



BRB International b.v.
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Bank ABN AMRO
Rek./Acc.nr. 24.46.32.790
KvK Roermond nr. 13020953
BTW nr. NL005945367B01

Cosmetic Ingredient Questionnaire

1.	General information	
1.1	Trade name	BRB DM 5
1.2	Chemical name (e. g. IUPAC)	Polydimethylsiloxane
1.2.1	INCI Name	Dimethicone
1.2.2	CTFA Name	Dimethicone
1.3	EC (EINECS/ELINCS) No.	polymer
1.3.1	CAS No.	63148-62-9
1.3.2	REACH Registration No.	exempted
1.3.3	Index no. (Annex VI 1272/2008)	Not present on annex VI
1.3.4	Colour Index No. (if colouring agent)	No colouring agent
1.3.5	HMIS Classification for Health, Flammability and reactivity:	0 1 0
1.4	Harmonised Tariff Code	39100000
1.5	Shelf Life	3 years
1.6	CLP Notified acc. Rt. No. 39 1272/2008	Not classified
1.7	Classification acc. EU	Not classified

2.	Chemical Composition incl. all by-products and additives (incl. preservatives, antioxidants, solvents, complexing agents, impurities, other additives).							
chemical / INCI name	conc. %	CAS No.	Einecs No.	Reach No.	function	source	SVHC?	Hazard class. Acc. CLP, EU 1272/2008
Dimethicone	>99	63148-62-9	polymer	-	divers	synthetic	No	Not classified
Cyclotetrasiloxane	< 0.1	556-67-2	209-136-7	-	impurity	synthetic	Yes	GH502, GH508, warning H226-361f - 413
Cyclopentasiloxane	< 0.1	541-02-6	208-764-9	-	impurity	synthetic	Yes	Not classified
Cyclohexasiloxane	< 0.1	540-97-6	208-762-8	-	impurity	synthetic	Yes	Not classified
2.1	Is product a VOC (Volatile Organic compounds)			No				
2.2	CH - Concentration VOC 014.018 in product (% m/m). Please state only when substances / products are on positive list. EU - Concentration VOC in product (% m/m), following director 1999/13/EG USA - Concentration VOC in product (% m/m), acc. EPA 40CFR 51.000			: 0 % CH : 100 % EU : 0 % USA				

3.	CMR substances, impurities and prohibited substances	
3.1	does product include any substances, impurities or by-products which are classified as CMR category 1a, 1b or 2 in accordance with commission Directive 1272/2008 Annex VI or category 1,2, or 3 according 67/548/EEC Annex I ?	yes, cyclotetrasiloxane CAS 556-67-2 < 0.1%
3.2	Does product contain any of the following materials as impurities, which only are acceptable if their presence is technically unavoidable in good manufacturing practice (GMP)? Yes	
material	yes / no	max % / ppm and substance name / CAS No.
nitrosamine	No	
free amidoamine	No	
free acrylamide	No	
secondary amines	No	
dimethyl aminopropyl amine	No	
anti oxidants	No	
pesticides	No	
insecticides	No	
formaldehyde	No	
unreacted / residual monomers	No	
1,4 - dioxane	No	
Cyclosiloxanes D4 silicones	Yes	< 0.1% cyclotetrasiloxane CAS 556-67-2
Cyclosiloxanes D3 silicones	No	
phenols	No	
nonyl phenol ethoxylate	No	
ethylene oxide	No	
propylene oxide	No	
phthalates	No	
glycol ethers	No	
residual solvents	No	
mycotoxins	No	



