	812.9449
VANILLA STABILISER (FRAGRANCE)	N/A	N/A	N/A	Permitted for use in cosmetic products.	1	0.006981	N/A
CI 16035	CI 16035	COLORANT HAIR DYEING	CI 16035 is classed chemically as a monoazo colour.	Permitted to be used in rinse off products without further restriction Reg EC 1223/2009 Annex IV/32. NOAEL (CIR) = 700mg/kg	2	0.004184	167304
CI 19140	CI 19140	COLORANT HAIR DYEING	CI 19140 is classed chemically as a pyrazole colour.	Permitted to be used in rinse off products without further restriction Reg EC 1223/2009 Annex IV/44. NOAEL data not available.	1	0.004184	N/A

CI 42090	CI 42090	COLORANT HAIR DYEING	CI 42090 is classed chemically as a triphenylmethane colour.	Permitted to be used in rinse off products without further restriction Reg EC 1223/2009 Annex IV/63. NOAEL (CIR) = 631mg/kg	2	0.004184	150812.6
CI 77007	CI 77007	COLORANT	CI 77007 is classed chemically as an inorganic colour. It is a synthetic pigment composed of complex sodium aluminum sulfosilicates.	Ultramarines are listed as CI77007 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77019	CI 77019	ANTICAKING BULKING COLORANT OPACIFYING	Mica is a series of silicate minerals of varying chemical composition but with similar physical properties. Mica may have well-defined cleavage and split into very thin sheets.	Micas are listed as CI77019 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77288	CI 77288	COLORANT	CI 77288 is classed chemically as an inorganic colour	CI 77288 is permitted for use as a colourant in cosmetics, without restriction - Reg (EC) 1223/2009 Annex IV/129.	1	0.004184	N/A
CI 77491	CI 77491	COLORANT	CI 77491 is classed chemically as an inorganic colour. It consists chiefly of ferric oxide that conforms to the formula:	Ferric oxides are listed as CI77491 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77492	CI 77492	COLORANT	CI 77492 is classed chemically as an inorganic colour. It consists chiefly of hydrated ferrous oxide that conforms to the formula:	Iron oxides are listed as CI77492 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77499	CI 77499	COLORANT	CI 77499 is classed chemically as an inorganic colour. It consists chiefly of ferrous-ferric oxide (see also INCI:Iron Oxides)	Iron oxides are listed in the Cosmetics Directive of the European Union (Annex IV/137) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77742	CI 77742	COLORANT	CI 77742 is classed chemically as an inorganic colour (see also INCI name: Manganese Violet).	Manganese violets are listed as CI77742 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A
CI 77891	CI 77891	COLORANT OPACIFYING UV ABSORBER UV FILTER	Titanium Dioxide is the inorganic oxide. To identify the colourant meeting the requirements for labelling purposes in the EU, the INCI Name 77891 must be used. It conforms generally to the formula:	Titanium dioxides are listed as CI77891 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	1	0.004184	N/A

[1]: Toxicological risk is calculated using a number of parameters and is determined either by using published, peer-reviewed studies or determined computationally. The TTC values, presence of Cramer Compounds and the CMR activity of the compounds are assessed to assign a "toxicological risk category" to each component of the product(s):

1) Low/limited toxicological significance: edible and inert substances with a NOAEL value of >1000mg/kg/day (or with no NOAEL value determined due to limited toxicological concern). Includes Cramer Class I compounds, no structural alerts and no CMR activity.

2) Limited toxicological significance: Functional components with a NOAEL of 100-500mg/kg/day. Cramer classes I and II, with limited structural alerts. No determined CMR activity.

3) Moderate toxicological significance: Functional and active components with a NOAEL of 50-100mg/kg/day. Cramer classes I and II with no structural alerts. No CMR activity at the levels used in the formulation.

4) High toxicological concern: components with NOAEL of <50mg/kg/day. Cramer class II and III compounds and compounds with known or potential CMR activity.

PROHIBITED AND RESTRICTED SUBSTANCES, AND ALLERGENS:

There are no substances in the formulations of each of the products defined as prohibited by Annex VI of Regulation (EC) No. 1223/2009.

