### **ISOLAN® PDI**

# Emulsifier for the formulation of cosmetic W/O creams and lotions

#### Intended use

W/O Emulsifier

#### Benefits at a glance

- Emulsifier for elegant W/O emulsions with a brilliant white appearance and pleasant application properties
- Low usage concentration (approx. 3.0%)
- Stable emulsions without co-emulsifiers and with low amounts of consistency-enhancing waxes
- · Formulations with all kinds of cosmetic oils
- · High compatibility with active ingredients
- · Emulsions with good heat and freeze stability
- PEG-free W/O emulsifier based on natural raw materials
- Liquid at room temperature

#### INCI (PCPC name)

Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate

# Chemical and physical properties (not part of specifications) Form liquid Color yellow HLB-value approx. 5

#### **Application**

ISOLAN® PDI is a PEG-free W/O emulsifier based on natural raw materials. Due to ist polymeric and

polyfunctional structure ISOLAN® PDI has a high stabilizing effect on emulsions.

- ISOLAN® PDI is suitable for the formulation of cosmetic W/O creams and lotions.
- The amount used, based on the whole emulsion, is approx. 3.0%.
- Consistency-enhancing or emulsion-stabilising waxes are only required in amounts up to 2%.
   Recommended is hydrogenated castor oil in combination with high-melting hydrocarbon waxes or beeswax.
- The optimum range for the oil phase content is
   20 32% for creams and
   24 35% for lotions.
- Substances which can be processed include not only mineral oils, which in emulsions provide relatively few problems, but also fatty acid esters of short- and long-chained alcohols and vegetable triglycerides which are often difficult to emulsify.
- Emulsions in which the oil phase mainly consists
  of lipids with good spreading properties have
  good rub-in characteristics and are rapidly
  absorbed by the skin. On the other hand, creams
  which contain only high viscous oils, e. g.
  vegetable triglycerides, for a "more rich" skin feel,
  maintain good application profiles.
- The creams and lotions are distinguished by high stability towards heat and freezing stress; stable emulsions between -25 °C and +50 °C are attainable.

#### Influence on the viscosity of the emulsion

The viscosity of W/O emulsions based on ISOLAN® PDI can be adjusted by three variables.

#### 1. Viscosity of the oil phase

The viscosity of the external phase correlates directly with the viscosity of the emulsion. This means that it increases if low viscous oils in a formulation are replaced by higher viscous oils or if waxes are added; even at a concentration of 0.5 – 2.0%.

#### 2. Phase ratio

In emulsions with a high content of dispersed phase – as in the cosmetic W/O emulsions – the viscosity increases significantly when the proportion of the dispersed internal phase is increased. The reason for this is the interaction between the dispersed water droplets which becomes stronger with the increased packing density. Therefore ISOLAN® PDI creams on average have a lower oil content than lotions. Depending on the emulsifiable substances, creams can be prepared with 20 – 32% and lotions with 24 – 35% oil phase.

A given oil phase can be processed to form stable viscous liquid or cream-like emulsions when its proportion is in the optimum range for stability of the emulsion.

#### 3. Degree of dispersion

An additional parameter having an influence on viscosity is the degree of dispersion. This should not be used to regulate the viscosity due to its effect on the stability of the emulsion. When the viscosity increases, due to mechanical processing, the diameter of the droplets is reduced and the specific boundary area between the phases is increased. For this reason cream formulations are often still liquid in the pre-emulsion state because of their coarse degree of dispersion.

#### Preparation

A pre-requisite for this is careful adjustment of the formulation (phase ratio, viscosity of the oil phase) and optimum emulsification.

The particle size for creams which are stable over a long period of time is below 1  $\mu$ m, for lotions approx. 2 – 4  $\mu$ m. More coarsely dispersed emulsions tend to separate.

Thorough, but not too intensive homogenization is required. Extreme energy input frequently causes the formation of highly viscous, metastable secondary structures which break down on storage. Under such conditions lotions may transiently reach cream-like consistency, e. g. by several passages through a colloid mill.

Optimum manufacturing conditions correspond to the principles of normal production processes for W/O emulsions.

The water phase is incorporated slowly into the oil phase which contains the emulsifier while stirring intensively. The coarsely dispersed pre-emulsion is then homogenized. The final homogenization should be performed below 30 °C.

The temperature programme is variable and can take the form of:

- hot/hot procedure (H/H)
- hot/cold procedure (H/C)

In addition to the traditional hot/hot procedure (both phases 80 – 90 °C) the hot/cold procedure can be used. It is characterised by incorporation of the cold water phase (15 – 30 °C) into the hot oil phase which significantly shortens the time of manufacture. Homogenization should be carried out below 30 °C in order to ensure that the waxes have recrystallised. The decisive criterion for production is the viscosity. Mechanical processing is discontinued when the viscosity is equal to that of the standard emulsion developed and tested in the laboratory.