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NTA	No	
fluorochemicals	No	
other impurities; please specify by CAS No. and concentration (PPM) if there are other impurities	other impurities: no	
3.3	Does product contain any of the following heavy metals, which only are acceptable if their presence is technically unavoidable in good manufacturing practice (GMP)?	
Total amount of heavy metals (PPM)	10 ppm	
If yes, are these heavy metals intentionally added?	no	if yes; state reason for adding:
3.4	does product include any substances listed on the most recent California Proposition 65 list?	no if yes specify CAS No. and concentration:
3.5	does product include any substances listed as POP in the Stockholm Convention on Persistent Organic Pollutants?	no
3.6	does product contain any substances listed as Priority substances on the European Water Framework Directive (2006/60/EC)?	no
3.7	does product contain any substances listed on the OSPAR List of Chemicals for Priority Action 2002?	no
3.8	Does product contain Endocrine disruptors (= hormonally active agents, endocrine disrupting chemicals or endocrine disrupting compounds)	no
3.9	Is product or one of its ingredients listed on the CWC (Chemical Weapons Convention) schedule 1, 2 or 3.	no
3.10	Is product a substance which depletes the ozone layer acc the Montreal Protocol	no
3.11	Is the packaging a nitrite free packaging?	yes

4.	Cosmetic Directive Compliance	
4.1	product complies according to Cosmetics directive 76/768/EEC and 1223/2009?	Yes
4.2	are there legal restrictions for use?	no
4.3	is this material or one of its components mentioned in, or foreseen to be adopted in one of the annexes of the EU Cosmetic Directive?	Yes, cyclotetrasiloxane (annex II). The impurity is technically unavoidable.
4.4	Does product complies with USA FDA "Cosmetics" Regulations Federal Food, drug and Cosmetic Act (FD&C Act.)	yes
4.5	is product a preservative and also accepted for cosmetical use acc. Cosmetic Directive Annex V	no
4.6	is product a coloring agent and accepted for cosmetical use acc. Cosmetic Directive Annex IV	no
4.7	is product a UV filter and also accepted for cosmetical use acc. Cosmetic Directive Annex VI	no
4.8	Is product a nano particle or does product contain nano particles acc. The definition in EU Cosmetics Directive 1223/2009?	no

	If yes, specify following acc. Written in lid 2, Annex II - VI Cosmetical directive IUPAC name: : particle size: : particle shape, structure and dimension: : particle solubility : specification: : Physical and Chemical properties: : Toxicological Profile :	
4.9	are there restrictions for use in sprays or aerosols?	Yes, for more information see : http://sehsr.americanchemistry.com/Research-Science-Health-and-Safety/Guidance-for-Aerosol-Applications-of-Silicone-Based-Materials.pdf
4.10	please state the maximum authorized concentration which can be used for a safe use of the Cosmetic ingredient in following categories: Oral Hygiene: Eye products: Baby products: Intimate Hygiene Products:	0 % 100 % 100 % 100 %
4.11	Has the product been tested on animals acc. EU cosmetic directive 1223/2009? If yes, when was it tested for the last time? if yes, state reason for testing on animals	no month / year: reason:
4.12	Is product (or its ingredients) a prohibited or restricted chemical on the Canadian CIH List	no
4.13	is product (or its ingredients) listed as a prohibited Chemical on the California CSCP List?	no

5.	International Legislation / certification	
5.1	Is product as whole (all substances) listed or exempted on the Chemical Inventories of the countries below EINECS / ELINCS (EU) TSCA (USA) MITI / ENCS (Japan) MOL / ISHL (Japan) DSL / NDSL (Canada) AICS (Australia) KECI (Korea) IECSC (China) PICCS (Philippines) HSNO (New Zealand)	yes yes yes yes yes yes yes yes yes yes

5.2	Is product certified in accordance for one of the following certifications? ECOCERT Certified? ECOLABEL Certified? BDIH certified? NATRUE Certified? FLO (Fair-trade) Certified? RSPO Certified? Kosher Certified? Halal Certified? NSF Certified?	no no no no no no no no no no
5.4	does product comply with EU regulation 1935/2004/EEC as a material intended to come into incidental contact with food?	no remark:

6.	Product Origin	
6.1	Is this material of Animal origin	no
6.1.1	If origin is Animal please state: Is EU-Directive 1774/2002/ Annex VIII fulfilled: Is US regulation Animal-derived ingredients form (Annex 1 of this questionnaire) fulfilled: treatment: Is origin and the supplied material Genetically modified?	species: country of origin: parts of animal used: yes / no yes / no, if no describe deviation: natural / chemically modified no
6.2	Is this material of Vegetable origin?	no
6.2.1	If origin is vegetable please state:	species: country of origin: parts of plant used:

