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SAFETY

ASSESSMENT

According to EC Regulation 1223/2009

HAIR AND BODY WASH BUBBLE GUM- NR0004

FORMULA:
NR0004-T(SG)-C(LIL2665)-F(BG)-R(01)

DEPESCHE VERTRIEB GMBH & CO. KG.

SAFETY EVALUATION OF FINISHED COSMETIC PRODUCT ACCORDING TO ANNEX I OF (EC) REGULATION 1223/2009

INDEX

DEPESCHE VERTRIEB GMBH & CO. KG.

PART A- COSMETIC PRODUCT SAFETY INFORMATION

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

Product Name: **HAIR AND BODY WASH BUBBLE GUM- NR0004**

Manufacturer **DEPESCHE VERTRIEB GMBH & CO. KG**

STUDY PERIOD **MAY 2024**

QACS LAB ID **23 06 00954**

Product Category **HAIR AND BODY WASH (BATHING, SHOWERING)**

TABLE I. FORMULA PROVIDED

RAW MATERIAL TRADE NAME	INCI	CAS No.	%	FUNCTION
WATER	AQUA	7732-18-5	50.680	SOLVENT
ALPHA OLEFIN SULFONATE	SODIUM C14-16 OLEFIN SULFONATE	68439-57-6	25.000	CLEANSING, FOAMING, SURFACTANT
	AQUA	7732-18-5		SOLVENT
APG-CH200	LAURYL GLUCOSDE	110615-47-9	6.000	CLEANSING, SURFACTANT
	AQUA	7732-18-5		SOLVENT
BETAINE CAB-35	COCAMIDOPROPYL BETAINE	61789-40-0	5.000	ANTISTATIC, CLEANSING, FOAM BOOSTING
	AQUA	7732-18-5		SOLVENT
	SODIUM CHLORIDE	7645-14-5		ANTISTATIC, CLEANSING, FOAM BOOSTING
TC-CARBOMER FD2010	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	N/A	2.600	FILM FORMING, EMULSION STABILISING
SODIUM HYDROXIDE, CAUSTIC SODA	SODIUM HYDROXIDE	1310-73-2	2.400	BUFFERING
POLYQUATERNIUM M-550H	POLYQUATERNIUM-7	26590-05-6	2.100	ANTISTATIC
	AQUA	7732-18-5		SOLVENT
AMINO ACID SURFACTANT LD-30-B	SODIUM LAUROYL SARCOSINATE	173-18-5	2.000	CLEANSING, FOAMING, SURFACTANT
	AQUA	7732-18-5		SOLVENT
REFINED GLYCERINE	GLYCERIN	56-81-5	2.000	HUMECTANT, SKIN CONDITIONING
MICROCARE PHG	PHENOXYETHANOL	122-99-6	1.000	PRESERVATIVE
	CAPRYLYL GLYCOL	1117-86-8		SKIN CONDITIONING
MICROCARE SB	SODIUM BENZOATE	532-32-1	0.450	PRESERVATIVE
	POTASSIUM SORBATE	24634-61-5		PRESERVATIVE

DX32-16	GUAR HYDROXYPRPYLTRIMONIUM CHLORIDE	65497-29-2	0.300	ANTISTATIC
	AQUA	7732-18-5		SOLVENT
GUANGDONG BAIFANG FLAVOURS & CHEMICALS CO., LTD - NBF091517 BUBBLE GUM	PARFUM	N/A	0.150	PERFUMING
PEPPERMINT OIL	MENTHA ARVENSIS LEAF OIL	68917-18-0	0.120	PERFUMING
ALOE BARBADENSIS GEL	ALOE BARBADENSIS LEAF EXTRACT	85507-69-3	0.100	SKIN CONDITIONING
	PROPANEDIOL	504-63-2		SOLVENT
	CAPRYLYL GLYCOL	1117-86-8		SKIN CONDITIONING
	PENTYLENE GLYCOL	5343-92-0		SKIN CONDITIONING
CITRIC ACID MONOHYDRATE	CITRIC ACID	5949-29-1, 77-92-9	0.100	BUFFERING, CHELATING
D&C RED #33	CI 17200	3567-66-6	<0.001	COSMETIC COLOURANT
BRILLANT BLUE FCF	CI 42090	3844-49-9	<0.001%	COSMETIC COLOURANT

Note: Exact composition breakdowns were not provided for all raw materials. The present assessment is based on the presented formula.

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

- Supplier's specifications for each raw material have been reviewed (Safety and Technical Data Sheets, MSDS and TDS).
- Specifications of Final Product: Have been reviewed.
- Stability of The Product: Has been reviewed (QACS Ltd.)-tested on a similar formulation.

3. MICROBIOLOGICAL QUALITY

Microbiological Quality: The product, due way of use-single use product (in addition to the presence of preservatives (Phenoxyethanol. Sodium Benzoate, Potassium Sorbate) is unlikely to present, under normal production conditions, any kind of bio burden (ISO 29621:2017).

Challenge Test: The test has been performed (QACS Ltd.) according to the current EUROPEAN PHARMACOPOEIA (Preservation Efficacy test).
The below mentioned strains have been studied separately:
P. aeruginosa ATCC9027, *S. aureus* ATCC6538, *E. coli* ATCC8739, *C. albicans* ATCC10231 and *A. brasiliensis* ATCC16404.
Results are satisfactory-tested on a similar formulation.

4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

- Regarding any traces and impurities from the raw materials please refer to Table I of section 1 Quantitative and qualitative composition of the cosmetic product and section 8. Toxicological Profile of the Substances.
- Properties of Packaging Material: The packaging materials' specifications have been reviewed. According to the presentation and the formula of the product, package is considered unlikely to affect its purity and stability.
  Type of packaging material: Plastic Container-see stability
- Production Method: Has been reviewed.
- G.M.P. Compliance: ISO 22716 / Certification Body: DEKRA / Certificate No: DH2023GMP(D)0081 / Exp. Date: August 29th 2026.

