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Cosmetic Ingredient Regulatory Data Sheet

1.	*General information*	
1.1	*Trade name*	Emfinity®SR TMS 50I
1.2	*Chemical name (e. g. IUPAC)*	Isododecane / Trimethylsiloxysilicate
1.2.1	*INCI Name*	Isododecane / Trimethylsiloxysilicate
1.2.2	*CTFA Name*	Isododecane / Trimethylsiloxysilicate
1.3	*EC (EINECS/ELINCS) No.*	236-757-0 / polymer
1.3.1	*CAS No.*	13475-82-6 / 56275-01-5
1.3.2	*REACH Registration No.*	01-2119490725-29 / 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 2 0
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*	GHS02, GHS08, Danger, H226, H304, H413 & EUH066
1.8	*Questionnaire version number:*	4.0

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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**
Isododecane	40-60	13475-82-6	236-757-0	01-2119490725-29	Solvent	Synthetic	No	GHS02, GHS08, Danger, H226-H304-H413, EUH066
Trimethylsiloxysilicate	40-60	56275-01-5	Polymer	-	Additive	Synthetic	No	Not classified
Cyclotetrasiloxane	< 0.025	556-67-2	209-136-7	-	Impurity	Synthetic	Yes	GHS02, GHS08, GHS09, warning, H226-H361f-H410 (M=10)
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	***The product is or contains a VOC (Volatile Organic compounds)?***					**Yes**		
2.2	***CH - Concentration VOC 814.018 in product (% m/m). Please state only when substances / products are on positive list:***					**40-60 % CH**		
	EU – Concentration VOC in product (% m/m), following directive 2010/75/EU :					**40-60 % EU**		
	USA – Concentration VOC in product (% m/m), acc. EPA 40CFR 51.000:					**40-60 % 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 < 0.025%
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	**Present?**	**Max concentration (% or 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	Cyclotetrasiloxane CAS 556-67-2 < 0.025%
Cyclosiloxanes D3 silicones	No	
Phenols	No	
Nonyl phenol ethoxylate	No	
Ethylene oxide	No	
Propylene oxide	No	
Phthalates	No	
Glycol ethers	No	
Residual solvents	Yes	Ethanol CAS 64-17-5 < 50 ppm
Mycotoxins	No	
NTA	No	
Fluorochemicals	No	
Other impurities – specify by CAS No. and concentration (% or ppm) if there are other impurities:	Yes	Cyclohexasiloxane CAS 540-97-6 < 0.1 Cyclopentasiloxane CAS 541-02-6 < 0.1

3.3	***Total amount of heavy metals (ppm)*** ***Are these heavy metals intentionally added?*** ***If intentionally added; state reason for adding:***	20 No
3.4	***Does product include any substances listed on the most recent California Proposition 65 list?*** ***If yes, specify CAS No. and concentration:***	No
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
	If yes, comment:	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 colouring 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?***	No
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:	0 % (m/m)
	Eye products:	100 % (m/m)
	Baby products:	100 % (m/m)
	Intimate Hygiene Products:	100 % (m/m)
4.11	***Has the product or any of its components been tested on animals acc. EU cosmetic directive 1223/2009?***	Yes, but only for REACH
	If yes, when was it tested (years)?	
	If yes, state reason for testing on animals:	In August 2020, ECHA's Board of Appeal published two decisions on the interface between REACH and the Cosmetics Regulation. In these decisions, the Board of Appeal found that the Cosmetics Regulation does not prohibit testing under REACH. Also an earlier decision from the European Ombudsman supports this interpretation. For more information, please check https://echa.europa.eu/documents/10162/9015407/Cosmetics_REACH_interface_en.pdf/ca6a7e41-64b0-aefa-acda-ff4993b296be?t=1617896699888
4.12	***Is product (or its ingredients) a prohibited or restricted chemical on the Canadian CIH List?***	No
4.13	***Are there ingredient(s) listed as reportable on the reportable ingredients list of the California Safe Cosmetics Act SB-484?***	D4, D5 & D6 are mentioned in the list as reportable ingredients for flavors or fragrance ingredients. D4, D5 & D6 are impurities in this product, and therefore they do not need to be reported.