Any allergens present in the fragrance oils used in any of the formulations that exceed 0.01% must be indicated on the labelling of the product(s). The manufacturer is responsible for calculating the allergens present and determining which – if any – must be included on the labelling.

8. INFORMATION ON THE COSMETIC PRODUCT(S).

There are no specific or medicinal claims made by the products. The product is intended for general cosmetic use by general consumers and does not contain any novel or previously unused cosmetic ingredients. All the ingredients used in the formulation for each of the products are widely used in cosmetic preparations and are generally considered safe for use in this type of cosmetic product.

REPORT PART B

9. ASSESSMENT CONCLUSIONS

Each of the products assessed by this report (specified in Part A) have been deemed safe for the prescribed use (as a rinse off bath bomb). These products satisfy the requirements as specified in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

10. LABELLED WARNINGS AND INSTRUCTIONS OF USE

No specific requirements for product labelling (other than as described in the next section). Labelling must comply with Regulation (EC) No. 1223/2009 as amended. It is recommended that general safety guidelines are included, e.g., avoid contact with the eyes, if irritation occurs discontinue use, do not use on broken or irritated skin etc.

11. REASONING

All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

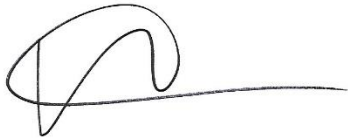
- The quantitative and qualitative composition
- Physical/chemical characteristics and stability of substances
- Microbiological quality
- Impurities, trace materials and packaging used
- The normal and reasonably foreseeable use of the product(s)
- Exposure to the product(s) (local and systemic)
- Exposure to the substances (local and systemic)
- Toxicological profile of the substances – including MoS and NOAEL values
- Undesirable and serious undesirable effects
- Any other information relevant to the product

The NOAEL and MoS were calculated using published, peer-reviewed studies of oral, dermal, systemic etc. toxicity of each of the ingredients included in the formulation(s). Where no peer reviewed data were available, suitable cross-over data were obtained. Various sources were used to obtain the required data,

including PubMed, COSMO database, CIR and SCSS etc. Full details of the sources used can be provided upon request.

12. ASSESSORS CREDENTIALS AND APPROVAL OF PART B

This product meets the requirements of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019 and is approved as of 09/03/2022.



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DATE: 09/03/2022

APPENDIX 1: ALLERGEN LABELLING REQUIREMENT

VARIANT	FRAGRANCE OIL	ALLERGEN REQUIRING LABELLING
1	PARFUM - RHUBARB FRAGRANCE OIL (PURE SCENTED)	Geraniol Hydroxycitronellal Linalool Limonene Citronellol
2	PARFUM - MONKEY FARTS FRAGRANCE OIL (CRAFTASTIK)	Limonene Linalool
3	PARFUM - CONONUT FRAGRANCE OIL (PURE SCENTED)	Coumarin
4	PARFUM - STRAWBERRY FRAGRANCE OIL (PURE SCENTED)	N/A
5	PARFUM - FANTASY FRAGRANCE OIL (CRAFTASTIK)	Benzyl salicylate Coumarin Hexyl cinnamal Linalool
6	PARFUM - THOUSAND WISHES FRAGRANCE OIL (CRAFTASTIK)	Benzyl salicylate Linalool
7	PARFUM - APPLE FRAGRANCE OIL (MYSTIC MOMENTS)	Benzyl alcohol
8	PARFUM - WATERMELON FRAGRANCE OIL (MYSTIC MOMENTS)	Benzyl alcohol Benzyl salicylate Coumarin Hydroxycitronellal
9	PARFUM - CHERRY FRAGRANCE OIL (PURE SCENTED)	Benzyl benzoate
10	PARFUM - AVOBATH FRAGRANCE OIL (PURE SCENTED)	Citral Linalool
11	PARFUM - FLOWERBOMB FRAGRANCE OIL (PURE SCENTED)	Benzyl salicylate Coumarin Limonene Linalool
12	PARFUM - ULTIMATE COMFORT FRAGRANCE OIL (CRAFTASTIK)	Limonene Linalool