5. NORMAL AND REASONABLY FORESEEABLE USE

The product is applied on the hair and body and it is rinsed off.

External use only.

6. EXPOSURE TO THE COSMETIC PRODUCT

The product is applied on the hair and body and it can be considered taking into account guidelines from SCCS/1647/22 opinion as a shampoo and shower gel (combined use) with an estimated daily amount applied 29.13 g and a calculated relative daily exposure 4.3 mg/Kg bw/day.

Target Group for Use: -

7. EXPOSURE TO THE SUBSTANCES

Please refer to Table I of section 1. 1. Quantitative and qualitative composition of the cosmetic product

8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

- The product itself has not been tested on animals (Article 18).

MSDS TOXICOLOGICAL REVIEW:

Respiratory : Not required for consumer use of this product. Inhalation exposure is not applicable for this type of product.

Skin : This product is unlikely to be sensitizing to human skin. It is not expected to produce allergy by skin contact, except the cases of people with known allergic reaction in the specific allergens referred on the label. The absorption through the skin is considered limited.

Eye : As with any material contacting the eye its accidental exposure may result in slight eye irritation.

Ingestion : Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous, under foreseeable use.

All information available refers to the relevant MSDS of each raw material that takes part in the formula of the product. The specific ingredients that have been chosen for the production of this product have been used for years, for same products, without any known toxicity problems, under foreseeable conditions of use.

- Especially for ‘hazardous’ raw materials (substances under restrictions listed in the Annexes i.e. Annex II-Substances Prohibited in Cosmetic Products, Annex III-Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions, Annex IV-Colorants Allowed, Annex V-Preservatives Allowed and Annex VI-UV Filters Allowed) there are already limits in legislation.

- There is no evidence from the formula of the product for interaction of substances.

- There are permissible **colours** in the formula (CI 42090, CI 17200).

i) The definition is reminded as in Article 2. 1 "(m) 'colorants' means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants".

ii) Preamble to ANNEX IV states that "without prejudice to other provisions in this Regulation, a colorant shall include its salts and lakes and when a colorant is expressed as a specific salt, its other salts and lakes shall also be included". It is noted however that specific lakes, salts or pigments might be explicitly restricted or allowed through ANNEXES. In the same time, certain cosmetic colorants must pass purity criteria as set out in Commission Directive 95/45/EC (including any up to-date subsequent legislative replacements) or specific purity criteria as set by REGULATION (EC) No 1223/2009 (see ANNEX IV - LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS), where applicable.

iii) Article 14.1 c) i) and ii) as well as 14.2 indicate additionally the necessity of compliance with ANNEX IV restrictions and explicitly cover any derogation from such limitations.

- It might contain Emodin (*Aloe Barbadensis*). In light of the findings so far, it cannot be excluded that emodin has a weak genotoxic potential and that it is also a low-potency carcinogen. Studies indicate a possible oral intake in humans through diet of up to 3mg/kg bw per day. However, the emodin content does probably not represent a high priority genotoxic risk in a balanced human diet, taking into consideration the measured concentrations of emodin in foodstuffs as well as the protective effects of other components in food. This risk should not be increased because of use of cosmetics. Therefore it is recommended to keep the amount of emodin in plant extracts used for cosmetics at the detection level (below 1ppm) (Plants in cosmetics Potentially harmful components-Volume III-prepared by the Committee of Experts on Cosmetic Products).

- It contain Menthol (*Mentha Arvensis*). Menthol isomers investigated are moderately irritating to the skin and slightly eye irritating. There are no data available for skin penetration. The potency for skin sensitisation of menthol isomers in animals and humans is low. Adverse effects were mainly reported for children after local administration or inhalation of menthol. Application in the nose, nostrils and near to the nose in newborns and children younger than two years of age may cause a severe and dangerous trigeminus reflex and should be avoided. Glucose-6-phosphate-dehydrogenase-deficiency in newborn babies may result in development of severe jaundice after menthol administration due to the inability of the neonates to conjugate menthol. There may be also a risk for health effects in older children or in adults with glucose-6-phosphate dehydrogenase deficiency after exposure to menthol-containing products, however no data for these groups were available so far. Consumers are exposed to menthol via several menthol containing products as cosmetic and oral care products, foodstuff,

pharmaceutical products, odour improving agents and tobacco while dermal and oral exposure routes as well as inhalation have to be considered. Exposure to menthol also occurs through the use of peppermint oil. The value for an acceptable daily intake of 0-4mg menthol per kg bw as set JECFA may be exceeded, when products with high amounts of menthol, especially pharmaceutical products were used. Therefore, it is recommended that the amount of menthol should not exceed 2% in cosmetic products. Furthermore, menthol should not be used in products for babies and children under the age of three. (Plants in cosmetics, Potentially harmful components-Volume III-prepared by the Committee of Experts on Cosmetic Products).
According to the presented documentation the product contains 0.06% Menthol

- It contains Polyquaternium-7 and according to ANNEX III/66 and SCCP opinion 0011/98, the maximum residual acrylamide content must be <0.1 ppm in body care leave-on products and <0.5 ppm in other cosmetic products. The manufacturer of the raw material must guarantee that the content in raw material is such so that the final product fulfils this restriction.

- Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NOAEL.

The following table includes the relevant available NOAEL and MoS calculated for each ingredient of the formula.

TABLE II.

