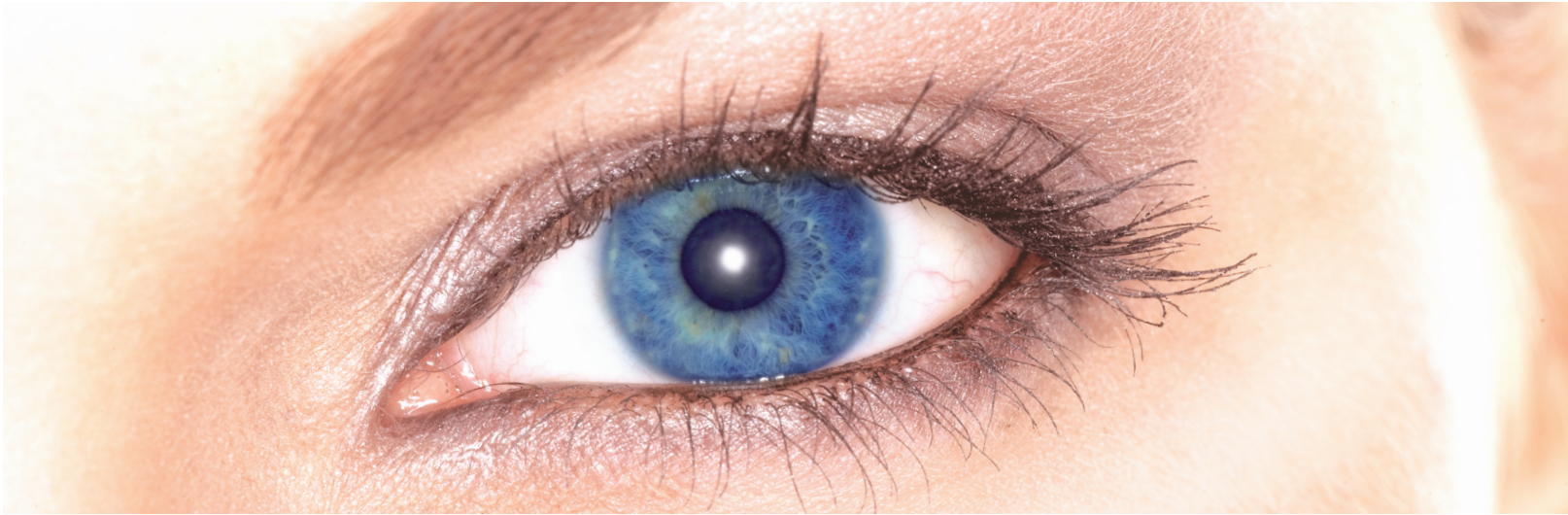


LifeScience – Pharma

**Spotlight Emulsion Technology for
Topical Pharmaceutical and Medical Device**

Know ...



... How!

Dow Corning®
TI-6021 W/O Formulation Aid

Dow Corning®
Emulsifier 10

Basic Formulation:
Relieving Emulsion (W/Si)

DOW CORNING

Dow Corning® Emulsifiers:
Water-in-oil (W/O), Water-in-silicone (W/Si) and
Water-in-silicone-and-oil (W/Si-O)

Three criteria are key for topical pharmaceutical and medical device applications:

- **Safety**
- **Efficacy**
- **Patient compliance**

Emulsions can offer enhanced aesthetics through a non-greasy and pleasant, smooth feel. Silicone emulsifiers combining water, silicones and oil allow to formulate systems with unique properties which are known to contribute to a higher acceptance by the patient during long term treatments. Dow Corning has transferred the well-established technology of silicone emulsifiers for water-in-oil/silicone and water-in-silicone-and-oil systems in appropriate healthcare grade materials:

Dow Corning® Emulsifier 10 and
Dow Corning® TI-6021 W/O Formulation Aid

The requirements for emulsions registered as topical pharmaceutical or medical device are high. This means that various requirements must be observed:

- **Regulatory compliance of ingredients**
- **Emulsion stability**
- **Release of active ingredients**
- **Skin compatibility**
- **Pleasant texture**
- **Cold processing as option to reduce costs and complexity**

