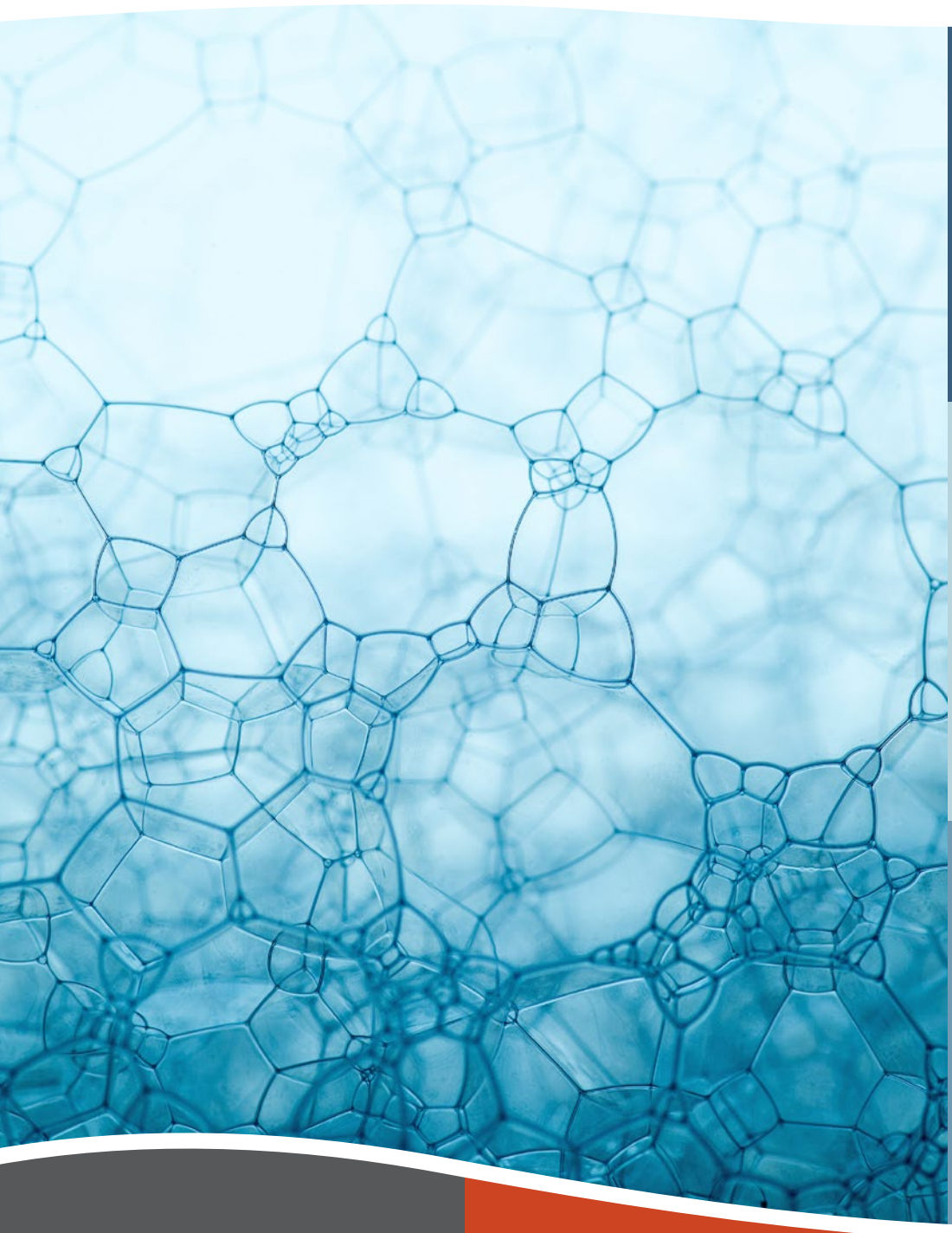
Biesterfeld
Competence in Solutions



Antifoams as API &
Process Aid

Solid Dosage
Forms with liquid API

Antifoam Solutions

The Importance of Antifoams

Foam is created when gas is dispersed into a continuous liquid phase and remains stabilized within the dispersion.

In pharmaceutical processes it is essential to keep the formation of foam under control. The presence of foam can cause serious problems during production. Excessive foaming leads to reduced equipment and container capacity and increased processing time. Foam may even negatively influence the quality of the final product (e.g. the surface of tablets).

In medical applications such as dialysis, where human blood is purified and redirected into the human body, the prevention of foam is an essential consideration.

In the 'human system' the formation of foam can also cause unpleasant gastrointestinal effects like bloating and stomachache.