INCI	%	NOAEL mg/Kg bw/da	MoS	NOAEL/SAFETY REFERENCE
AQUA	76.7220	SAFE	-	-
SODIUM C14-16 OLEFIN SULFONATE	8.7500	>100	>133	i) NOAELs of about 100 mg a.i./kg bw/day were found for rats in comprehensive oral 6 month- and 2-year studies with C14– and C14-16- α-olefin sulfonates. (https://hpvchemicals.oecd.org/ui/handler.axd?id=97AEE5B8-EFE9-4096-859B-D3AFBFD03CFD) ii) Dermal absorption intact skin: 0.62% recovery from urine, bile and main organs after 24 h. Dermal absorption damaged skin: 50.36% recovery from urine, bile and main organs after 30 h. (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/16004/7/2/3) iii) Data from industry specifically on Sodium C14-16 Olefin Sulfonates indicate use at 3.6% in facial cleansing foams; >5-10% in skin care preparations; and > 10% in personal cleanliness products (CTFA 1995). Based on the available data, the CIR Expert Panel concludes Sodium a-Olefin Sulfonates (of chain lengths C12-14, C14-16, C14-1s, and C16-18) to be safe as used in rinse-off* products and safe up to 2% in leave-on products. The concentration of the gamma sultone impurity of any formulation (leave-on or rinse-off) is limited to unsubstituted alkane sultones <10 ppm; chlorosultones <1 ppm; and unsaturated sultones <0.1 ppm. * The highest concentration reportedly is 16% in shampoos and bath and shower products. See also: (www.cir-safety.org/sites/default/files/admin_0.pdf; http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr45.pdf) iv) https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1721
LAURYL GLUCOSIDE	3.0000	1000	3876	i) Sprague-Dawley rats were dosed by gavage with 0, 250, 500 and 1000 mg/kg bw/day C12/16 APG for 90 days. An additional 5 male and 5 female control and high dose rats were used as a recovery group. There were two fatalities, neither of which was linked to the test material. No treatment-related changes in body weights, organ weights, or

				biochemistry or hematology parameters were observed. Absolute gonad weights were decreased in all test groups, but the decrease was not considered treatment related by the researchers because of a lack of a dose-response. A dose-dependent, slowly reversible, irritation and ulceration of the forestomach mucosa was observed in animals of the 0.5 and 1 g/kg bw groups. Systemic toxicity was not observed in any group. The NOAEL for systemic toxicity was 1000 mg/kg bw. The NOEC for "local compatibility" (irritation and ulceration of the mucous membrane of the forestomach) was deduced as 2.5% active ingredient. (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/6208/7/6/1) ii) Up to 10% dernal contact 8% for leave on products / no concentration reported for babies. Across data might indicate lower than 100% dermal abs.: In an in vitro dermal absorption study using human skin samples, the mean absorbed dose of 10% caprylyl/caprylglucoside was 0.01%. (http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR586.pdf) ii)The Cosmetic Ingredient Review (CIR) Expert Panel assessed the safety of 19 alkyl glucosides as used in cosmetics and concluded that these ingredients are safe in the present practices of use and concentration when formulated to be nonirritating. Most of these ingredients function as surfactants in cosmetics, but some have additional functions as skin-conditioning agents, hair-conditioning agents, or emulsion stabilizers. The Panel reviewed the available animal and clinical data on these ingredients. Since glucoside hydrolases in human skin are likely to break down these ingredients to release their respective fatty acids and glucose, the Panel also reviewed CIR reports on the safety of fatty alcohols and were able to extrapolate data from those previous reports to support safety. (https://www.ncbi.nlm.nih.gov/pubmed/24174472)
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	2.6000	N/A	N/A	The CIR Expert Panel concluded that the crosslinked alkyl acrylates listed below are safe in the present practices of use and concentration described in this safety assessment, except when they are polymerized in benzene. Acrylates/C10-30 Alkyl Acrylate Crosspolymer may be polymerized in benzene, and the available data are insufficient to make a determination of safety for this crosslinked alkyl acrylate when it is polymerized in benzene. When not polymerized in benzene max leave on/rise off 5%, when

				polymerized in benzene max leave on 0.4%, max rinse off 1.1%. (ntp.niehs.nih.gov/ntp/roc/nominations/2013/.../attachmentcir_508.pdf NOV 17,2011)
SODIUM HYDROXIDE	2.4000	ANNEX III/15a	>100	i) **ANNEX III/15a** **Product type, body parts:** (a) Nail cuticle solvent (b) Hair straightener (c) pH adjuster for depilatories (d) Other uses as pH adjuster **Maximum concentration in ready for use preparation:** (a) 5 % (b) 2 % for general use or 4.5% for professional use **Other restrictions:** (c) pH < 12,7 (d) pH < 11 **Wording of conditions of use and warnings:** (a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children (b) *General use:* Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children *Professional use:* For professional use only Avoid contact with eyes Can cause blindness (c) Keep out of reach of children Avoid contact with eyes (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813)
GLYCERIN	2.0000	2000	11628	i) In a two generation study not fully matching current OECD Guidelines, male and female rats (10/treatment) were dosed daily with glycerol (20% solution in water) during 8 weeks before mating. Females received glycerol throughout pregnancy or until weaning of the F1 generation (5 each). When the F1 generation was ~100 days of age, pups were killed except for 10/sex. These animals were used to produce the F2-generation. No effects were found on the reproductive efficiency of the parents, nor on the growth, fertility, reproductive performance of the untreated F1 generation, and no histological changes occurred in the tissues of both the F1 and F2 generation. Although the data are limited, a **NOAEL of 2000 mg/kg bw** was identified from this study (Wegener 1953). (https://hpvchemicals.oecd.org/ui/handler.axd?id=4b0a2d87-3183-40d4-84f5-0e118c647b19; https://onlinelibrary.wiley.com/doi/10.1002/3527600418.mb5681kske4215)

