Product specification

Material **TEGO SP 13 SUN UP**
Spec.Code **K00 STANDARD**

Evonik Nutrition & Care GmbH
Business Line Care Solutions
Goldschmidtstrasse 100
45127 Essen
Phone: +49 (201) 173-2524
http://www.evonik.com/personal-care
personal-care@evonik.com

Inspection Characteristics	Method	Limits	Units	Z
Appearance 25°C	GM_0170_00			X
Viscosity	GM_0101_06	200-650	cP	X
melting point 1	GM_2152_03	43.0-53.0	°C	X
melting point 2	GM_2152_03	61.0-71.0	°C	X

Appearance 25°C	white to off-white pellets

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

This document is computer printed and therefore valid without signature.
All warranty claims in respect of the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the criteria for our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.

Edition 2
13 March 2020

TEGO® SP 13 Sun Up

Product data record (PDR)

1. General information

1.1 Supplier

Evonik Nutrition & Care GmbH
Business Line Care Solutions
Goldschmidtstrasse 100
D-45127 Essen / Germany
personal-care@evonik.com
http://www.evonik.com/personal-care

1.2 Product Description

TEGO® SP 13 Sun Up is in full compliance with current Cosmetic Regulation (EC) No. 1223/2009.

1.2.1 Raw material category/function

Film Former

1.2.2 Ingredients according to INCI

Poly C10-30 Alkyl Acrylate

1.2.3 Composition (INCI)

Components	Source	Percentage
Poly C10-30 Alkyl Acrylate	synthetic	100 %

This composition information serves for information of our customers only.
It is neither relevant for the composition listing according to Regulation (EC) No 1223/2009, nor does it reflect the chemical composition according to the different chemical regulations in the world which is disclosed in the table "information on ingredients/hazardous components" in the relevant parts of the respective (Material) Safety Data Sheets.

1.2.4 Additives

INCI	CAS No./ REACH Reg. No.	EINECS / EC No.	content	Function
No additives				

Unless mentioned in our PDR under section 2.1 (By products) or 2.2 (CMR), no components which are listed in Annex II of the Regulation (EC) No 1223/2009 and its modifications and updates are added to and are not to be expected in the above mentioned product due to the raw materials used and the production process.

2. Production Process

2.1 General description of production process:

Polymerization of alkyl acrylate.

Irridiation: TEGO® SP 13 Sun Up is not irradiated with γ-rays.

TEGO® SP 13 Sun Up is produced in the absence of any animal derived material of any type. Based on the information on the manufacturing process and production site no contamination with BSE/ TSE risk materials is to be expected.

CITES:
TEGO® SP 13 Sun Up is not based on raw materials from species listed in CITES appendices.

GMO-Status:
Not applicable (synthetic origin)

2.2 By products/Impurities

Potentially occurring by - products are not added intentionally. Impurities e.g. residual solvents are technically unavoidable.

Residual solvents	Isopropanol max. 1500 ppm
Residual monomers	max. 1200 ppm
Free amines	not applicable
Nitrosamines	not applicable
Monochloroacetic acid	not applicable
Dichloroacetic acid	not applicable
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Total heavy metals	max. 20 ppm
As, Cd, Co, Cr, Hg, Ni, Pb, Sb	Each < 1 ppm
Latex	not to be expected in the product due to the raw materials used and the production process
VOC	< 3 % according to SR (Swiss Right) 814.018

Any by-products are not added intentionally during the process and are technically unavoidable.

2.3 CMR (Carcinogenic, Mutagenic or Reprotoxic)

According to Cosmetic Regulation 1223/2009 the use of substances classified as CMR (Carcinogenic, Mutagenic or Reprotoxic) substances of category 1A or 1B or 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 in cosmetic products shall be prohibited.

Some of the CMR substances mentioned below and listed in Annex VI to Regulation (EC) 1272/2008 may be used as starting materials or solvents for the production of our cosmetic raw materials and may require reporting under California Proposition 65 or the California Safe Cosmetics Act, SB 484.

The presence of these substances has to be seen as non-intended and it is technically unavoidable in good manufacturing practice.
Traces of CMR substances can derive from impurities of the starting materials or the manufacturing process.