#### **Emulsifying machines**

Stirring equipment or planetary mixers with high sheering force are suitable for the manufacture of creams and lotions in the laboratory and production scale, provided that they can insure uniform work-up of the emulsion. Machines predominately used in the cosmetic industry, which are equipped with stirrer, stripper and rotor-stator homogenizer, fulfil all requirements for optimum emulsification. However, utilization of their maximum capacity may result in over-emulsification. High-pressure emulsifiers may cause problems because of the danger of over-emulsification and liberation of water due to cavitation.

#### Recommended usage concentration

Approx. 3.0% ISOLAN® PDI

#### **Packaging**

4 x 200 kg drum

We recommend storing ISOLAN® PDI at room temperature to keep the product pumpable.

#### Hazardous goods classification

Information concerning

- · classification and labelling according to regulations for transport and for dangerous substances
- · protective measures for storage and handling
- measures in case of accidents and fires
- toxicity and ecological effects

is given in our material safety data sheets.

#### **Guideline formulations**

W/O Lotion F 11/97	
Phase A	
ISOLAN° PDI	3.0%
Hydrogenated Castor Oil	0.3%
Microcrystalline Wax1)	0.2%
TEGOSOFT® DO	7.0%
TEGOSOFT® P	7.5%
TEGOSOFT® CT	7.0%
Phase B	
Magnesium Sulfate Heptahydrate	1.0%
Water	74.0%
Preservative, Perfume	q.s.

W/O Cream (light) F 6/99	
Phase A	
ISOLAN® PDI	3.0%
Hydrogenated Castor Oil	0.5%
Microcrystalline Wax <sup>1)</sup>	0.5%
TEGOSOFT® P	5.0%
TEGOSOFT® CI	6.0%
Ethylhexyl Octanoate	6.0%
Phase B	
Glycerin	2.0%
Magnesium Sulfate Heptahydrate	1.0%
Water	76.0%
Preservative, Perfume	q.s.

1)e. g. Paracera M, Paramelt B. V.

W/O Hand Cream F 51/96	
Phase A	
ISOLAN® PDI	3.0%
TEGOSOFT® liquid	9.5%
TEGOSOFT HP	9.5%
Beeswax	0.6%
Hydrogenated Castor Oil	0.4%
Phase B	
Glycerin	3.0%
Magnesium Sulfate Heptahydrate	1.0%
Water	73.0%
Preservative, Perfume	q.s.

W/O Cream with Ethanol F 7/99	
Phase A	
ISOLAN® PDI	3.0%
Beeswax	1.2%
Hydrogenated Castor Oil	0.8%
Mineral Oil (30 mPas)	10.0%
Isohexadecane	10.0%
Phase B	
Glycerin	3.0%
Magnesium Sulfate Heptahydrate	1.0%
Water	61.0%
Phase C	
Ethanol	10.0%
Preservative, Perfume	q.s.

W/O Sun Protection Lotion Ma 83/98		
Phase A		
ISOLAN® PDI	3.0%	
Beeswax	0.2%	
Hydrogenated Castor Oil	0.3%	
Ethylhexyl Methoxycinnamate	4.0%	
Butyl Methoxydibenzoylmethane	2.0%	
TEGOSOFT® TN	9.0%	
TEGOSOFT® CT	8.5%	
TEGOSOFT® MM	1.0%	
Phase B		
Glycerin	3.0%	
Magnesium Sulfate Heptahydrate	0.6%	
Water	68.4%	
Preservative, Perfume	q.s.	

W/O Sun Protection Cream with Zinc Oxide F 91/96		
Phase A		
ISOLAN° PDI	3.0%	
Mineral Oil (30 mPas)	12.0%	
TEGOSOFT® CT	12.0%	
Hydrogenated Castor Oil	0.8%	
Microcrystalline Wax1)	1.2%	
Ethylhexyl Methoxycinnamate	5.0%	
Isostearic Acid	1.0%	
Zinc Oxide	5.0%	
Phase B		
Glycerin	3.0%	
Magnesium Sulfate Heptahydrate	0.5%	
Water	56.5%	
Preservative, Perfume	q.s.	

W/O Sun Protection Cream (high SPF) Ma 43/98-6		
Phase A		
ISOLAN° PDI	3.00%	
TEGOSOFT® OS	11.75%	
Mineral Oil (30 mPas)	11.50%	
ABIL® Wax 9840	0.25%	
Hydrogenated Castor Oil	0.50%	
Microcrystalline Wax1)	1.00%	
Isostearic Acid	1.00%	
Ethylhexyl Methoxycinnamate	7.00%	
Zinc Oxide	15.00%	
Titanium Dioxide (and) Alumina (and) Simethicone <sup>2)</sup>	4.00%	
Phase B		
Water	44.50%	
Magnesium Sulfate Heptahydrate	0.50%	
Preservative, Perfume	q.s.	