With regard to the pharmaceutical industry, it is clear that in many applications a fast and effective antifoaming agent is needed to prevent uncontrolled foaming and to maintain smooth and efficient processes.

Biesterfeld Spezialchemie GmbH offers highly effective and versatile defoamers which can be used as supplied or further diluted with water. Typical applications are foam suppression and inhibition in fermentation, manufacturing and filling processes. We also offer antifoams for critical medical applications, which are used as APIs in antiflatulents for solid or liquid dosage forms.

Application	Manufacturer/ Brand	Products to consider
Therapeutic and Diagnostic API for use in • Antiflatulent or antigas for solid or liquid dose formulations (treatment for gastrointestinal gas) • Elimination of gas during endoscopy and X-ray examination	DuPont/ Liveo™	Liveo™ Q7-2243 LVA, Simethicone USP Liveo™ Antifoam M Compound Liveo™ Q7-2587 30% Simethicone Emulsion USP
Pharmaceutical Processing Process aid for • Fermentation, cell culture, mixing • Container filling	DuPont/ Liveo™ ADEKA/ ADEKA NOL	Liveo™ Q7-2243 LVA, Simethicone USP Liveo™ Antifoam M Compound Liveo™ Medical Antifoam A Compound Liveo™ Q7-2587 30% Simethicone Emulsion USP Liveo™ Medical Antifoam C Emulsion ADEKA NOL LG-109 ADEKA NOL LG-126

DuPont – Silicone Antifoams

DuPont™ Liveo™ simethicone compounds and emulsions are manufactured at an FDA-registered production site under ICH Q7 GMP conditions.

Applications:

- Active for prescription/OTC/medical device antiflatulents
- Foam control in medical and pharmaceutical applications
- Process aid for biofermentation

	Simethicone Compounds 100% Simethicone			Simethicone Emulsions 30% Simethicone	
	Liveo™ Q7-2243 LVA, Simethicone USP	**Liveo™ Antifoam M Compound**	**Liveo™ Medical Antifoam A Compound**	**Liveo™ Q7-2587 30% Simethicone Emulsion USP**	**Liveo™ Medical Antifoam C Emulsion**
Appearance	Light grey liquid	Light grey liquid	Grey liquid	Off-white liquid	Off-white liquid
Grade	Simethicone USP/ PhEur (CEP)	Simeticone PhEur (CEP)	Simethicone USP	Simethicone Emulsion USP	Simethicone Emulsion USP
API	Yes (PhEur)	Yes (PhEur)	No	Yes (USP)	No
Simethicone level	100%	100%	100%	30%	30%
Defoaming	< 15 sec	< 15 sec	< 15 sec	< 15 sec	< 15 sec

ADEKA – EO/PO-based Antifoaming Agents

The ADEKA NOL LG series are non-ionic EO/PO-based defoamers (polyalkylene glycol structure). ADEKA NOL LG-109 & LG-126 are used in numerous applications as defoaming, wetting and emulsifying agents.

Applications:

- Process aid in the production of pharmaceuticals and cosmetics
- Fermentation processes (e.g. of astaxanthin, EPA/DHA, amino acids and yeast)
- Food processing

Benefits:

- Excellent foam-breaking effects
- Non-ionic
- No residues (water-soluble)
- Easy to sterilize (no separation of water/oil phase)
- pH-independent
- Resistance to alkalis (chemical stability)
- Halal/kosher certification

Physical Properties	**Unit**	**LG-109**	**LG-126**
Appearance	-	Liquid	Liquid
pH (2.5%aq)	-	6.0 - 8.0	6.0 - 8.0
Moisture	%	≤ 0.50	≤ 0.1
Hydroxyl value	Mg KOH/g	54.2 – 57.9	33.0 – 38.0
Color (APHA)	-	≤ 100	≤ 100
Viscosity (25°C)	mPas (cP)	490 – 660	750 – 1100
Cloud point	°C	10.0 – 15.0	9.0 – 13.0

Solid dosage forms with liquid API

A major advantage of liquid dosage forms is that the API is already dissolved, so the dosage can be taken as it is. Solid dosage forms, on the other hand, have the advantage of not requiring preservatives and are generally more stable and easier to handle. A liquisolid is a tablet or powder with a liquid API absorbed into a solid carrier excipient which combines the advantages of both liquid and solid dosage forms.*

Below we present a fast and easy solution for turning liquid simethicone into a solid dosage form.