5.	International Legislation / certification	
5.1	*Is product as a 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
	MOL / ISHL (Japan)	Yes
	DSL / NDSL (Canada)	Yes
	AICS / AIIC (Australia)	Yes
	KECL (Korea)	Yes
	IECSC (China)	Yes
	PICCS (Philippines)	Yes
	HSNO / NZIoC (New Zealand)	Yes
5.2	*Is product certified in accordance with one of the following certifications?*	
	ECOCERT Certified?	No
	ECOLABEL Certified?	No
	BDIH certified?	No
	NATRUE Certified?	No
	FLO (Fair-trade) Certified?	No
	RSPO Certified?	No
	Kosher Certified?	No
	Halal Certified?	No
	NSF Certified?	No
5.3	*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
	If origin is Animal please state:	
	Species:	
	Country of origin:	
	Parts of animal used:	
	Is EU-Directive 1774/2002/ Annex VIII fulfilled:	
	Is US regulation Animal-derived ingredients form (Annex 1 of this questionnaire) fulfilled:	
	If no, describe deviation:	
	Treatment:	
	Is origin and the supplied material Genetically modified?	
6.2	*Is this material of Vegetable origin?*	No
	If origin is vegetable please state:	
	Species:	
	Country of origin:	
	Parts of plant used:	
	Treatment:	
	Does product contain AFLA toxins?	
	Is origin and the supplied material genetically modified?	
	Does product contain palm Oil?	
	If yes, what is max. Concentration in product (%):	
	Is product produced in a sustainable way?	
	Is product pesticide residue free?	
	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):***	Blending of raw materials
7.2	***Advised storage conditions:***	Ambient conditions
7.3	***Is product sensitive to UV-Radiation?***	No
7.4	***Storage Class:***	UN 3295, ADR class 3, III

8.	REACH	
8.1	***Is this product REACH compliant?***	Yes (see Section 2 for registration numbers, if applicable)
	Comment regarding REACH compliance:	Product is considered a mixture within the scope of REACH. All substances contained in this mixture have already been registered by BRB International B.V. or further up our supply chain by our raw materials suppliers or they are exempt from registration.
8.2	***Is the product or one of the components, listed in SVHC list and present ≥0.1%?***	No (see Section 2 for further details)
8.3	***Is the product or one of the substances, listed in annex XVII?***	Yes
	Further information:	There is a restriction for cyclotetrasiloxane and/or cyclopentasiloxane content for wash-off cosmetic products with a concentration of ≥ 0.1 % of either. Both cyclotetrasiloxane and 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 fragrance Allergens acc. EU cosmetic directive 1223/2009?***	No
INCI / **common name** (CAS) - Concentration		
Not applicable		
9.2	***If product is a perfume, is it safe for use according IFRA standards (43th amendment)?***	Not applicable
9.3	***If product is a fragrance / flavor, is it compatible with latex for condoms?***	Not applicable

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

LeDa Code	GS1 code	Name Allergen	Present?
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	Almonds	No
8.2	SH	Hazelnuts	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	Sulfite (at conc. > 10 mg/kg expressed as SO2)	No
13.0	NL	Lupine	No
14.0	UM	Molluscs	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	Legumes	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?*	
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	
13.1	***Is an external report available?***	Yes
	If yes, specify and provide link:	For Trimethylsiloxysilicate see final safety assessment silylates and surface modified siloxysilicates: http://www.cir-safety.org/ingredient/silica-silylate UK Environmental Risk Assessment Report D4, D5 & D6: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290561/scho0309bpqx-e-e.pdf https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290565/scho0309bpqz-e-e.pdf https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290562/scho0309bpqy-e-e.pdf
13.2	***Persistence and degradability:***	Isododecane: Readily biodegradable.
13.3	***Aquatic toxicity data on four endpoints:***	Isododecane: LL50 fish: > 1000 mg/L (96h; Oncorhynchus mykiss) (OECD 203) EL50 invertebrates: > 3000 mg/L (48h; Acartia tonsa) EL50 invertebrates: > 10000 mg/L (72h; Skeletonema costatum) (ISO 10253) NOELR invertebrates: > 10000 mg/L (72h; Skeletonema costatum) (ISO 10253) NOEC invertebrates: < 1 mg/L (21d; Daphnia magna) (OECD 211)
13.4	***Data on Bioaccumulation potential (e.g. Octanol/water partition coefficient (log Pow) or BCF fish)***	Isododecane: Bioconcentration factor (BCF): 870.96 Partition coeficient n-octanol/water: logPow 6.96
13.5	***Water solubility***	
13.6	***Water Hazard class:***	
13.7	***provide specific LC50 or EC50 information about N R50 or N R50-53 classified ingredients.***	
13.8	***Other information:***	

