

## Regulatory Product Information

### Only Valid for Use in Cosmetics (Version 3.2)

#### Nipaguard® SCE

1. General Information		
1.1	Trade name	Nipaguard® SCE
1.2	Manufacturer / Supplier <i>(address, phone no., fax no., contact person)</i>	Clariant Produkte (Deutschland) GmbH, 65926 Frankfurt  BU Industrial & Consumer Specialties Application Development Personal Care Phone: +49 (0)69 305 82331  Corporate Product Stewardship PS-CustomerSupport-ICS@clariant.com
1.3	Raw material category	Preservative blend for cosmetic products
1.4	Chemical name	Benzoic Acid based Cosmetic Preservative
1.5	INCI (CTFA) name Composition	Sorbitan Caprylate (and)      62-68% Propanediol (and)                18-22% Benzoic Acid                        14-16%
1.6	EC (EINECS/ELINCS) no.	262-098-3, 207-997-3, 200-618-2
1.7	CAS no.	60177-36-8, 504-63-2, 65-85-0
1.8	Registration status <i>(e.g. EU, US, Japan)</i>	Listed on the chemical inventories of Australia, Canada, China, European Union, Japan, Korea, Malaysia, New Zealand, Philippines, Switzerland.  USA: To be used as cosmetic ingredient only (not TSCA listed)
1.9	Regulations for cosmetic use	In conformity with the requirements relevant to cosmetic ingredients of the Cosmetics Regulation (EC) 1223/2009.  For any other countries please contact Clariant.
1.10	Country of manufacturing site	Germany
2. Information on Production		

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<p>2.1 Origin of starting material (plant, animal,</p>	<table border="1"> <tr> <td data-bbox="710 548 821 660"><input checked="" type="checkbox"/></td> <td data-bbox="821 548 1412 660">Synthetic</td> </tr> <tr> <td data-bbox="710 660 821 761"><input checked="" type="checkbox"/></td> <td data-bbox="821 660 1412 761">Plant</td> </tr> <tr> <td data-bbox="710 761 821 974"></td> <td data-bbox="821 761 1412 974">           Kind of plant: Coconut Oil, Palm Kernel Oil, Corn            Latin name:            Cocos Nucifera, Elaeis Guineensis, Zea Mays         </td> </tr> <tr> <td data-bbox="710 974 821 1052"></td> <td data-bbox="821 974 1412 1052">Country of origin: Malaysia, Indonesia, Philippines, mainly Europe</td> </tr> <tr> <td data-bbox="710 1052 821 1153"><input type="checkbox"/></td> <td data-bbox="821 1052 1412 1153">Mineral</td> </tr> <tr> <td data-bbox="710 1153 821 1254"><input type="checkbox"/></td> <td data-bbox="821 1153 1412 1254">Animal</td> </tr> </table>	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Plant		Kind of plant: Coconut Oil, Palm Kernel Oil, Corn Latin name: Cocos Nucifera, Elaeis Guineensis, Zea Mays		Country of origin: Malaysia, Indonesia, Philippines, mainly Europe	<input type="checkbox"/>	Mineral	<input type="checkbox"/>	Animal
<input checked="" type="checkbox"/>	Synthetic												
<input checked="" type="checkbox"/>	Plant												
	Kind of plant: Coconut Oil, Palm Kernel Oil, Corn Latin name: Cocos Nucifera, Elaeis Guineensis, Zea Mays												
	Country of origin: Malaysia, Indonesia, Philippines, mainly Europe												
<input type="checkbox"/>	Mineral												
<input type="checkbox"/>	Animal												
<p>2.2 Renewable Carbon Index (RCI) (DIN ISO 16128)</p>	<p>85 % (without solvent/ water)</p>												
<p>2.3 Classification according to DIN ISO 16128</p>	<table border="1"> <tr> <td data-bbox="710 1462 821 1563"><input type="checkbox"/></td> <td data-bbox="821 1462 1412 1563">Non-natural Ingredient</td> </tr> <tr> <td data-bbox="710 1563 821 1664"><input type="checkbox"/></td> <td data-bbox="821 1563 1412 1664">Natural Ingredient, Natural Index (NI)</td> </tr> <tr> <td data-bbox="710 1664 821 1765"><input checked="" type="checkbox"/></td> <td data-bbox="821 1664 1412 1765">Derived Natural Ingredient, Natural origin Index (NOI: 0.85)</td> </tr> </table>	<input type="checkbox"/>	Non-natural Ingredient	<input type="checkbox"/>	Natural Ingredient, Natural Index (NI)	<input checked="" type="checkbox"/>	Derived Natural Ingredient, Natural origin Index (NOI: 0.85)						
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<input type="checkbox"/>	Natural Ingredient, Natural Index (NI)												
<input checked="" type="checkbox"/>	Derived Natural Ingredient, Natural origin Index (NOI: 0.85)												
<p>2.4 Does the material contain genetically modified organisms?</p>	<p>Product does not contain genetically modified organisms (GMOs).</p>												