<sup>&</sup>lt;sup>1)</sup>e. g. Paracera W 80, Paramelt B. V.

E 01/00

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The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used. (Status: April, 2008)

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<sup>&</sup>lt;sup>2)</sup>e. g. Eusolex T 2000, Merck



#### **Product specification**

Material ISOLAN PDI Spec.Code K00 STANDARD

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Inspection Characteristics	Method	Limits	Units	Z
Hydroxyl value	GM_0020_01	90.0-130.0	mg KOH/g	Χ
Acid Value	GM_0010_01	<=10.00	mg KOH/g	Χ
Saponification Value	GM_0030_01	145.0-180.0	mg KOH/g	Χ

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

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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.

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Print date: 03.07.2015	Valid from: 13.11.1998	Version: 4	



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## ISOLAN® PDI

#### Product data record

#### 1. General information

#### 1.1 Manufacturer/Supplier

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#### 1.2 Product Description

1.2.1 Raw material category W/O Emulsifier

#### 1.2.2 Ingredients according to INCI

Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate

#### 1.2.3 Composition

Components	Source	Ratio
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	vegetable	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 Solvents, preservatives and other additives

	CAS No.	EINECS / EC No.	content	Function
no additives				

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. Information on production process

General description of production process: Conversion of polyglycerol with fatty acids

The product is not irradiated.

ISOLAN® PDI is produced in the strictest absence of any animal derived material of any type.

Origin of vegetable starting material: rapeseed oil

#### GMO-Status:

The item contains ingredients derived from rapeseed (including oils and other refined ingredients), but these ingredients are sourced from an "Identity Preserved" program and can be certified NON-GMO.

However, max. 0.9% cross-contamination is possible. Any protein or DNA is not present. Consequently the product will be PCR negative when tested.

#### 2.1 By products

		method
Residual solvents	not applicable	
Free amines	not applicable	
Nitrosamines	not applicable	
Monochloroacetic acid	not applicable	Chromatography
Dichloroacetic acid	not applicable	Chromatography
1,4-Dioxane	not applicable	
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides	
Total heavy metals	max. 20 ppm	AAS-ICP
As, Cd, Co, Cr, Hg, Ni, Pb, Sb	Each < 1 ppm	AAS-ICP
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	

#### 2.2 CMR (Carcinogenic, Mutagenic or Reprotoxic)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

#### Further Information:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Some of the CMR substances mentioned below and listed in Annex VI to Regulation (EC) No 1272/2008 are used as starting materials or solvents for the production of our cosmetic raw materials and may require reporting under California Proposition 65 or the Safe Cosmetics Act, SB 484.



The presence of these prohibited substances has to be seen as non-intended. It is stemming from impurities of the starting materials or the manufacturing process which is technically unavoidable in good manufacturing practice.

CMR substance	Starting material	max. concentration	method
Ethylene Oxide	no		
Propylene Oxide	no		
Octamethylcyclotetrasiloxane (D4)	no		
2-Ethylhexanoic Acid	no		
n-Hexane	no		
Methyl Chloride	no		
Dimethyl Sulphate	no		

#### 2.3 "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, shall be indicated in the list of ingredients in addition to the terms parfum or aroma.

The cosmetic raw materials and the cosmetic actives supplied by Evonik Personal Care are manufactured without the use of perfumes and fragrances. An analytical proof for the absence in traces of the substances to be mentioned in addition to the terms parfum or aroma is not performed in cosmetic raw materials, which are chemically produced.

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.

#### 2.4 Food Ingredients listed in Annex Illa of Commission Directive 2007/68/EC.

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.

#### 3. Microbiological status

Total Viable Count max. 100 cfu/g

Pathogens\* absent/g

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

#### 4. Shelf life / storage conditions

24 months after production (unopened original packaging)



#### 5. Regulatory Status

#### 5.1 Customs tariff number

39072020

#### 5.2 Regulatory status (chemical regulations)

#### Europe

Components	REACH status	CAS No.	EINECS / EC No.
Diisostearoyl	Polymer	187547-43-9	Polymer
Polyglyceryl-3 Dimer			
Dilinoleate			

#### Other countries

Country		yes / no	Remark
Australia	AICS:	no	
China	IECSC:	yes	up to 10 t/a
Canada	DSL: NDSL:	no	
Taiwan	TCSI:	yes	

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

Brazil, Japan, South Korea, Philippines, USA

#### 5.2.1 Regulatory status (cosmetic regulation)

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

#### 6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data