				ii) "The CIR Expert Panel concluded that glycerin is safe in cosmetics in the present practices of use and concentrations described in this safety assessment" Maximum reported concentrations: Rinse-off dermal contact products: up to 99.4% Leave-on dermal contact products: up to 79.2% Eye area products: up to 40.6% Incidental ingestion & Mucous Membrane contact products: up to 68.6% Baby products: up to 21% (http://www.cir-safety.org/sites/default/files/glycer_122014_FR.pdf; https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR679.pdf)
COCAMIDOPROPYL BETAINE	1.5000	30	233	i) The NOAEL – based on the forestomach findings – is 250 mg/kg bw and 1000 mg/kg bw with respect to systemic toxic effects. The Margin of Exposure (MOE) is the ratio of the No Observed Adverse Effect Level (NOAEL) or an appropriate substitute to the estimated or actual level of human exposure to asubstance. A systemic NOAEL for CAPB was determined using the 3 months oral NOAEL of 300 mg/kg bw for 100% active ingredient (see 5.2.3) and an absorption of about 10% from the gastrointestinal tract seen in the ADME study of lauramidopropyl betaine (see 5.2.1.1). The resulting value of 30 mg/kg bw/day was used as the systemic NOAEL to calculate the MOE values in the different exposure scenarios. Thus NOAEL=30 mg/kg bw/.day, and DAp=10% absorption after dermal exposure section. [...] Unreacted free amines (I, II) seem to be the most critical impurities in cocamidopropyl betaine formulations, as they are likely to be mainly responsible for occasionally seen skin sensitization reactions (see below). These byproducts can be avoided by a moderate excess of chloroacetate and the exact adjustment of pH value during the betainization reaction accompanied by regular control analyses (Uphues, 1998). The amount of amidoamine (II) and dimethylaminopropylamine (I) present in cocamidopropyl betaine formulation decreased during the last 10 years (Armstrong et al, 1999). Typical levels of impurities are now 0 to 15 mg/kg (I) and 0 to 0.3 % (II), (nevertheless there are qualities on the market with up to 3 % of (II). (http://www.heraproject.com/files/45-HH-E101023F-D12F-6A30-DEB0770E9BF8E4D0.pdf) ii) safe in cosmetics as long as it is formulated to be nonsensitizing

				Rinse off: up to 10% and Mucous membrane up to 10%. (https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr518.pdf)
PHENOXYETHANOL	0.6500	ANNEX V/29	>100	i) **ANNEX V/29** **Maximum concentration in ready for use preparation:** 1% (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) ii) **SCCS/1575/16 OPINION ON Phenoxyethanol:** Liver, kidney and thyroid weights were increased at 2000 mg/kg bw/day. Inflammation of the kidneys was also seen in males at 400 mg/kg bw/day. Minor testicular changes were noted in a few high-dose male rats, but these changes were considered to be of equivocal toxicological significance. The **NOEL in this study was reported as 80 mg/kg bw/day** based on the finding of inflammation in the kidney in males at 400 mg/kg bw/day. Based on the lack of treatment-related effects on body weight, organ weights, haematological and clinical chemistries and gross and histopathological examinations, the no-observed-adverse-effect level (NOAEL) for systemic toxicity was concluded to be **500 mg/kg bw/day** under the conditions of this study. (https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_195.pdf)
SODIUM LAUROYL SARCOSINATE	0.6000	1000	19380	i) Safe for rinse-off max.5%. (http://www.nicnas.gov.au/publications/CAR/new/Ltd/LtdFULLR/ltd1000FR/ltd1490FR.pdf) ii) These ingredients are nonirritating and nonsensitizing to animal and human skin, although they can enhance the penetration of other ingredients through the skin. For that reason, caution should be exhibited in formulating cosmetic products that contain these ingredients in combination with other ingredients whose safety is based on their lack of absorption or where dermal absorption is a concern. Because sarcosine can be nitrosated to form N-nitrososarcosine, a known animal carcinogen, these ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed. NOAEL (oral, chronic, rat) ≥ 1000 mg/kg bw/day. (http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8940a6-4bbf-49c3-e044-00144f67d249/AGGR-3d197803-11be-44b4-aa83-6e65cb24913c_DISS-9d8940a6-4bbf-49c3-e044-

				00144f67d249.html; http://www.ncbi.nlm.nih.gov/pubmed/11358107
CAPRYLYL GLYCOL	0.3508	1000	33147	Weil. et al [106] concluded that the NOAEL for chronic propylene glycol toxicity in dogs was 2 g/kg/d because at the higher dose tested, i.e. 5 g/kg, some changes in haematological parameters were observed. Most of these were not statistically significant compared to concurrent controls and all remained within normal biological ranges. Therefore, in our opinion no real adverse propylene glycol - related effects appear to occur up to the highest dose in this study. Interestingly, the authors determined plasma concentrations of a single 5 g/kg dose in an additional experiment. Cmax was 560 mg/dL. The oral subchronic study by Thackaberry et al. [100] provides supporting evidence that the NOAEL in mice, rats, dogs, and cynomolgus monkeys is higher than 1 g/kg, the highest dose tested. In a chronic dietary study with rats [30] the NOEL was the highest dose tested (1700/2100 mg/kg/day in males/females respectively). In a mouse prenatal developmental toxicity study [22], no relevant treatment-related effects were seen in the dams at the only dose tested, leading to a maternal NOAEL ≥ 10 g/kg /day. In rat fertility and rat teratology study, as well as a rabbit teratology study [25], propylene glycol did not exhibit toxicity after oral dosing of 1 g/kg/day. (https://www.ema.europa.eu/en/documents/report/background-review-excipient-propylene-glycol-context-revision-guideline-excipients-label-package_en.pdf)
SODIUM CHLORIDE	0.3000	844	32713	Normal constituent of bodily fluids for mammals, absorbed and distributed extensively and freely within the mammalian body, excretory processes-based metabolism, modulated by the kidneys. Excess oral intake associated with hypertension. LOAEL 2 533 mg/kg bw/day / **Study duration chronic / Species: rat, assumed : 3 = 844 mg/Kg bw/day as a typical NOAEL.** (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/15467/7/2/1)
POLYQUATERNIUM-7	0.1680	ANNEX III/66	>100	i) **ANNEX III/66** (Polyacrylamides) **Product type, body parts:** (a) Body- leave-on products (b) Other products **Other:** (a) Maximum residual acrylamide content 0,1 mg/kg (b) Maximum residual acrylamide content

