

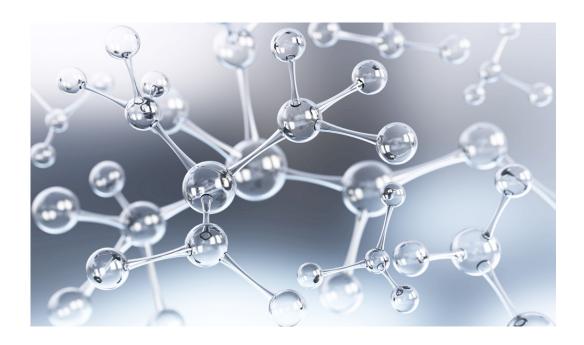
## Exceptional versatility for topical formulations RHEOLOGY MODIFIER

MOTUSFLEX™



## Your needs OUR EXPERTISE

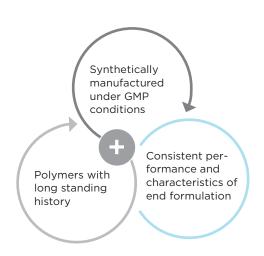
Pharma formulators have specific needs that polymer chemistry can address. With decades of experience in skin care applications, Clariant's scientists offer a deep know-how and expertise for topical formulations requiring quality products with exceptional features.



### How to guarantee **PERFORMANCE**

Our Motusflex polymers are the ideal rheology modifiers providing many advantages for pharmaceutical formulations. Being synthetically manufactured under GMP conditions, they provide batch to batch consistency with defined impurity profile allowing robust formulation development with minimal risk of variations in end product performance and characteristics.

Motusflex polymers are based on Clariant's successful rheology modifier range - giving you the confidence of using a well established ingredients for your pharmaceutical formulations.



## Offering FORMULATION FREEDOM

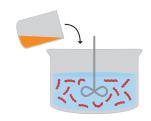
We understand the complexity of pharmaceutical topical formulations associated with difficult to handle APIs. Thus we offer you easy handling features of these polymers to reduces the complexity of your formulations.

#### **EASY TO HANDLE**

- > Ready to use: pre-neutralized
- > Stable in a broad pH range
- > High temperature resistance
- > Instant swelling of the dry polymer particles: no brine necessary
- > Crosslinked: good for particle/oil stabilization
- > Cold-processable: ideal for temperature sensitive APIs
- > Add to oil or water phase

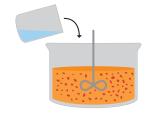
#### **EASY TO USE AT ANY STEP**

#### Aqueous phase



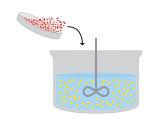
Immediate viscosity build-up, without the use of neutralizing agent

#### Oil phase



Polymer is easily dispersed, viscosity build-up occurs after aqueous phase has been added

#### Final phase



Immediate viscosity build-up, allowing for final adjustment of viscosity

#### **EXCEPTIONAL VERSATILITY - FOR YOUR API'S FOR TOPICAL FORMULATIONS**

Based on AMPS (acrylamido-2-methylpropanesulfonic acid), the Motusflex polymers range provides high performance thickening combined with outstanding sensory characteristics such as superior skin feel without sticky or tacky after feel.

For each challenge of topical formulations we have launched our Motusflex family with three prominent polymers:

#### MOTUSFLEX™ HV

> ideal for high viscosity formulations

#### MOTUSFLEX™ LV

> ideal for low viscosity formulations

#### MOTUSFLEX™ MF

> multi-functional ideal for challenging formulations

## Most versatile polymer for efficient thickening **MOTUSFLEX™ HV**

Motusflex<sup>™</sup> HV is an ammonium acryloyldimethyltaurate/VP Copolymer which offers excellent thickening properties and provides stable rheological performance to pharmaceutical formulations even at lower concentration.

