

Postbus/ P.O. Box 3552 – 6017 ZH Thorn
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KvK Roermond nr. 13020953 BTW nr. NL005945367B01

Cosmetic Ingredient Questionnaire

1.	General information		
1.1	Trade name	BRB SF 240	
1.2	Chemical name (e. g. IUPAC)	siloxanes & silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy-terminated	
1.2.1	INCI Name	Amodimethicone	
1.2.2	CTFA Name	Amodimethicone	
1.3	EC (EINECS/ELINCS) No.	polymer	
1.3.1	CAS No.	75718-16-0	
1.3.2	REACH Registration No.	Exempted	
1.3.3	Index no. (Annex VI 1272/2008)	No	
1.3.4	Colour Index No. (if colouring agent)	No colouring agent	
1.3.5	HMIS Classification for Health, Flammability and reactivity:	010	
1.4	Harmonised Tariff Code	39100000	
1.5	Shelf Life	3 years	
1.6	CLP Notified acc. Rt. No. 39 1272/2008	Yes	
1.7	Classification acc. EU	GHS07, warning, H315	



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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
Amodimethicone	> 99	75718-16-0	polymer	-	Divers	synthetic	No	GHS05, warning, H315
cyclopentasiloxane	< 0.5	541-02-6	208-764-9	-	impurity	synthetic	No	Not classified
cyclotetrasiloxane	< 0.5	556-67-2	209-136-7	-	impurity	synthetic	No	GHS02, GHS08, warning H226- 361f - 413
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 / : 0 % CH products are on positive list.				% CH			
	EU - Concentration VOC in product (% m/m), following director 1999/13/EG					: 0		% EU
	USA - Conc	USA - Concentration VOC in product (% m/m), acc. EPA 40CFR 51.000				: 0		% USA

3.	CMR substances, impurities and prohibited substances		
3.1	does product include any substances, impurit 1a, 1b or 2 in accordance with commission Di according 67/548/EEC Annex I ?	yes, cyclotetrasiloxane CAS 556-67-2 < 0.5%	
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.
nitrosami	ine	No	
free amic	doamine	No	
free acry	lamide	No	
secondar		No	
dimethyl	aminopropyl amine	No	
anti oxidants		No	
pesticides		No	
insecticides		No	
formaldehyde		No	
unreacted / residual monomers		yes	Max 0.5% cyclotetrasiloxane CAS 556-67-2; Max. 0.5% CAS 541- 02-6 cyclopentasiloxane
1,4 - dioxane		No	
	xanes D4 silicones	Yes	Max 0.5% cyclotetrasiloxane CAS 556-67-2
Cyclosilo	xanes D3 silicones	No	
phenols		No	
	enol ethoxylate	No	
ethylene		No	
propylene oxide		No	
phthalates		No	
glycol ethers		No	
residual solvents		No	
mycotoxins		No	
NTA		No	
fluoroche	emicals	No	
other impurities; please specify by CAS No. and concentration (PPM) if there are other impurities		other impurities: no	



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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 amo	unt of heavy metals (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	e most recent California Proposition 65 list?	no if yes specify CAS No. and concentration:
3.5	does product include any substances listed as PC Organic Pollutants?	P in the Stockholm Convention on Persistent	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 forseen to be adopted in one of the annexes of the EU Cosmetic Directive?	no → if yes, state:
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:	:



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	particle solubility specification: Physical and Chemical properties: Toxicological Profile	: : : : : : : : : : : : : : : : : : : :
4.9	are there restrictions for use in sprays or aerosols?	Do not use in aerosols or sprays
4.10	please state the maximum authorized concentration which can be used for a safe use of the Cosmetic ingredient in following categories:	Typical application amount is 0.25-3%
	Oral Hygiene:	%
	Eye products:	%
	Baby products:	%
	Intimate Hygiene Products:	%
4.11	Has the product been tested on animals acc. 7th amendment?	no
	If yes, when was it tested for the last time?	month / year:
	if yes, state reason for testing on animals	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)	yes
	TSCA (USA)	yes
	MITI / ENCS (Japan)	yes
	DSL / NDSL (Canada)	yes
	AICS (Australia)	yes
	KECI (Korea)	yes
	IECSC (China)	yes
	PICCS (Philippines)	yes
	HSNO (New Zealand)	yes
5.2	Is product certified in accordance for one of the following certifications?	
	ECOCERT Certified?	no
	ECOLABEL Certified?	no
	BDIH certified?	no
	NATRUE Certified?	no
	FLO (Fair-trade) Certified?	