				0,5 mg/kg (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) ii) **SCCNFP/0011/98** Safe if : (a) Maximum residual acrylamide content 0.1mg/kg body care-leave on products (b) Maximum residual acrylamide content 0.5mg/kg, other cosmetics iii) In response to a survey conducted by the Personal Care Products Council, industry reported current use concentrations of 0.009%-5% for polyquaternium-7. (https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRNS609.pdf)
PARFUM	0.1500	N/A	N/A	-
SODIUM BENZOATE	0.1350	ANNEX V/1	>100	i) **ANNEX V/1** **Product type, Body parts:** Rinse-off products, except oral products, Oral products, Leave-on products **Maximum concentration in ready for use preparation:** 2,5 % (acid) for Rinse-off products, except oral products, 1,7 % (acid) for Oral products 0,5 % (acid) for Leave-on products (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) ii) **SCCP/0891/05 Opinion on Benzoic Acid and Sodium benzoate:** No observed adverse effect level (NOAEL) from a 4-generation study 500 mg/kg bw/d. (https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_015.pdf)
MENTHA ARVENSIS LEAF OIL	0.1200	N/A	N/A	i) Background: The aim of the present study was to evaluate the radioprotective effect of Mentha arvensis (mint) on the survival of mice exposed to various doses of whole-body gamma radiation. Material and methods: The radioprotective effect of various doses (0, 2.5, 5, 10, 20, 40 and 80 mg/kg body weight) of chloroform extract of mint (Mentha arvensis Linn.) was studied in mice exposed to 10 Gy gamma radiation. Results: The 10 mg/kg of mint extract was found to afford best protection as evidenced by the highest number of survivors in this group at 30 days post-irradiation, and further experiments were carried out using this dose of mint extract. The mice treated with 10 mg/kg body weight mint extract or oil were exposed to 6, 7, 8, 9 and 10 Gy of gamma radiation and observed for the induction of radiation-sickness and mortality up to 30 days

				post-irradiation. The mint extract pretreatment was found to reduce the severity of symptoms of radiation sickness and mortality at all exposure doses and a significant increase in the animal survival was observed when compared with the oil + irradiation group. All of the animals that were treated with 10 mg/kg mint extract and then exposed to 7 Gy irradiation were protected against the radiation-induced mortality when compared with the concurrent oil + irradiation group, in which 20% animals died by 30 days post-irradiation. The mint extract treatment protected the mice against the gastrointestinal death as well as bone marrow deaths. The DRF was found to be 1.2. The drug was non-toxic up to a dose of 1,000 mg/kg body weight, the highest drug dose that could be tested for acute toxicity. Conclusion: From our study it is clear that mint extract provides protection against the radiation-induced sickness and mortality and the optimum protective dose of 10 mg/kg is safe from the point of drug-induced toxicity. (http://www.ncbi.nlm.nih.gov/pubmed/11942043)
CITRIC ACID	0.1000	1200	139535	i) The available data confirm the low acute and (sub)chronic toxicity profile of Citric Acid. The NOAEL for repeated dose toxicity (for rats) is 1200mg/kg/d. It is not suspected of being a carcinogen nor a reprotoxic or teratogenic agent. Citric Acid is not mutagenic in vitro and in vivo, and its sensitising potential is seen as low. (https://www.heraproject.com/ExecutiveSummary.cfm?ID=219) ii) Based on many experimental data in animals and on human experience, citric acid is of low acute toxicity. The NOAEL for repeated dose toxicity for rats is 1200 mg/kg/d. The major, reversible (sub)chronic toxic effects seem to be limited to changes in blood chemistry and metal absorption/excretion kinetics. Citric acid is not suspected of being a carcinogen nor a reprotoxic or teratogenic agent. The NOAEL for reproductive toxicity for rats is 2500 mg/kg/d. Further, it is not mutagenic in vitro and in vivo. Also, the sensitising potential is seen as low. In contrast, irritation, in particular of the eyes but also of the respiratory pathways and the skin, is the major toxicological hazard presented by citric acid; this conclusion is confirmed by a series of reports relating to eye and skin irritation. (https://hpvchemicals.oecd.org/ui/handler.axd?id=ff78c453-36c1-430d-9034-63e15899d24b)
ALOE BARBADENSIS LEAF EXTRACT	0.0940	N/A	N/A	Aloe barbadensis (also known as Aloe vera)-derived ingredients were not toxic in acute oral studies using mice and rats (anthraquinone levels