14.	Toxicological Data	
14.1	***Is an external report available?***	Yes
	If yes, specify and provide link:	For trimethylsiloxysilicate see final safety assessment silylates and surface modified siloxysilicates: http://www.cir-safety.org/ingredient/silica-silylate SCCS opinion D4 & D5: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm D6 is comparable with D4 & D5
14.2	***Acute Toxicity:***	
	Oral:	Isodecane: > 5000 kg/mg (rat, male and female) (OECD 401)
	Dermal:	Isodecane: > 5000 kg/mg (rabbit, male and female) (OECD 402)
	Inhalation:	Isodecane: > 4.951 mg/L (4h; rat, male and female) (OECD 403)
14.3	***Sub Chronic Toxicity (NOAEL):***	
	Oral:	Isododecane: NOAEL: ≥ 5,000 mg/kg (90d; rat male and female) (OECD 408)
	Dermal:	Isododecane: NOAEL: ≥ 10.4 mg/L (90d; rat male and female) (OECD 413)
	Inhalation:	
14.4	***Information on sensitization potential (NOEL):***	Isododecane: Not a sensitizer (guinea-pig) (OECD 406)
14.5	***Information on irritation:***	
	Skin:	Isododecane: Not irritating (rabbit) (OECD 404)
	Eye:	Isododecane: Not irritating (rabbit) (OECD 405)
	Inhalation:	
14.6	***Information on chronic toxicity or carcinogenicity:***	
14.7	***Information on genotoxicity (e.g. Ames-Test):***	Isododecane: In vitro: negative, Ames-test (Salmonella typhimurium) (OECD 471) In vivo: negative, Chromosomal aberration essay (Rat) (OECD 478)
14.8	***Information on reproductive toxicity (fertility and teratogenicity):***	Isododecane: Effects on parents, NOAEC: ≥ 1,720 mg/m³ (Rat, male and female) (OECD 421) Effects on fetal debelopment NOAEC: ≥ 5,220 mg/m³ (Rat, male and female) (OECD 414)
14.9	***Information on phototoxicity/photosensitivity:***	
14.10	***Are there any data on human experience (sensitization, skin irritation, etc.)?***	
14.11	***Information on toxicokinetics (absorption, distribution, metabolism, elimination):***	
14.12	***Information on dermal bioavailability:***	

15.	Chinese Cosmetics Legislation (CSAR)		
15.1	***Raw material manufacturer (in English):***	BRB International B.V.	
	Raw material manufacturer (in Chinese):	碧乐璧国际.	
15.2	***Notification code:***	104064-04381-7716	
15.3	***Recommended amount to be added to cosmetics:***	The amount meets the requirements of Chinese cosmetics laws and regulations.	
15.4	***Substances mentioned in risk information:***	None	
15.5	***Ingredient composition:***		
Items	**Chinese INCI name**	**INCI name**	**Concentration (%)**
1	异十二烷	Isododecane	40-60
2	三甲基硅烷氧基硅酸酯	Trimethylsiloxysilicate	40-60

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DATE: 20 AUGUST 2025

STAMP AND SIGNATURE

NAME: ANGELICA BARILLAS



FUNCTION: REGULATORY AFFAIRS OFFICER

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