	<i>treatment:</i> <i>Does product contain AFLA toxins</i> <i>is origin and the supplied material genetically modified?</i> <i>Does product contain palm Oil?</i> <i>is product produced in a sustainable way?</i> <i>Is product pesticide residue free?</i>	<i>natural / chemically modified</i> <i>Yes / no</i> <i>Yes / no</i> <i>yes / no, if yes what is max. Concentration in product: %</i> <i>yes / no</i> <i>yes / no , if yes give detailed information about which pesticide and concentration:</i>
6.3	<i>Is this material of mineral origin?</i>	<i>no</i>
6.4	<i>Is this material of synthetic origin?</i>	<i>yes</i>

7.	<i>Production Process and storage</i>	
7.1	<i>Information on production process (general / brief description)</i>	<i>Ring opening polymerization</i>
7.2	<i>advised storage conditions</i>	
7.3	<i>Is product sensitive for UV-Radiation</i>	<i>no</i>
7.4	<i>Storage Class</i>	<i>Not ADR/IMDG/IATA</i>

8.	<i>REACH</i>	
8.1	<i>is product pre-registered?</i>	<i>No, polymer exemption (monomer(s) preregistered)</i>
8.2	<i>is this product registered for REACH?</i>	<i>No, polymer exemption (monomer(s) registered)</i>
8.3	<i>what is the registration deadline?</i>	<i>Not applicable</i>
8.4	<i>is the product or one of the substances, listed in SVHC list?</i>	<i>Cyclotetrasiloxane, cyclopentasiloxane & cyclohexasiloxane are SVHC, but not for this product as it below threshold 0.1%.</i>
8.5	<i>is the product or one of the substances, listed in annex XVII?</i>	<i>There is a restriction for cyclotetrasiloxane and/or cyclopentasiloxane impurity content for wash-off cosmetic products with a concentration of ≥ 0.1 % of either.</i>



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		Cyclotetrasiloxane & cyclopentasiloxane are below this threshold, so this product is not restricted according to annex XVII.
The above mentioned reach compliance is only valid for our EU customers. Non-EU customers have to ask reach@brbbv.com if reach compliance is possible.		

9.	Fragrance Flavour Allergens		
9.1	Does product contain any of the 26 SCCNFP fragrance Allergens acc. EU cosmetic directive 1223/2009? No		
	INCI (common name)	CAS No.	Max Content (ppm)
	Alpha-iso-Methylionone	127-51-5	
	Amylcinnamal	122-40-7	
	Amylcinnamyl alcohol	101-85-9	
	Anisel alcohol	105-13-5	
	Benzyl alcohol	100-51-6	
	Benzyl benzoate	120-51-4	
	Benzyl cinnamate	103-41-3	
	Benzyl salicylate	118-58-1	
	Cinnamal	104-55-2	
	Cinnamyl alcohol	104-54-1	
	Citral	5392-40-5	
	Citronellol	106-22-9	
	Coumarin	91-64-5	
	Limonene	5989-27-5	
	Eugenol	97-53-0	
	Farnesol	4602-84-0	
	Geraniol	106-24-1	
	Hexyl cinnamal	101-86-0	

Hydroycitronellal	107-75-5	
Isoeugenol	97-54-1	
Butylphenyl Methylpropional (Lilial)	80-54-6	
Linalool	78-70-6	
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyril)	31906-04-4	
Methyl-2-octynoate	111-12-6	
Evernia Prunastri Extract (Oak moss Extract)	90028-68-5	
Evernia Furfuracea Extract (Tree moss Extract)	90028-67-4	
9.2	If product is a perfume, is it safe for use according IFRA standards (43th amendment)?	Not a perfume
9.3	If product is a fragrance / flavor, is it compatible with latex for condoms?	Not a fragrance / flavor