#### **UNIQUE BENEFITS**

- · Excellent thickening properties
- · Good compatibility with organic solvents
- · Stable towards high shear stress
- · Enable formulation at low and high pH conditions
- · Emulsifying on its own a great amount of oils, without additional emulsifiers

#### A SUPERIOR SENSORY PROFILE FOR YOUR PRODUCTS

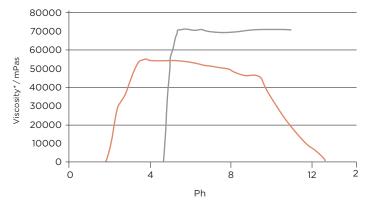
- · Light and fresh skin feel
- · No sticky after feel

#### **APPLICATIONS**

- · O/W emulsions
- · Cream gels & emulsifier free cream gels
- · Hydroalcoholic gels



#### pH stability



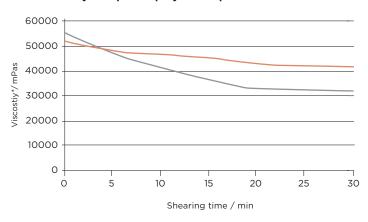
\*1.0% aqueous gel, Brookfield RVT, 20 rpm, 20°C

■ Motusflex<sup>™</sup> HV ■ Carbomer

#### **DESCRIPTION**

| Trade name        | Motusflex™ HV  |
|-------------------|--|
| Polymer type      | crosslinked copolymer based on<br>2-acrylamido-2-methylpropane sulfonic acid<br>and N-vinylpyrrolidone |
| Appearance [20°C] | white powder   |
| Regulatory        | DMF Type IV (under submission)   |

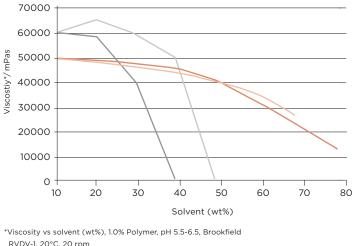
#### Shear stability of aqueous polymer dispersion



\*Viscosity vs shearing time, Ultraturrax high shear mixer 20000 rpm, 1.0% Polymer, pH 5.5-6.5, Brookfield RVDV-1, 20°C, 20 rpm

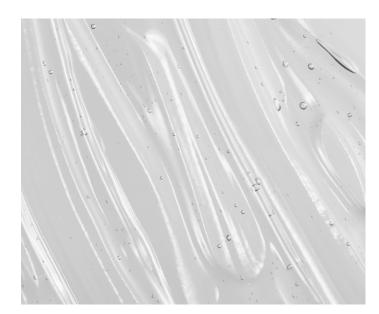
> ■ Motusflex<sup>TM</sup> HV (EtOH) Carbomer

#### Compatibility with organic solvents



RVDV-1, 20°C, 20 rpm

Motusflex™ HV (EtOH) Carbomer (EtOH) Motusflex™ HV (Aceton) Carbomer (Aceton)



Versatile thickener, offers significant viscosity at lower polymer concentration.

# Low viscosity, perfect for sprayable formulations **MOTUSFLEX™ LV**

Motusflex™ LV is an ammonium salt of acrylamidopropane sulphonic acid with hydrophobic side-chains which allows stable low viscosity lotions and gels. Motusflex™ LV has excellent emulsification properties due to its associative thickening mechanism. The rheology modifier shows broad pH stability and good suspension and stabilization properties.

#### **UNIQUE BENEFITS**

- · Emulsification of high oil contents up to 40%
- · Polymeric emulsifier for low viscosity cream gels
- · Excellent formulation stability
- · Very good suspension properties
- · Quick breakdown for fresh sensory during application
- · Effective at low usage levels

#### A SUPERIOR SENSORY PROFILE FOR YOUR PRODUCTS

· Enhanced skin feel

#### **APPLICATIONS**

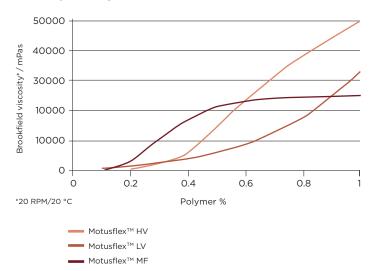
- · Suitable for low viscosity o/w lotions and sprayable formulations
- · Emulsifier free cream gels



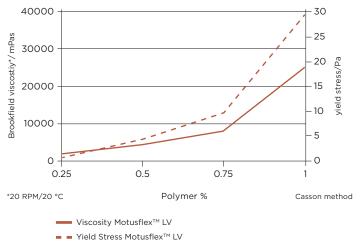
#### **DESCRIPTION**

| Trade name        | Motusflex™ LV  crosslinked copolymer based on 2-acrylamido-2-methylpropane sulfonic acid and ethoxylated behenyl alcohol methacrylate |  |
|-------------------|---|--|
| Polymer type      |   |  |
| Appearance [20°C] | white powder  |  |
| Regulatory        | DMF Type IV (under submission)  |  |
|                   |   |  |

#### **Viscosity building**



#### **Excellent yield stress profile**





Perfect for low viscosity formulations like sprayable emulsions.