				should not exceed 50ppm). (http://gov.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR274.pdf)
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	0.0900	N/A	N/A	Safe as used from 0.005 to 2% Max rinse off products is 2.00% (http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR600.pdf; http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR600.pdf)
POTASSIUM SORBATE	0.0675	ANNEX V/4	>100	**ANNEX V/4: Maximum concentration in ready for use preparation:** 0.6% (acid) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813)
PROPANEDIOL	0.0050	1000	2325581	i) A study of repeated dose dermal toxicity is not available. Dermal absorption and oral absorption are assumed (worst case) to be equivalent). A corrected dermal NOAEL of 1000 mg/kg bw/d is therefore derived. (https://echa.europa.eu/el/registration-dossier/-/registered-dossier/10041/7/1) ii) The CIR Expert Panel concluded that Propanediol is safe in cosmetics in the present practices of use and concentration described in its report. Maximum reported concentrations of Propanediol in cosmetics: 39.9% in Dermal Contact Leave-On products [Deodorant (underarm)] 10% in Incidental Ingestion and products in contact with Mucous Membranes Used in 8 baby products but the concentrations were not reported (https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR731.pdf)
PENTYLENE GLYCOL	0.0004	1000	29069767	i) Generic use 0.001 to 5%. (http://www.cir-safety.org/sites/default/files/ADIOLS062016rep.pdf) ii) Developmental and reproductive toxicity studies were conducted in animals that were orally exposed to several alkane diols reviewed in this safety assessment. In rat studies evaluating Propanediol at dose rates up to 1000 mg/kg/day, spermatogenic endpoints were unaffected (90-day exposure duration)71 and no maternal (dosing on days 6-15 of gestation) or fetal toxic effects were observed (maternal and fetal NOAEL of 1000 mg/kg/day).42 In a mouse study evaluating 1,4-Butanediol at up to 600 mg/kg/day, a maternal and developmental NOAEL of 100 mg/kg/day and a LOAEL of 300 mg/kg/day were reported; maternal central nervous system intoxication (300-600

				mg/kg/day) and maternal and fetal body weight reduction (maternal 300-600 mg/kg/day) were observed.72 Results were mixed in rat studies evaluating 1,4-Butanediol. For males and females dosed with up to 800 mg/kg/day (14 days prior to mating and for females through day 3 of lactation), the following were reported: a reproductive parental and developmental NOAEL of 800 mg/kg/day,57,68 a maternal toxicity NOAEL of 200 mg/kg/day, and a developmental toxicity/ teratogenicity NOAEL of 400 mg/kg/day.57A maternal and developmental NOAEL of 1000 mg/kg/day was reported in animal studies on Hexanediol (rats dosed on days 6-19 of gestation)63 and for Methylpropanediol (rats dosed on days 0-20 of gestation; rabbits dosed on days 0-29 of gestation).18,73 In a rat study evaluating Butyl Ethyl Propanediol up to 1000 mg/kg/day (dosing on days 6-19 of gestation) a maternal NOAEL of 150 mg/kg/day (reduced activity, staggering, limb dragging, slow respiration, and reduced food consumption/body weight observed with 1000 mg/kg dose) and a developmental NOAEL of 1000 mg/kg/day were reported. (http://www.cir-safety.org/sites/default/files/ADIOLS062016rep.pdf) iii) Daily dermal administration of the test item to Sprague-Dawley rats for 91-93 days was associated with treatment-related rough coat, fur staining, and slight dermal irritation at 1000 mg/kg/day. Treated skin changes included a low incidence of slight focal erythema/demal thickening observed at necropsy and minimal epidermal hyperplasia and hyperkeratosis observed microscopically. The microscopic changes observed would not be expected to Progress to ulceration or chronic skin damage. A mild increase in urine protein in females at 1000 mg/kg bw/day and mild changes in other urine parameters were observed but taken together with a mild increase in total leucocyte count this suggests rather a hidden infection than a test article-related effect at this dose level. Not any adverse effect was reported from FOB or additional male fertility examination and histopathology. The systemic dermal NOAEL of this 90 day study is 1000 mg/kg as systemic effects describe above are not considered to be treatment related. The local dermal NOAEL is 700 mg/kg/day due to the local effects described above. (https://echa.europa.eu/registration-dossier/-/registered-dossier/2101/7/6/4) iv) NOAEL derived from oral study: 1000 mg/Kg bw/day.

				(https://echa.europa.eu/registration-dossier/-/registered-dossier/2101/7/6/2/?documentUUID=8ced0a95-1407-41a4-a398-5d1ef0f19f36) v) Safe up to 50%. (http://www.alegesanatos.ro/dbimg/files/1,2-Glycols.pdf)
CI 17200	<0.001	25	>290698	i) **ANNEX III/254** **Product type, body parts:** Hair dye substance in non-oxidative hair dye products (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) ii) **ANNEX IV/37** (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) iii) In a multi-generation study in rats, the NOAEL was set at 25 mg/kg bw/d. (https://nailessentialz.com/images/msds/Spider%20Gel%20-%20safety%20assessment.pdf)
CI 42090	<0.001	630	>7325581	i) **ANNEX IV/63** Purity criteria as set out in Commission Directive 95/45/EC (E 133) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) ii) **ANNEX III/190** **Product type, Body parts:** Hair dye substance in non-oxidative hair dye products **Maximum concentration in ready for use preparation:** 0,5 % (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20190813) iii) **SCCNFP/0787/04 OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS CONCERNING ACID BLUE 9 COLIPA n° C40:** The NOAEL of 630 mg/kg bw/day is used for the calculation of the MOS. (https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out261_en.pdf)

- Traces of ETHYL ACETATE and CYCLOHEXANE (<0.0117%) and, Acrylic Acid (<0.0065%) derived from the raw material with the trade name TC-Carbomer FD2010, might be present in the final product at a concentration of < 0.004275%.