CMR substance	CAS No.	Starting material	max. concentration/Remark
Ethylene Oxide	75-21-8	no	
Propylene Oxide	75-56-9	no	
Octamethylcyclotetrasiloxane (D4)	556-67-2	no	
2-Ethylhexanoic Acid	149-57-5	no	
n-Hexane	110-54-3	no	
Methyl Chloride	74-87-3	no	
Dimethyl Sulphate	77-78-1	no	
1,4-Dioxane	123-91-1	no	
Mequinol	150-76-5	no	50 ppm
Formaldehyde	50-00-0	no	For more information on formaldehyde please refer to our factsheet available via our IntoBeauty website. https://intobeauty.evonik.com/

2.4 "Allergens" according to the Regulation (EC) No 1223/2009

The presence of substances, the mentioning of which is required under the column 'Other' in Annex III of Cosmetic Regulation 1223/2009, shall be indicated in the list of ingredients in addition to the terms "Perfume" or "Aroma".

None of those substances have been intentionally added to our cosmetic ingredients or are formed during the manufacturing process according to our knowledge of the chemistry.
An analytical proof for the absence of traces of those substances is not performed in our cosmetic ingredients.

2.5 Food Ingredients listed in Annex II of Regulation (EU) No 1169/2011

None of these substances have been intentionally added to our cosmetic raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

2.6 Nanomaterial

The product is not a nanomaterial according to the Cosmetics Regulation (EC) No 1223/2009, the Commission Recommendation on the definition of nanomaterial 2011/696/EU and the French Decree No. 2012-232. For details, a separate statement is available on request.

2.7 Substances of Very High Concern (SVHC)

The candidate list of substances of very high concern is regularly updated and published by ECHA. If applicable, the information on the substance/s from the candidate list, contained in our product in reportable amounts, is included in section 3 of the product related Safety Data Sheet (SDS).

2.8 Country of Origin

TEGO® SP 13 Sun Up is manufactured in: USA

3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product TEGO® SP 13 Sun Up nor that we have ordered such tests at third parties or third parties have conducted such tests with our knowledge and acceptance to fulfil the requirements of Cosmetic Regulation 1223/2009/EC.

Therefore TEGO® SP 13 Sun Up is in full compliance with Cosmetic Regulation 1223/2009/EC.

4. Microbiological status

Total Viable Count	max. 100 cfu/g
Pathogens*	absent/g

*Pathogens are: Enterobacteria, Pseudomonas, Enterococci, Candida albicans, Staphylococci

5. Shelf life / storage conditions

1440 days after production (unopened original packaging)

6. Regulatory Status

6.1	**HS-Code**	390690
	EU-CN-Code	39069090

6.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Poly C10-30 Alkyl Acrylate	Exempt (Polymer)	25703-24-6 & 25986-77-0	n.a.

Other Countries

Country		yes / no	Remark
CAS 25703-24-6			
Australia	AICS:	no	Substance is listed on ARTG (AAN: poly C10-30 alkyl acrylate); restriction: Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
China	IECSC:	no	Notified by Evonik Corp. for a max. import of 1000 t/a
Canada	DSL: NDSL:	yes n.a.	
Taiwan	TCSI:	yes	
CAS 25986-77-0			
Australia	AICS:	no	Substance is listed on ARTG (AAN: poly C10-30 alkyl acrylate); restriction: Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
China	IECSC:	no	Notified by Evonik Corp. for a max. import of 1000 t/a
Canada	DSL: NDSL:	no yes	
Taiwan	TCSI:	yes	

In the following countries the relevant authorities currently do not request pre-market approval for cosmetic raw materials:

Brazil, Japan, South Korea, Philippines, USA

6.2.1 Regulatory status (cosmetic regulation)

Country		yes / no	Remark
China	CFDA:	yes	
Japan	JSQI: JCIA:	no no	

7. Toxicology and Ecotoxicology

Refer to our document: “Summary of Product Data with Reference to Toxicology and Ecology”

8. Packaging

396 kg (36 x 11 kg box)

Technical Information

TEGO® SP 13 SUN UP

Smart Polymers – Smart Solutions!