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	RSPO Certified? Kosher Certified? Halal Certified? NSF Certified?	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:	species:	
		country of origin:	
		parts of animal used:	
	Is EU-Directive 1774/2002/ Annex VIII fulfilled:	yes / no	
	Is US regulation Animal-derived ingredients form (Annex 1 of this questionnaire) fulfilled:	yes / no, if no describe deviation:	
	treatment:	natural / chemically modified	
	Is origin and the supplied material Genetically 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:	
	treatment:	natural / chemically modified	
	Does product contain AFLA toxins	Yes / no	
	is origin and the supplied material genetically modified?	Yes / no	
	Does product contain palm Oil?	yes / no, if yes what is max. Concentration in product: %	



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	is product produced in a sustainable way?	yes / no
	Is product pesticide residue free?	yes / no , if yes give detailed information about which pesticide and concentration:
6.3	Is this material of mineral origin?	No
6.4	Is this material of synthetic origin?	Yes

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

8.	REACH	
8.1	is product pre-registered?	Exempted (polymer)
8.2	is this product registered for REACH?	Exempted (polymer)
8.3	what is the registration deadline?	Not applicable
8.4	is the product or one of the substances, listed in SVHC list?	No

9.	Fragrance Flavour Allergens
9.1	Does product contain any of the 26 SCCNFP fragrance Allergens acc. 7 th amendment of the EU Cosmetic Directive? No



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	<u> </u>	<u> </u>
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 (Lyral)	31906-04-4	
Methyl-2-octynoate	111-12-6	
Evernia Prunastri Extract (Oak moss Extract)	90028-68-5	



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Evernia Furfuracea Extract (Tree moss Extract)		90028-67-4		
9.2	9.2 If product is a perfume, is it safe for use according IFRA standards (43th amendment)?		Not a perfum	ne
9.3	9.3 If product is a fragrance / flavor, is it compatible with latex for condoms?		Not a fragra	nce / flavor

10.	Alba Allergens		
10.1	Does product contain any of the	ALBA (Food Allergen database) Allergens listed below?	
LeDa Co	de 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?	



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11.3	if yes, is the total Count of yeasts / moulds (cfu/g) < 10 CFU/g?	
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: Amodimethicone		
13.1	Persistence and degradability	Not biodegradable	
13.2	Aquatic toxicity data on four endpoints:	No adverse effects on aquatic organisms known.	
13.3	Data on Bioaccumulation potential (e.g. Octanol/water partition coefficient (log Pow) or BCF fish)		
13.4	Water solubility	Not soluble in water	
13.5	Water Hazard class:	2	
13.6	provide specific LC50 or EC50 information about N R50 or N R50-53 classified ingredients.	NA	
13.7	Other information		



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14.	Toxicological Data: Amodimethicone		
14.1	Acute Toxicity:	Oral (mg/kg): > 2000 (rat)	
14.2	Sub Chronic Toxicity (NOAEL)	Oral (mg/kg):	
		Dermal (mg/kg):	
		Inhalation (mg/m3):	
14.3	Information on sensitization potential	No sensitization potential known	
14.4	Information on irritation	Skin: irritation (rabbit; OECD 404)	
		Eye: no irritation (rabbit; OECD 405)	
		Inhalation:	
14.5	Information on chronic toxicity or carcinogenicity	Not listed in IARC	
14.6	Information on genotoxicity (e.g. Ames-Test)		
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.)?		
14.10	Information on toxicokinetics (absorption, distribution, metabolism, elimination)		
14.11	Information on dermal bioavailability		



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DATE: 17-11-2017

NAME: MARCO VANDEWALL

FUNCTION: REGULATORY AFFAIRS

OFFICER

STAMP AND SIGNATURE

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