- For ETHYL ACETATE:
  SED= 4.3 x 0.0117/100 x 100/100 = 0.0005031mg/Kg/ bw/day
  NO(A)EL: 900 mg/Kg/ bw/day
  (*ref:https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0157_summary.pdf)*
  MoS=900 / 0.0005031/ 2 = 894454 > 100 Satisfactory

- For CYCLOHEXANE:
  SED= 4.3 x 0.0117/100 x 100/100 = 0.0005031 mg/Kg/ bw/day
  NO(A)EL: 250 mg/Kg/ bw/day
  (*ref:https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0157_summary.pdf)*
  MoS=250 / 0.0005031/ *2 = 248460* > 100 Satisfactory

- For ACRYLIC ACID:
  SED=4.3 x 0.0065/100 x 100/100 = 0.0002795 mg/Kg/ bw/day
  NOAEL = 53 mg/Kg/ bw/day (ref:
  https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=2)
  MoS=NOAEL/SED/2= 94812 >100, Satisfactory

ALLERGEN FACTORS:

- *Allergens in the final product (determined by analysis): (An allergen is declared on the label when its concentration in the final preparation is >0.01% for rinsed off)*

  No data available.

- Allergens from the perfume: GUANGDONG BAIFANG FLAVOURS & CHEMICALS CO., LTD - NBF091517 BUBBLE GUM *(An allergen is declared on the label when its concentration in the final preparation is >0.01% for rinsed off)*:

  Allergens free certificate has been presented.

- Allergens from plant-derived raw materials (extracts, oils, waxes etc) *(An allergen is declared on the label when its concentration in the final preparation is >0.01% for rinsed off):*

Mentha Arvensis leaf Oil
Aloe Barbadensis Leaf extract

No data presented.

The SCCS is of the opinion that for substances identified as posing a high risk to the consumer and for which no individual thresholds could be derived (Table 13-5,

Opinion 1459/11), the general threshold of 0.01% would limit the problem of fragrance allergy in the consumer significantly (for this product:).

On July 26, 2023, the European Commission published a new amendment, EU 2023/1545, to EU Cosmetics Regulation 1223/2009, adding new entries to Annex III as regards allergens needed to be indicated on cosmetic product labels. The updates must be performed according to the following deadlines: 31st July 2026 for new products and 31st July 2028 for existing products.

SUGGESTIONS

- Since the product contains **plant-derived ingredients** an allergen determination in the final preparation is recommended; otherwise, absence-of must be proved with relevant documentation.

- Documentation on IFRA 50th Amendment has been reviewed for the perfume. However, compliance with the **IFRA 51st Amendment** should be ensured.

- The product contains ALOE BARBADENSIS. Anthraquinone content of the raw material should be presented.

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

Not known or reported.

10. INFORMATION ON THE COSMETIC PRODUCT

- Patch Test: Have been reviewed (QACS Ltd.).
  NR0004-T(SG)-C(PIN210)-F(ST)-R(01): Satisfactory

- Other Tests: Test for Water Activity, Formaldehyde, Nitrosamine and Phthalates Tests have been performed NR0004-T(SG)-C(PIN210)-F(ST)-R(01)

- Literature Data: Not Applicable

PART B- COSMETIC PRODUCT SAFETY ASSESSMENT

Product Name	**HAIR AND BODY WASH BUBBLE GUM- NR0004**
Product Category	**HAIR AND BODY WASH (BATHING, SHOWERING)**

Name and Address of Responsible Person

Company Name	Depesche Vertrieb GmbH & Co. KG
Address	Vierlander Str. 14 21502 Geesthacht , Germany
Tel	+49 4152 936 0
Fax	-
URL	-
e-mail	-

Name and Address of Product Manufacturer

Company Name	Depesche Vertrieb GmbH & Co. KG
Address	Vierlander Str. 14 21502 Geesthacht , Germany
Tel	+49 4152 936 0
Fax	-
URL	-
e-mail	-

Name and Address of Product Producer

Company Name	Huizhou New Road Cosmetics Company Ltd.
Address	3 and 4 floor, No.5 Building, Dongtai Heng, Industry, Chagbu Village, Xinxu Town, Huiyang Region, Huizhou City, Guangdong Province, China
Tel	-
Fax	-
URL	-
e-mail	-

1. ASSESSMENT CONCLUSION

The product is considered **safe with restrictions** for human health when used under normal or reasonably foreseeable conditions of use.

In order the product to be characterized as safe all the suggestions (regarding safety) within the assessment should be met.

For any precaution phrases that need to appear on the label or any matters regarding safety phrases please refer to section below.

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE

- Preamble note: According to EC 1223/2009, current section by default establishes a "Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d)". It is hereby stated that a full assessment of all labelling elements other than "precautions to be observed in use", "those listed in Annexes III to VI" and any "special precautionary information on cosmetic products for professional use" remains a subject of a different task upon request. Thus, overall labelling compliance relies upon Responsible Person and/or Distributor obligations according to Articles 5 and 6 respectively. The same applies for evaluation of support for any labelled product claims below: unless consumer safety is endangered, it constitutes a distinct task to evaluate compliance under EC Regulation 655/2013 and the guidelines to this Regulation
- Responsible Person's data have been reviewed.
- The container and packaging of the cosmetic product must bear all the necessary information in indelible, easily legible and visible lettering according to Article 19 of the Regulation (EC) No 1223/2009.
- The presentation of the cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size does not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers.
- The information about the address (the country of responsible person must be in EU) and name of responsible person must be written with indelible, easily legible and visible lettering.
- All ingredients referred in formula and the MSDS of the raw materials should be written on the label with their INCI names in descending order (see Table II). Ingredients in concentrations of less than 1 % may be listed in any order

after those in concentrations of more than 1 %. The labelling must follow Article 19 of regulation 1223/2009.

Claim support:

- All claims on the label should be in compliance with Regulation (EU) 655/2013 and the guidelines to this Regulation.
- A Dermatological in vivo test (cutaneous irritancy test-patch test) has been performed with satisfactory results (Non Irritant-QACS Ltd.). Based on these results the claim 'Dermatologically tested' can be referred on the label, even though the number of volunteers is not statistically significant.