Intended use

Film former, sensory additive

Benefits at a glance

- "Dry feel" sensory additive improving absorption and reducing oily residue / gloss
- Enables the formulation of effective sun care formulations due to optimized film formation properties leading to greater filter performance efficiency
- Provides improved pigment dispersion in inorganic sunscreens
- Superior SPF boosting & excellent water resistance compared to market benchmark
- Reduced sun care formulation costs due to SPF boosting effect and consequently minimized UV filter use level

INCI (PCPC name)

Poly C10-30 Alkyl Acrylate (CFDA: yes, TGA[1]: yes)

[1] TGA = Australian Therapeutic Goods Administration

Chemical and physical properties

Form	pellets
Color	white to light yellow

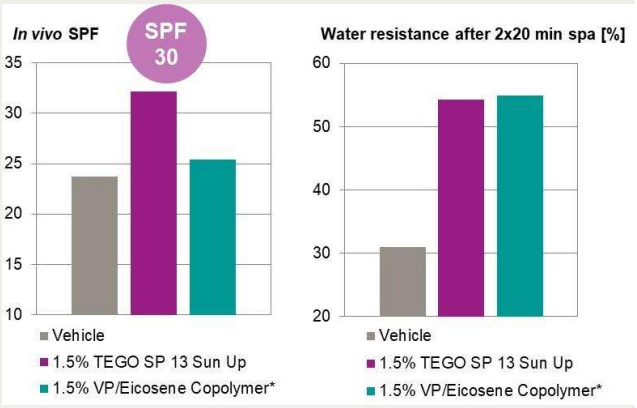
Oil thickening alkyl-modified acrylate homopolymer

Our studies based on TEGO® SP 13 Sun Up

in vivo SPF boosting and water resistance

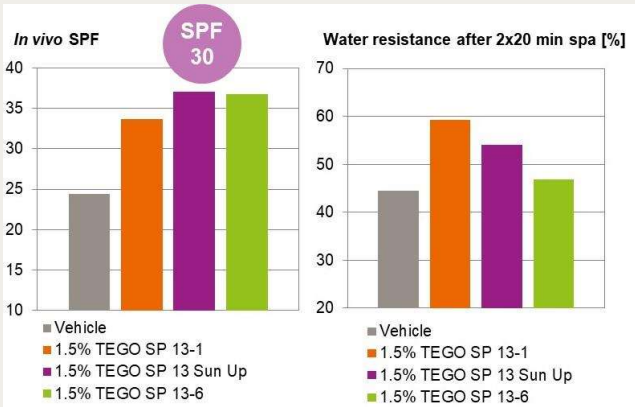
All SPF studies were conducted according to ISO 24444:2010 and water resistance according to Colipa guidelines, 2005, either as screening study (4 volunteers per formulation) or complete study (10 volunteers per formulation).

Test I – US test formulation, 28.0% organic UV filters (oil soluble), screening study



1.5% TEGO® SP 13 Sun Up boosts SPF by 36% which can result in significant reduction of UV filter formulation costs. It also provides >50% water resistance. UV filter efficiency* increases from 0.85 (vehicle) to 1.15. Market benchmark VP/Eicosene Copolymer only provides water resistance.

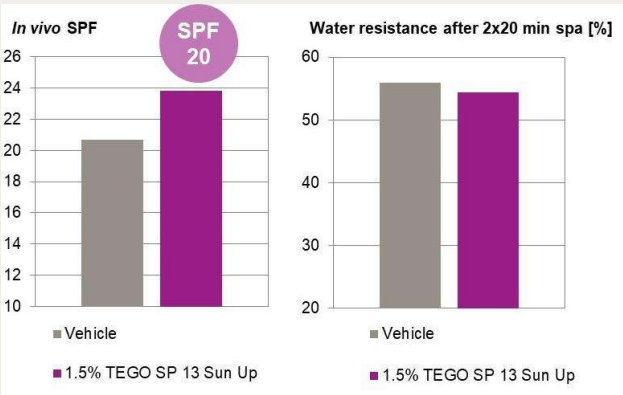
Test II – European test formulation, 20.5% organic UV filters (oil soluble), screening study (TEGO® SP 13-1 and 13-6), complete study (TEGO® SP 13 Sun Up)



1.5% TEGO® SP 13 Sun Up boosts SPF by 52% which can result in significant reduction of UV filter formulation costs. It also provides >50% water resistance and thereby combines the joint benefits of TEGO® SP 13-1 (>50% water resistance) and TEGO® SP 13-6 (superior SPF boosting). UV filter efficiency* increases from 1.19 (vehicle) to 1.81.