Visit us!
...at CPhI in Madrid
13. - 15. October 2015

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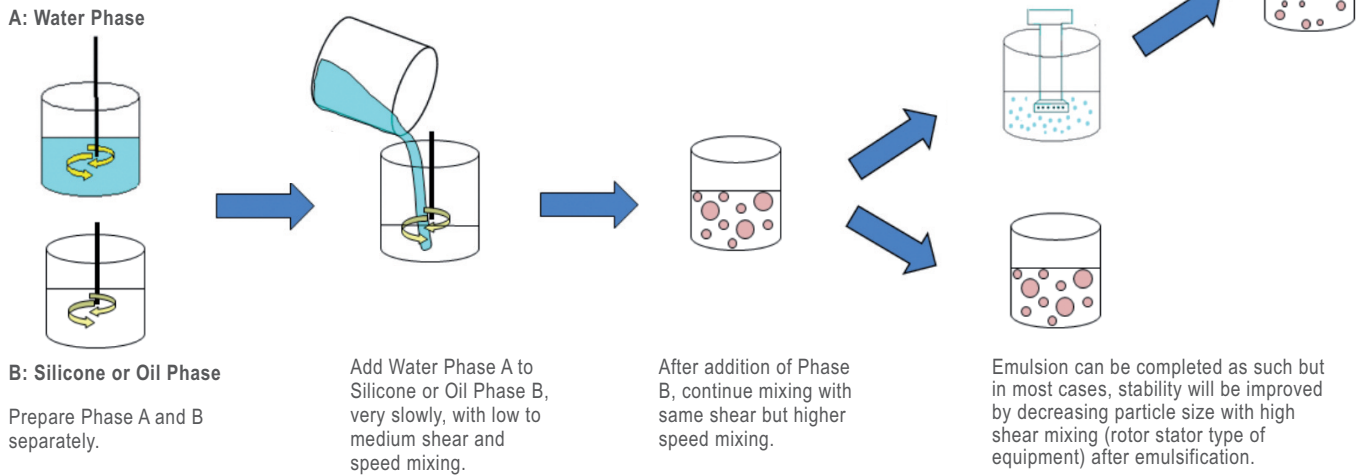
Companion Product Applications	Consumer Healthcare & Topical Medical Device	Pharmaceutical Applications																
Dow Corning® TI-6021 W/O Formulation Aid		Dow Corning® Emulsifier 10																
<p>Water-in-silicone and water-in-silicone-and-oil emulsifier for low viscosity emulsions. Non-diluted material.</p>	<p>Water-in-oil and water-in silicone-and-oil emulsifier, very effective at producing water-in-oil emulsions with a low to medium polarity oil phase. Can also be used as co-emulsifier in oil-in-water-systems. Non-diluted material.</p>																	
<p>Low molecular weight ethoxylated silicone surfactant</p>	<p>Alkylmethyl siloxane copolyol</p>																	
<p>Calculated HLB ~ 4</p>	<p>Calculated HLB ~ 2,2</p>																	
<p>Formulation Benefits:</p> <ul style="list-style-type: none"> • Provides water-in-silicone and water-in-silicone-and-oil emulsions with textures from lotion to cream • Formulation flexibility with a broad range of silicones and organic oil phases • Non-greasy feel • Low odor • Cold or hot processing 	<p>Formulation Benefits:</p> <ul style="list-style-type: none"> • Provides very stable water-in-oil systems without addition of waxes; up to ~80% of water phase • Enables water-in-wax emulsions and sticks • Non-greasy feel • Easy to spread • Light skin conditioning properties • Cold or hot processing • Rich but “light feel” • Reduces tackiness 																	
<p>Recommended use-level (RUL): Allows an addition level as low as 2 %. This addition level needs to be increased up to 6 % when working at lower W/Si-Oil ratio.</p>	<p>Recommended use-level (RUL): 2 % for an oil phase ranging from 18-25 % for low polarity oil and from 25-28 % for medium polarity oil.</p>																	
<table border="1"> <thead> <tr> <th>Water/Si+Oil Ratio</th> <th>RUL (%)*</th> </tr> </thead> <tbody> <tr> <td>80/20</td> <td>2 - 3</td> </tr> <tr> <td>70/30</td> <td>3 - 5</td> </tr> <tr> <td>60/40</td> <td>5 - 6</td> </tr> </tbody> </table>	Water/Si+Oil Ratio	RUL (%)*	80/20	2 - 3	70/30	3 - 5	60/40	5 - 6	<table border="1"> <thead> <tr> <th>Water/Si+Oil Ratio</th> <th>RUL (%)*</th> </tr> </thead> <tbody> <tr> <td>80/20</td> <td>1 - 2</td> </tr> <tr> <td>70/30</td> <td>2 - 4</td> </tr> <tr> <td>60/40</td> <td>3 - 6</td> </tr> </tbody> </table>		Water/Si+Oil Ratio	RUL (%)*	80/20	1 - 2	70/30	2 - 4	60/40	3 - 6
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<p>Formulation Recommendations:</p> <ul style="list-style-type: none"> • Stable emulsions can be prepared by slowly adding the water phase to the oil phase under mixing; common mixing devices can be used. The oil phase should be prepared first by mixing Dow Corning® TI-6021 W/O Formulation Aid with the selected low viscosity silicone fluid and/or organic fluid. High shear mixing at the end of the emulsification process helps to decrease particle size. 	<p>Formulation Recommendations:</p> <ul style="list-style-type: none"> • Use of 1 % sodium chloride in the water phase for formulation stability. • Consistent, slow addition of the water phase to the oil phase using a variety of common mixing devices. Oil phase should be prepared first by mixing Dow Corning® Emulsifier 10 with selected fluid (from low to medium polarity). High shear mixing at the end of the emulsification process will decrease particle size and build the viscosity. 																	
<p>Regulatory Documentation:</p> <ul style="list-style-type: none"> • Ingredient Information Package (IIP): • Ingredient Regulatory Information (IRI) • Elemental Impurities (EI) • Summary of Health Data or Opinion Letter 	<p>Regulatory Documentation:</p> <ul style="list-style-type: none"> • US DMF 16909, European Technical File • Product Regulatory Information Sheet • Elemental Impurities (EI) • Tested for Mutagenicity/Genotoxicity, Skin Sensitization 																	

*Use levels are simply suggested starting points and will need to be adjusted based on other formulation ingredients.