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2.5	Information on production process (general description)	Blending of Sorbitan Caprylate with 1,3-Propanediol and Benzoic Acid.
<b>3. Additives</b>		
3.1	Preservatives	not added by recipe
3.2	Antioxidants	not added by recipe
3.3	Solvents	not added by recipe
3.4	Bleaching agents	not added by recipe
3.5	Fragrances (Allergens) according to the European Cosmetics Regulation (EC) 1223/2009, Annex III	not added by recipe
3.6	CMR classified ingredients	not added by recipe
3.7	Dangerous ingredients according to Regulation (EC)1272/2008 (CLP)	See EU safety data sheet, chapter 2 or 3 (regulatory information, hazardous components).
3.8	Others	Food allergens as of Directive 2000/13/EC (as amended), Annex IIIa and Regulation (EU) 1169/2011, Annex II are not added by recipe.
<b>4. Microbiological Specification</b>		
4.1	Total viable count (colony-forming units/g)	< 10
<b>5. By-products</b>		
<p><i>The presence of traces of the substances listed in Annex II of Regulation (EC)1223/2009 (incl. cmr category. I-III substances marked with *) shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 3 of Regulation (EC)1223/2009.</i></p>		
5.1	1,4-Dioxane *	not expected from the process

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5.2	Ethylene oxide *	not expected from the process
5.3	Residual solvents	not expected from the process
5.4	Residual monomers	not expected from the process
5.5	Amines	not expected from the process
5.6	Nitrosamines	not expected from the process
5.7	Heavy metals	max. 10 ppm Ni,Cr,Co,Cd,Hg,Pb,As,Sb, each < 1 ppm
5.8	Monochloroacetic acid	not expected from the process
5.9	Dichloroacetic acid	not expected from the process
5.10	Phthalates	not expected from the process
5.11	Pesticides	Based on information concerning raw materials, production process and equipment used, pesticides are not likely to be present.
5.12	Glycol ethers	Based on information concerning raw materials, production process and equipment used, Butyldiglycol, Ethyldiglycol and 2-Butoxyethanol are not likely to be present.
5.13	Others	
<b>6. Toxicology</b>		
6.1	Information on acute toxicity	Acute oral toxicity: Method OECD 423 LD <sub>50</sub> = 2000 mg/kg(rat) Data relating to main component.
6.2	Information on skin irritation	Irritant (rabbit) Data relating to benzoic acid.
6.3	Information on irritation of the mucous membrane	Risk of serious damage to eyes (rabbit eyes) Data relating to benzoic acid.

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6.4	Information on sensitisation potential	Method OECD 429 Non sensitizing (guinea pig) Data relating to main component.
6.5	Information on gene toxicity	No data available
6.6	Information on percutaneous permeation	No data available
6.7	Others	
<b>7. Ecology</b>		
7.1	Degradability/Elimination	Method OECD 301B Approx. 88% The product is readily biodegradable according to OECD criteria. Data relating to main component.
7.2	Acute aquatic toxicity	Fish toxicity: LC <sub>50</sub> > 100 mg/l (96 h, zebra fish) Data relating to main component.
7.3	Others	
<b>8. Additional Information</b>		
<i>(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</i>		
8.1	Nanomaterial	Product is not considered as a nanomaterial according (EC) No.1223/2009 definition art.2 (1k).

Date: 09.03.2021

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Dr. Andreas Dierdorf  
Regulatory Affairs Manager

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NO EXPRESS OR IMPLIED WARRANTY IS MADE OF THE MERCHANTABILITY, SUITABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE OF ANY PRODUCT OR SERVICE.

## CERTIFICATE OF COMPOSITION

<b>Trade Name</b>	<b>Nipaguard® SCE</b>
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INCI Name	Concentration	CAS number	EINECS number	Function
Sorbitan Caprylate	62 - 68 %	60177-36-8	262-098-3	Active
Propanediol	18 - 22 %	504-63-2	207-977-3	Solvent
Benzoic acid	14 – 16 %	65-85-0	200-618-2	Active

Company representative: Dr. Andreas Dierdorf

Date: 09.03.2021

Function: Product Stewardship Expert

Signature:



*This product information is based on the present state of our knowledge and experience according to the current state of the art. We may modify this declaration any time, in particular in case of changes of applicable national and international regulations and laws, or new scientific findings. No responsibility or liability can be accepted for factors outside our knowledge and control. Guarantees of product characteristics must be expressly described in writing. No guarantee is given that the product is suitable for any particular application. Users remain solely responsible for assessing the suitability of the product for the intended application and compliance with legal requirements applying to such application.*

**Geschäftsführer:**  
 Oliver Kinkel (Vorsitz)  
 Kolja Hosch

**Sitz der Gesellschaft:**  
 Frankfurt am Main

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**Handelsregister:**  
 Frankfurt am Main, Abteilung HRB 42045

**Bankverbindung:**  
 Deutsche Bank AG (EUR)  
 IBAN: DE93500700100091870600  
 SWIFT: DEUTDEFFXXX

**Aufsichtsratsvorsitzender:**  
 Stephan Lynnen

 Citibank N.A. (USD)  
 Bank Code: 021000089  
 Account No.: 31210836  
 SWIFT: CITIUS33