* Filter efficiency = SPF / w/w-% of UV filters used

Test III – Inorganic sunscreen, 15.0% inorganic UV filters (coated), screening study

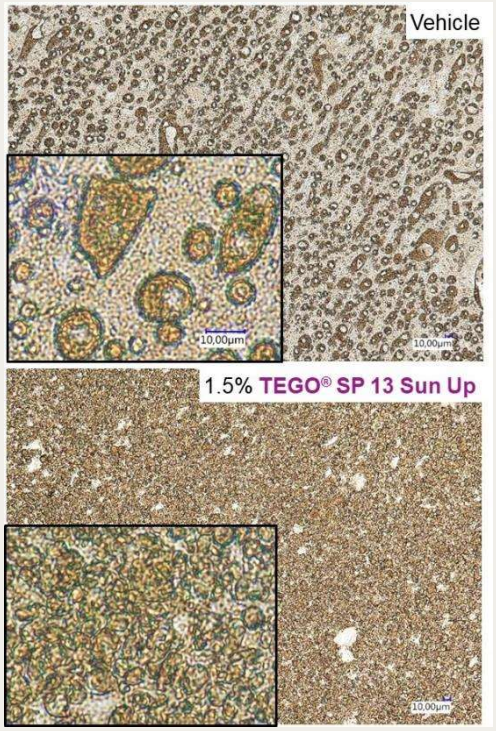


1.5% TEGO® SP 13 Sun Up boosts SPF by 15%. It also provides >50% water resistance. Vehicle formula is already on a very good level of water resistance due to UV filter coating, no further increase by film former is observed. UV filter efficiency* increases from 1.38 (vehicle) to 1.59.

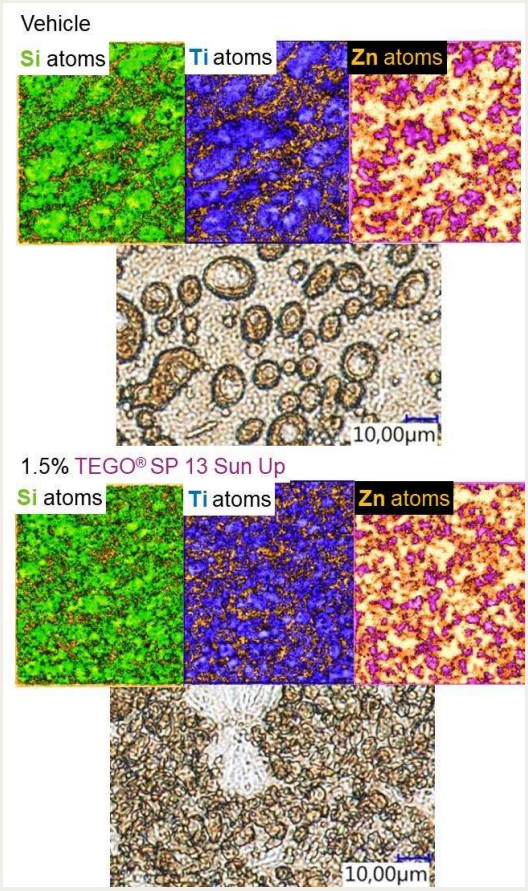
Pigment dispersion

O/W emulsion with 15.0% coated inorganic UV filters (7.8% Zinc Oxide; Triethoxycaprylylsilane plus 7.2% Titanium Dioxide, Silica, Dimethicone).

Light microscopy



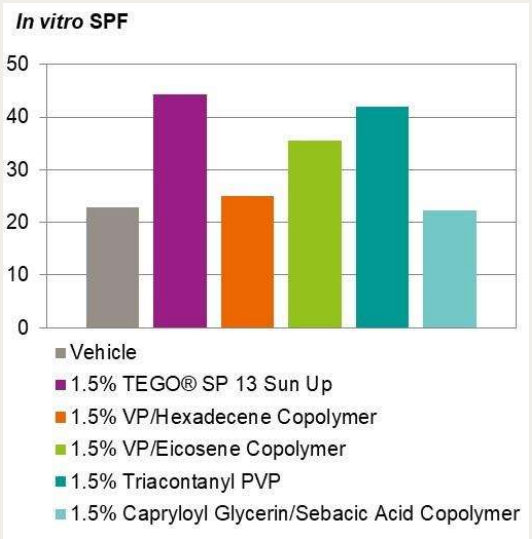
Scanning electron microscopy – EDX analysis (light microscopy images with same resolution at bottom for comparison and scale information)