10.	Alba Allergens		
10.1	Does product contain any of the ALBA (Food Allergen database) Allergens listed below?		
LeDa Code	GS1 code	Name Allergen	yes / no
1.1	UW	Wheat	No
1.2	NR	Rye	No
1.3	GB	Barley	No
1.4	GO	Oats	No
1.5	GS	Spelt	No
1.6	GK	kamut	No
1	AW	Gluten	No
2.0	AC	Crustaceans	No
3.0	AE	Egg	No
4.0	AF	Fish	No
5.0	AP	Peanuts	No
6.0	AY	Soy	No
7.0	AM	Milk	No
8.1	SA	Almonda	No
8.2	SH	Hazelnuta	No
8.3	SW	Walnuts	No
8.4	SC	Cashew	No
8.5	SP	Pecan Nut	No
8.6	SR	Brazil nut	No
8.7	ST	Pistachio nut	No
8.8	SM	Macadamia nut / queen land nut	No
8	AN	Nut	No
9.0	BC	Celery	No
10.0	BM	Mustard	No
11.0	AS	Sesame	No
12.0	AU	at conc. > 10 mg/kg expressed as SO2	No
13.0	NL	Lupine	No
14.0	UM	Molluaca	No
20.0	ML	Lactose	No
21.0	NC	Cocos	No
22.0	MG	Glutamate	No
23.0	MK	Chicken meat	No
24.0	NK	Coriander	No

25.0	NM	Corn / Maize	No
26.0	NP	Legumea	No
27.0	MC	Beef	No
28.0	MP	Pork	No
29.0	NW	Carrot	No

11.	Microbiological Specification		
11.1	does product support microbiological growth?	No	
11.2	if yes, is the total Viable Count (cfu/g) < 10 CFU/g?	yes / no	
11.3	if yes, is the total Count of yeasts / moulds (cfu/g) < 10 CFU/g?	yes / no	
11.4	is the product free from Pathogens?	Yes	

12.	Intellectual properties (e.g. patents)		
12.1	Have patents been applied which restricts the use of this raw material		
12.2	The production process does not infringe any third party IP right.		

13.	Ecology		
13.1	Anaerobic Biodegradability including used test method (OECD)	%	OECD:
13.2	Aerobic Biodegradability including used test method (OECD)	%	OECD
13.3	Aquatic toxicity data on four endpoints:	LC0 fish: 200 mg/L (96 h; <i>Leuciscus idus</i>) ECO bacteria: > 10.000 mg/L (<i>Pseudomonas putida</i>)	
13.4	Data on Bioaccumulation potential (e.g. Octanol/water partition coefficient (log Pow) or BCF fish)	Bioaccumulation is not expected to occur	
13.5	Water solubility	Not soluble in water	
13.6	Water Hazard class:	1	
13.7	provide specific LC50 or EC50 information about N R50 or N R50-53 classified ingredients.	NA	

13.8	Other information	Removed > 90% by binding onto sewage sludge. No adverse effects on bacteria. The Siloxanes in this product do not contribute to the BOD.
14.	Toxicological Data	
14.1	Acute Toxicity:	Oral (mg/kg): > 5000 (rat) Dermal (mg/kg): > 2008 (rat) Inhalation (mg/m3):
14.2	Sub Chronic Toxicity (NOAEL)	Oral (mg/kg): Dermal (mg/kg): Inhalation (mg/m3):
14.3	Information on sensitization potential	Skin : Magnusson-Kligmann test is not sensitizing (guinea-pig)
14.4	Information on irritation	Skin: not irritating (rabbit) Eye: slightly irritating (rabbit) Inhalation:
14.5	Information on chronic toxicity or carcinogenicity	Polydimethylsiloxane is not listed in IARC
14.6	Information on genotoxicity (e.g. Ames-Test)	Ames test is negative; bacterial reverse mutation test: not mutagenic
14.7	Information on reproductive toxicity (fertility and teratogenicity)	
14.8	Information on phototoxicity/photosensitivity	
14.9	Are there any data on human experience (sensitization, skin irritation, etc.)?	Human patch test: product displays good compatibility with the skin
14.10	Information on toxicokinetics (absorption, distribution, metabolism, elimination)	
14.11	Information on dermal bioavailability	



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DATE: 15-10-2020

STAMP AND SIGNATURE

NAME: KRISTOF REPRIELS

**FUNCTION: REGULATORY AFFAIRS
OFFICER**