## Multifunctional - for challenging formulations **MOTUSFLEX™ MF**

Motusflex<sup>™</sup> MF is a sodium salt of acrylamidopropane sulphonic acid which provides an outstanding flexibility in application. As a multi-benefit rheology modifier it has an excellent salt tolerance, broad pH compatibility and stabilizes high amounts of oil combined with soft texture and a silky after feel.

#### **UNIQUE BENEFITS**

- · Great salt tolerance
- · Fast dispersion
- · Stable viscosity across broad pH range
- · Texturizer and thickener for emulsions
- · Compatible with solvents, glycerine and propylenglycol
- · Stabilization of high amounts of oils

#### A SUPERIOR SENSORY PROFILE FOR YOUR PRODUCTS

· Silky and soft skin feel

#### **APPLICATIONS**

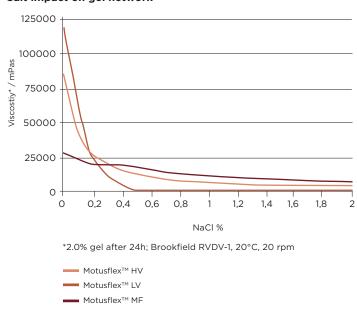
- · Suitable for a broad range of topical formulations: emulsions, cream gels, aqueous gels and ointments
- · Ideal for formulations with an elevated salt content



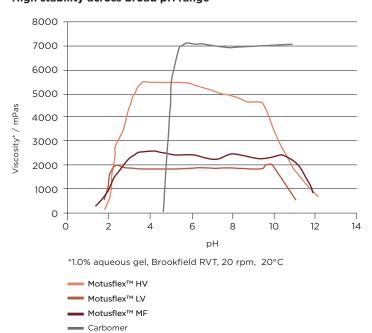
#### **DESCRIPTION**

| Trade name        | Motusflex™ MF   |
|-------------------|---|
| Polymer type      | crosslinked homopolymer based on 2-<br>acrylamido-2-methylpropane sulfonic acid |
| Appearance [20°C] | white powder  |
| Regulatory        | DMF Type IV (under submission)  |

#### Salt impact on gel network



#### High stability across broad pH range





Excellent salt tolerance combined with an outstanding pH stability make challenging formulations easy.

MOTUSFLEX<sup>™</sup> LV

### **Formulations**

### STABILITY STUDY WITH ACTIVE PHARMACEUTICAL INGREDIENTS

#### Formulation with Hydrocortisone

| TD 4 DE / INIGI NIA ME      |  |  |
|-----------------------------|--|--|
| TRADE / INCI NAME           |  | As is  |
| Water                       | Diluent  | 74.55  |
| Propylene Glycol            | Humectant  | 8.00   |
| Motusflex HV                | Rheology<br>Modifier   | 0.75   |
| Cprylic Capric Triglyceride | Emollient  | 12.00  |
| Cetearyl alcohol            | Stabilizer   | 3.50   |
| DMDM Hydantoin              | Preservative   | 0.20   |
| Citric Acid solution 10%    | Neutralizer  | q.s. pH 4.4 to 4.6   |
| Hydrocortisone              | API  | 1.00   |
|                             | Water Propylene Glycol  Motusflex HV  Cprylic Capric Triglyceride Cetearyl alcohol  DMDM Hydantoin  Citric Acid solution 10% | Water Diluent Propylene Glycol Humectant  Motusflex HV Rheology Modifier  Cprylic Capric Triglyceride Emollient Cetearyl alcohol Stabilizer  DMDM Hydantoin Preservative  Citric Acid solution 10% Neutralizer |

#### MANUFACTURING DESCRIPTION

- Mix the components of A and heat up to 75°C.
- II Mix the components of C and heat up to 75°C.
- III Add B to I.
- IV Add II to III and homogenize with a high shear mixer at 15000 rpm for 2 minutes.
- V Change to a finger stirrer and stir at 200 rpm until cool.
- VI Add D and stir.
- VII Adjust the pH with E to 4.4 4.6.
- VIII Add F and stir until homogenous.