TEGO® SP 13 Sun Up provides improved pigment dispersion and finer emulsion droplet size distribution resulting in SPF boosting and emulsion stabilization effect.

in vitro SPF boosting

O/W sun care formulations SPF 30 (calculated) with different film formers. *in vitro* SPF (PMMA plates, Labsphere UV2000S)



TEGO® SP 13 Sun Up outperforms market benchmarks with respect to SPF boosting.

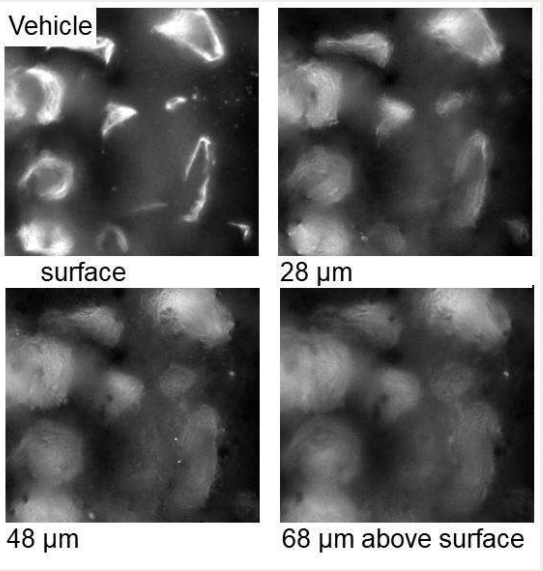
Film formation working mechanism

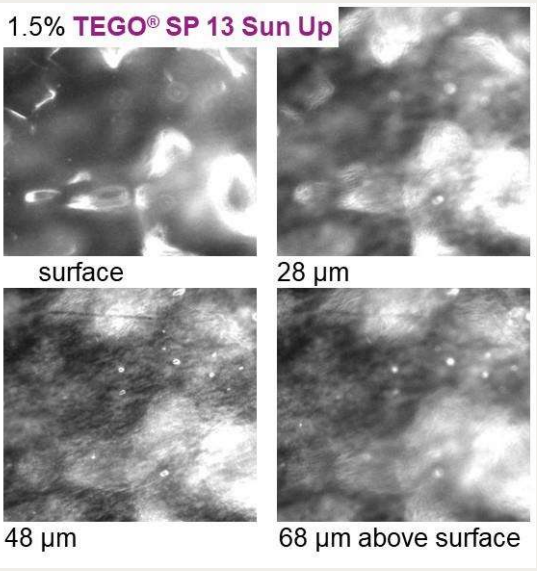
Test formulations were prepared with 0.1% of a 10% solution of fluorescent stain DiI (https://www.thermofisher.com/order/catalog/product/D282) in TEGOSOFT® XC MB added to the oil phase at 70 °C, just prior to homogenization, resulting in 0.01% active matter fluorophor. Fluorescence microscopy was performed with an Olympus IX83 microscope at wavelengths of 523 nm (excitation) and 580 nm (emission).