3. REASONING

Taking under consideration

- The composition of the product
- The physicochemical properties of the raw material contained in the final product
- The stability of the product
- The possible interactions of the substances contained in the final product
- The manufacturing process of the product
- The microbial purity of the raw materials and final product.
- Impurities –Traces in the final product or substances
- Properties of packaging material
- The preservation efficacy of the final product.
- The chemical structure and toxicological properties of the raw materials
- Studies on human volunteers / relevant literature.
- The level of exposure of the consumer to the final product
- Data on documented undesirable effects to the product (no such data reported/available)
- Labelled warnings & instructions of use

Additionally, the Product Manufacturer / Responsible person is aware of the following:

- All necessary measurements have been followed for the product to comply with the article 18 (Animal testing) of Regulation 1223/2009.
- All colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 1962 concerning foodstuffs and purity criteria as set out in Commission Directive 95/45/EC including any up-to-date regulatory amendments (ANNEX IV).
- The Product Manufacturer / Responsible Person is responsible for the accuracy of primary information contained in the product dossier.
- For each cosmetic product placed on the market, the Responsible Person shall ensure compliance with the relevant obligations set out in this Regulation (Art. 4 of EC Regulation 1223/2009).
- This safety assessment relates to the information received up until the date the assessment was performed.

- The particular report needs to be amended whenever an update in the Regulation occurs that affects the toxicological assessment of its ingredients, its way of use or any relevant aspect of the product.

All information provided by the technical dossier may be used, for any legal purpose within the EU, and according to the best current scientific knowledge, the product fulfils the requirements for safety for the consumers, under conditions of normal use, as long as data contained will be updated in accordance with the **SUGGESTIONS** mentioned above and the guidelines of the current Regulation 1223/2009.

In the case that any complaint is communicated to the Responsible Person and/or Product Manufacturer or there are any alterations in the information regarding the product these should be also taken into the consideration of the signatory of this certificate.

4. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

NAME: **IOANNIS KAPETANSTRATAKIS**

EDUCATION: **CHEMIST MSc, in Forensic Science**

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DATE: **28/05/2024**

Member of The Hellenic Society of Toxicology and The Forensic Science Society

DEPESCHE VERTRIEB GMBH & CO. KG.

FORMULA PROVIDED

THE BEAUTY CARE COMPANY

Beauty & Care (HK) Limited
5/F, Yat Chau Building
262 Des Voeux Road Central, Hong Kong
Phone: 852-2302-1988

FORMULATION: RD0004

NR0004-T(SG)-C(LIL2665)-F(BG)-R(01)			**Rev: 01**	**Jul 23**
Type: 2in1 Shower Gel and Shampoo **Fragrance: Guangdong Baifang flavours & Chemicals Co., Ltd - NBF091517 Bubble Gum** **Colour: lilac, Pantone 2665C**				
INCI-Name	**Function**	**Raw Material Trade Name**	**CAS-No**	**Content (%)**
Aqua	Solvent	Water	7732-18-5	50,23%
Sodium C14-16 Olefin Sulfonate (ca 35%)	Cleansing Foaming Surfactant	Alpha olefin sulfonate	68439-57-6	25,00%
Aqua		Water	7732-18-5	
Lauryl Glucoside (ca 50%)	Cleansing Surfactant	APG-CH200	110615-47-9	6,00%
Aqua (ca 50%)	Solvent		7732-18-5	
Cocamidopropyl Betaine (ca 30%)	Antistatic Cleansing Foam Boosting	Betaine CAB-35	61789-40-0	5,00%
Sodium Chloride (< 6%)			7645-14-5	
Acrylates/C10-30 Alkyl Acrylate Crosspolymer	Film Forming Emulsion Stabilising	TC-Carbomer FD2010	n/a	2,80%
Sodium Hydroxide	Buffering		1310-73-2	2,40%
Polyquaternium-7 (ca 8%)	Antistatic	Polyquaternium M-550H	26590-05-6	2,10%
Aqua (ca 92%)	Solvent		7732-18-5	
Sodium Lauroyl Sarcosinate (ca 30%)	Cleansing Foaming Surfactant	Amino Acid Surfactant LD-30-B	173-16-6	2,00%
Aqua (ca 70%)	Solvent		7732-18-5	
Glycerin	Humectant Skin Conditioning	Refined Glycerine	56-81-5	2,00%
Phenoxyethanol (50-100%)	Preservative	Microcare PHG	122-99-6	1,00%
Caprylyl Glycol (25-50%)	Skin Conditioning		1117-86-8	
Sodium Benzoate (ca.30%)	Preservative	Microcare SB	532-32-1	0,45%
Potassium Sorbate (ca 15%)	Preservative		24634-61-5	
Guar Hydroxypropyltrimonium Chloride	Antistatic	DX32-16	65497-29-2	0,30%
Aqua	Solvent		7732-18-5	
Parfum	Perfuming	Guangdong Baifang flavours & Chemicals Co., Ltd - NBF091517 Bubble Gum	n/a	0,40%
Mentha Arvensis Leaf Oil	Perfuming	Peppermint oil	68917-18-0	0,12%
Aloe Barbadensis Leaf Extract (90.0-95.0%)	Skin Conditioning	Aloe Barbadensis Gel	85507-69-3	0,10%
Propanediol (3.0-7.0%)	Solvent		504-63-2	
Caprylyl Glycol (0.6-1.0%)	Skin Conditioning		1117-86-8	
Pentylene Glycol (0.2-0.6%)	Skin Conditioning		5343-92-0	
Citric Acid	Buffering Chelating	Citric Acid Monohydrate	5949-29-1 77-92-9	0,10%
CI 17200	Cosmetic Colorant	D&C Red #33	3567-66-6	< 0,001%
CI 42090	Cosmetic Colorant	Brillant Blue FCF	3844-49-9	< 0,001%

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PRODUCT LABELLING