#### Formulation with Diclofenac-Na

|   | TRADE / INCI NAME        |  | As is  |
|---|--------------------------|--|--|
| Α | Ceteareth-20             | Emulsifier   | 2.00   |
|   | Mineral oil h.v.         | Emollient  | 2.00   |
|   | Caprylic triglyceride    | Emollient  | 2.00   |
| В | Motusflex LV             | Rheology<br>Modifier,<br>Thickener<br>& Emulsifier | q.s.<br>(concentration to be<br>adjusted as per re-<br>quired physical form) |
| С | Water                    | Diluent  | 83.14  |
| D | Diclofenac-Na            | API  | 1.16   |
|   | Isopropanol              | Solvent  | 5.00   |
|   | Propylene Glycol         | Humectant  | 3.00   |
| Е | Motusflex LV             |  | q.s.   |
| F | DMDM Hydantoin           | Preservative                                       | 0.20   |
| G | Citric Acid solution 10% | Neutralizer  | q.s. pH 4.4 to 4.6   |
|   |                          |  |  |

#### MANUFACTURING DESCRIPTION

- Mix the components of A and melt at approx. 70°C.
- II Mix the components of D.
- III Add B to I and stir at 200 rpm.
- ${
  m IV}$  C to III and stir for 1 hour at 250 rpm until cool.
- ${f V}$  Change to a finger stirrer and stir at 200 rpm until cool.
- VI Add mixture of II into IV and stir.
- VII Add F to step V.
- VIII Adjust the pH with G to 4.4 4.6.

#### Formulation with Betamethasone

|   |   | TRADE / INCI NAME         |                      | As is             |
|---|---|---------------------------|----------------------|-------------------|
|   | Α | Trilaureth-4 Phosphate    | Emulsifier           | 2.00              |
|   |   | Mineral oil h.v.          | Emollient            | 6.00              |
|   |   | Isopropyl Palmitate       | Emollient            | 8.00              |
|   |   | Octyldodecanol            | Emollient            | 6.00              |
|   | В | Motusflex MF              | Rheology<br>Modifier | 2.00              |
|   | С | Water                     | Diluent              | 75.7 - 76.9       |
| _ |   | DMDM Hydantoin            | Preservative         | 0.20              |
|   | D | Citric Acid solution 10%  | Neutralizer          | q.s pH 4.4 to 4.6 |
|   | Е | Betamethasone Valerate 17 | API                  | 0.10              |

#### MANUFACTURING DESCRIPTION

- I Mix the components of A.
- II Mix the components of C.
- III Mix B into I.
- IV Add II into C and homogenize with a high shear mixer at 15000 rpm for 2 minutes.
- V Change to a finger stirrer and stir at 200rpm .
- VI Adjust the pH with D to 4.4 4.6.
- VII Finally add E and stir until homogenous.

#### RESULTS

- Appearance: White cream
- Viscosity: (Brookfield, 20°C, 20 rpm) 3100 mPas (benchmark 33000)
- pH: 4.4 (benchmark 4.7)
- Physical stability: No change of appearance during 3 months at RT and 40°C
- Assay stability: No significant deviation during 3 months at RT and 40°C (benchmark 1%)

#### **RESULTS**

- Appearance: White cream/Gel/sprayable lotion/ topical solution
- Viscosity: Function of polymer concentration (benchmark 19000/10000)
- pH: 7.5 (benchmark 7.38)
- Physical stability: No change of appearance during 3 months at RT and 40°C
- Assay stability: No significant deviation during 3 months at RT and 40°C (benchmark 1.3%)

#### RESULTS

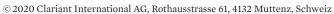
- Appearance: White cream
- Viscosity: (Brookfield, 20°C, 20 rpm) 18700 mPas (benchmark 20000)
- pH: 4.5 (benchmark 3.7)
- Physical stability: No change of appearance during 3 months at RT and 40°C
- Assay stability: No significant deviation during 3 months at RT (benchmark 0.1%)

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