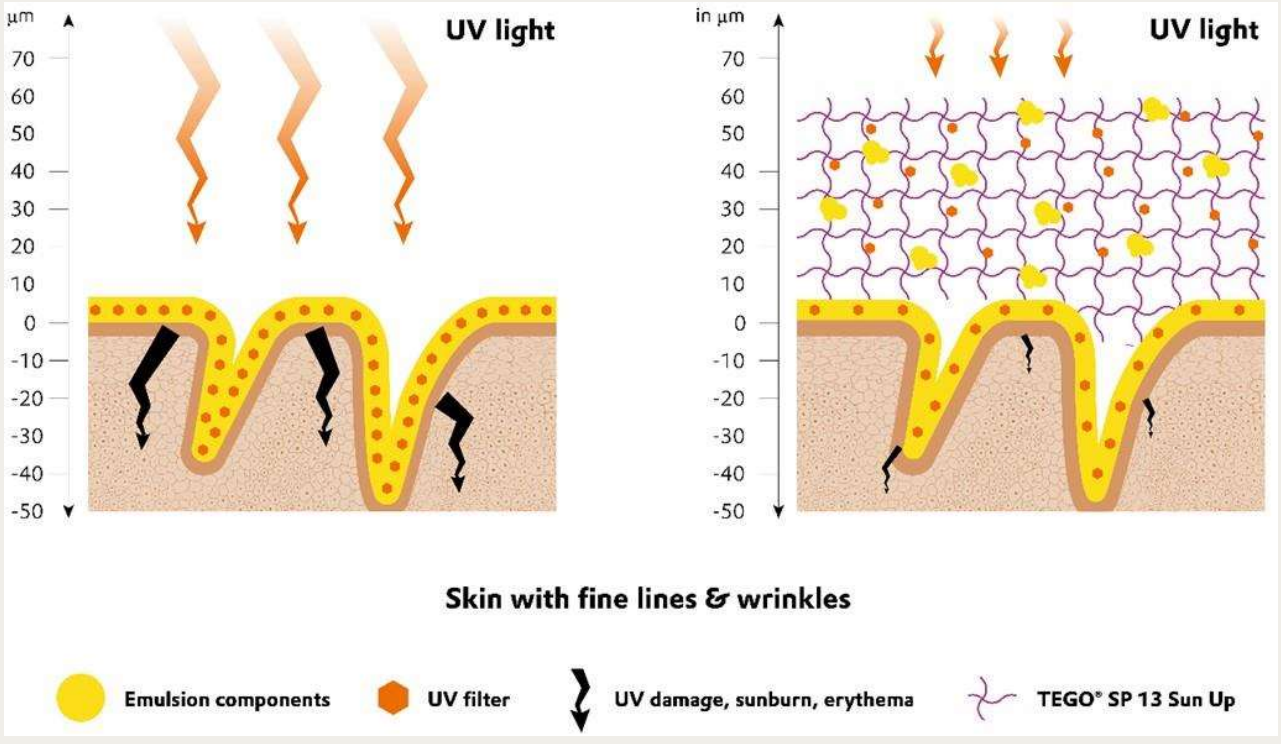
VITRO-SKIN (IMS Inc.) was used as a model substrate that effectively mimics the surface properties of human skin. It has been formulated to have topography, pH, critical surface tension, chemical reactivity and ionic strength that is similar to human skin (https://www.ims-usa.com/vitro-skin-substrates/vitro-skin/). 3D light microscopy shows VITRO-SKIN surface with indentations up to ~50 µm depth, similar to human fine lines and wrinkles. Fluorescent test formulations were gently applied and let dry for 30 min at 30 °C. 3D fluorescence imaging (non-confocal microscopy) reveals film topography by fluorescent signal above the VITRO-SKIN surface.

Using vehicle formulation, no fluorescence signal can be detected above VITRO-SKIN surface, only little on surface and in indentations. Using 1.5% TEGO® SP 13 Sun Up, a film is indicated by fluorescence signal widely scattered up to 70 µm above VITRO-SKIN surface.

Height information can be used to construct a mechanistic model. Use of TEGO® SP 13 Sun Up leads to formation of a particularly broad film thickness (up to 70 µm). This film is the reason for the observed SPF boosting effect (according to Lambert Beer's law).