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Formulation process: Water-in-silicone/oil emulsions

Process to make W/Si-oil emulsion



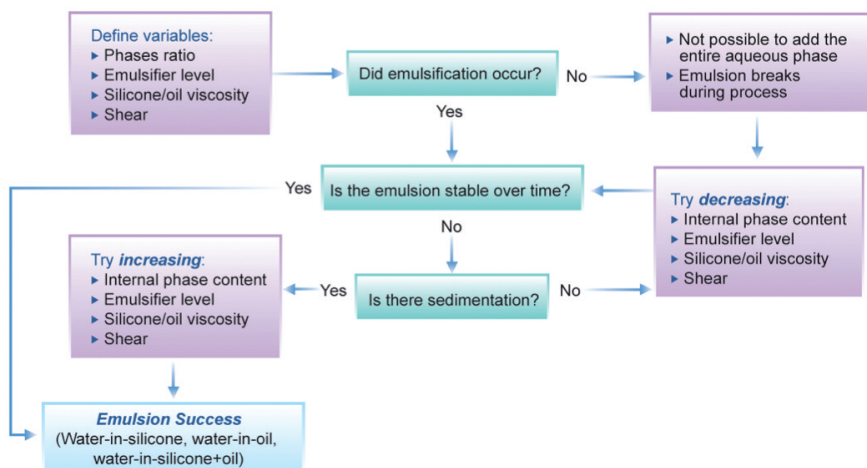
Emulsions:

Emulsions are basic dosage forms for topical pharmaceutical and medical device applications. They are systems of two immiscible fluids, like water and oil, where one fluid is finely dispersed in the other by using an emulsifier. Depending on which phase forms the droplets you distinguish in oil-in-water (O/W) or water-in-oil (W/O) emulsions. W/O, W/Si and W/Si-O systems are emulsions in which small water droplets are dispersed in the continuous oil/silicone-phase. W/Si-O emulsions have gained considerable importance in applications that require the special properties of silicones – in particular, the excellent

spreading and film-forming properties, e.g. substantivity, wash-off resistance and a non-occlusive film. (*1) (*2)

Dow Corning has long term experiences with W/Si-O emulsifiers which combine performance with sensory effects. One of the formulators' biggest challenges is balancing the stability of a formulation, where the emulsifier level, phase ratio, silicone/oil phase viscosity and shear/mixing have to be considered, with aesthetic and performance parameters. (*1)

Troubleshooting information Formulation Guide



Extracted from:
(*1) Cindy Delvallé,
Dow Corning Europe S.A., Belgium, Yasue Kanzaki,
Sayuri Sawayama,
Seiki Tamura,
Dow Corning Co Ltd.; Japan, Rose Bao, Dow Corning
Co.Ltd., China
„Expanding Formulation Possibilities with a
Water-in-oil Silicone Emulsifier
Offering Broad Oil Phase Flexibility”

(*2) Dow Corning Tool Box Tips,
Chemical Manufacturing Solutions,
“Silicone Surfactants: Emulsification”

(*3) Dow Corning Presentation
„Dow Corning Emulsifier Success Kit”

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Relieving Emulsion (W/Si) BSC - Ph.1501

Water in Silicone Emulsion - Non-occlusive

Skin hydration - Skin protection - Excellent sensory feel and smoothness - Reduces tackiness

Phase	Trade Name	Ingredient	Supplier	%
A	Deionised Water	Aqua		54,0
	Emprove® Urea Beads	Urea	Merck	8,0
	Sodium Chloride	Sodium Chloride		1,0
	Saliguard® PG	Phenoxyethanol, Caprylyl Glycol	Salicylates & Chemicals	1,0
	B	1,2 Propanediol	Propylene Glycol	Merck
	Salicylic Acid	Salicylic Acid		2,0
C	Dow Corning® TI-6021 W/O Formulation Aid	PEG-10 Dimethicone	Dow Corning	4,0
	Dow Corning® TI-3021 Silicone Elastomer Blend	Dimethicone, Dimethicone Crosspolymer	Dow Corning	5,0
	Dow Corning® Q7-9120 Silicone Fluid, 20 cSt	Dimethicone	Dow Corning	15,0

Manufacturing Procedure:

1. Premix phases A, B and C separately.
2. Mix phase B until a clear solution is obtained.
3. Ensure that Silicone Elastomer Blend (Dow Corning® TI-3021) is completely dispersed in phase C.
4. Emulsify slowly phase B to phase C while stirring.
5. Emulsify slowly and stepwise phase A to phase B/C while strong stirring. Homogenize.

Product Features:

Appearance: White emulsion

Viscosity (Brookfield RV: Helipath TF, Speed 10 rpm): Approx. 37.000 mPas

Centrifugation (4.000 rpm, 15 min.): No separation

For further detailed information regarding products, basic formulations or technical details please contact our healthcare team.

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