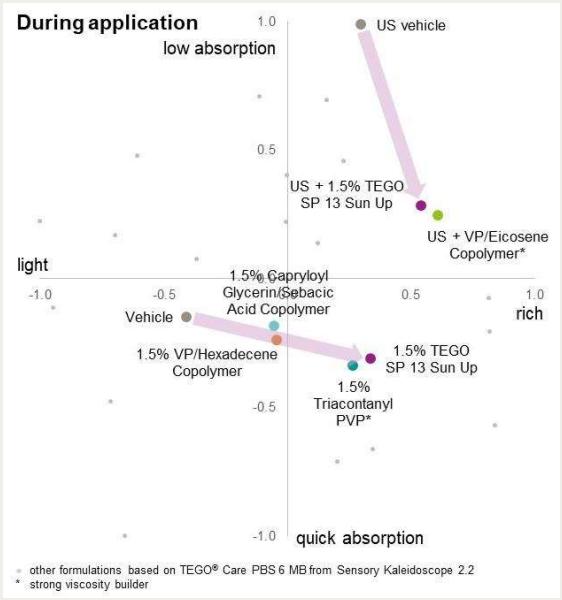


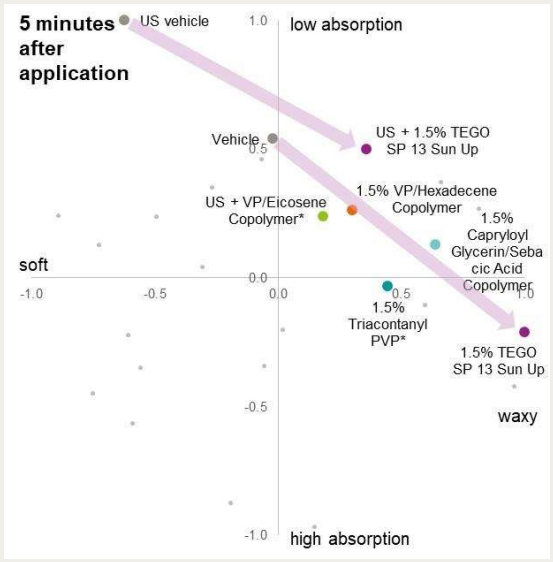




Sensory profiling

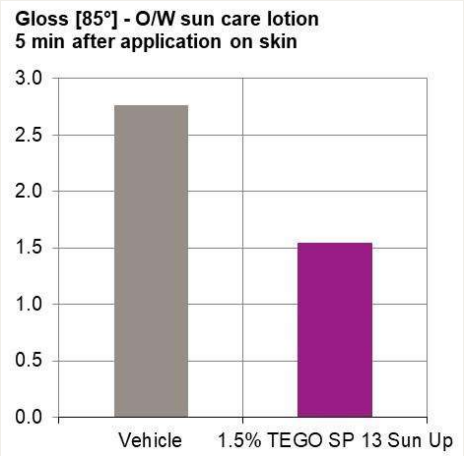
Test formulations from *in vivo* SPF study (test I – US test formulation, 28.0% organic UV filters) and from *in vitro* SPF boosting study (20.5% organic UV filters) were evaluated by our in-house sensory panel and sensory mapping was performed.
TEGO® SP 13 Sun Up improves absorption during application and provides a nice "dry" (high absorption / low oiliness, waxy) afterfeel. Good absorption during application is essential for an efficient film formation ("intact" film).





Gloss measurement

Test formulations from *in vitro* SPF boosting study were evaluated with respect to gloss reduction effect. Five minutes after application onto the volar forearm of nine panelists, gloss values were determined with a Zehntner ZGM 1130 glossmeter.



TEGO® SP 13 Sun Up perceivably reduces the gloss of an O/W sun care lotion on skin.

Suggested usage concentration

1.5% in emulsions
Up to 10% in special applications (e.g. sticks).

Preparation

TEGO® SP 13 Sun Up can be easily processed by addition to the oil phase. Heating above the melting point is required in order to properly melt the material. Then the formulation is processed as usual.
In O/W emulsions the thickening efficacy depends on the oil phase composition. Low viscous (fluid, sprayable) systems can be formulated e.g. based on TEGO® Care PBS 6 MB, with relatively low amount of consistency enhancers (e.g. 0.5–1.0%) and relatively low total oil phase content (e.g. 14–19%). In general, consistency enhancer concentration can be partially substituted with TEGO® Smart Polymers.
In W/O emulsions the thickening efficacy depends on the concentration of TEGO® SP 13 Sun Up. The higher the concentration, the higher the viscosity. In general, oil phase can be increased or wax/ clay/ silica concentration reduced to counteract a strong viscosity increase.
For the preparation of sticks TEGO® SP 13 Sun Up is added to the oil/wax mixture which is heated until uniformly molten, before pouring into the mold.

Hazardous goods classification

Information concerning

- classification and labelling according to regulations for transport of chemicals
- protective measures for storage and handling
- measures in case of accidents and fire
- toxicological and ecotoxicological effects

is given in our safety data sheets.

Guideline formulations

If you are interested in guideline formulations please visit our homepage https://personal-care.evonik.com.

B 04/20

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