* [cf. Tablets & Capsules Magazine, "eye on excipients", Suedzucker/Beneo-Palatinit, April 2018, page 39]

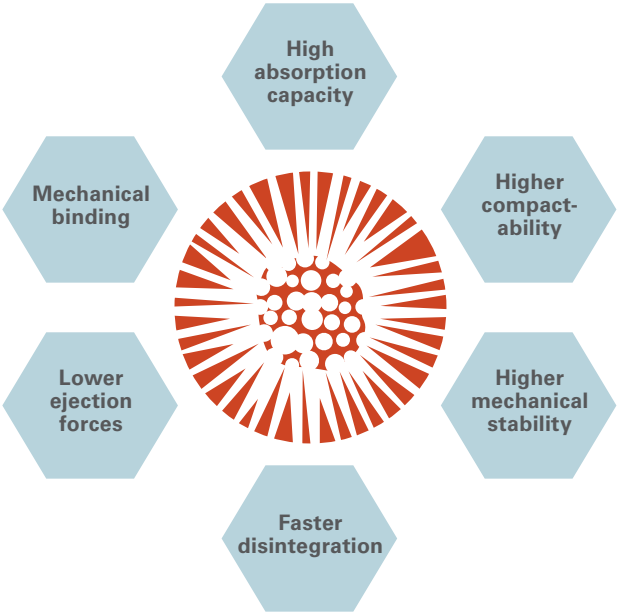
Liquid API: Liveo™ Q7–2243 LVA Simethicone

Liveo™ Q7–2243 LVA Simethicone as offered by Biesterfeld Spezialchemie is an antifoaming agent that is used in pharmaceutical formulations for the treatment of certain disorders within the lower gastrointestinal tract.
[In compliance with USP/ Ph.Eur. / CEP available]

Solid carrier excipient: Omyapharm®

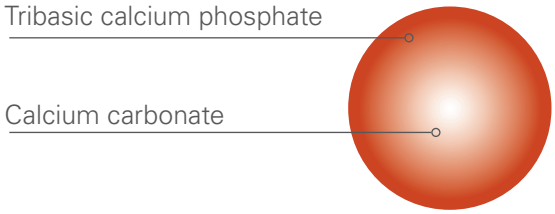
Omyapharm® 500 - OG

A multifunctional mineral excipient

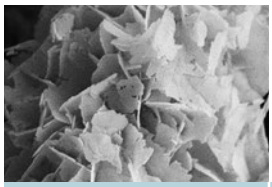


Features

- Lamellar structure
- Brittle material, plastic behaviour
- Mineral composition
- Monographed components
- High porosity



Carrier



Omyapharm® 500-OG is a porous compressible carrier composed of calcium carbonate and tribasic calcium phosphate, which can be loaded by impregnation with up to 40% crystalline actives and 55% oils, converting oils into compressible powders.

Image: unloaded Omyapharm® carrier

	Calcium-carbonate (%)	Tribasic calcium phosphate (%)	d50 (µm)	Loose bulk density (g/ml)	Oil absorption (g/100g)
Omyapharm® 500-OG	40-60	40-60	5-8	~0,13	150

Ingredients	Milled lactose monohydrate	SD milled lactose monohydrate	DC dicalcium phosphate anhydrous	Tricalcium phosphate	Omyapharm®
Oil absorbed (gr/100gr total weight)	93	111	115	117	150

Solid dosage form with liquid API

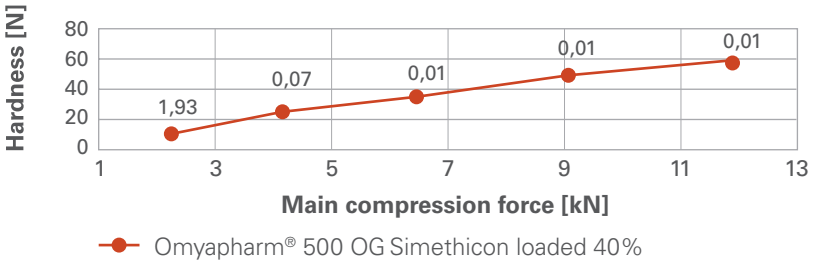
Application example with Omyapharm® loaded with Simethicone (Liveo™ Q7-2243 LVA, Simethicone USP)

Loading of Omyapharm® [%]	40
Active Simethicone amount in tablet [%]	10
Tablet ingredients	**%**
Omyapharm® loaded with Simethicone	25
Mannitol	56,5
Sorbitol	15
Croscarmellose sodium	2
Sucralose	0,2
Magnesium stearate	1,5

Tablet press	Fette 1200i
Tablet size	13 mm
Tablet weight	680 mg

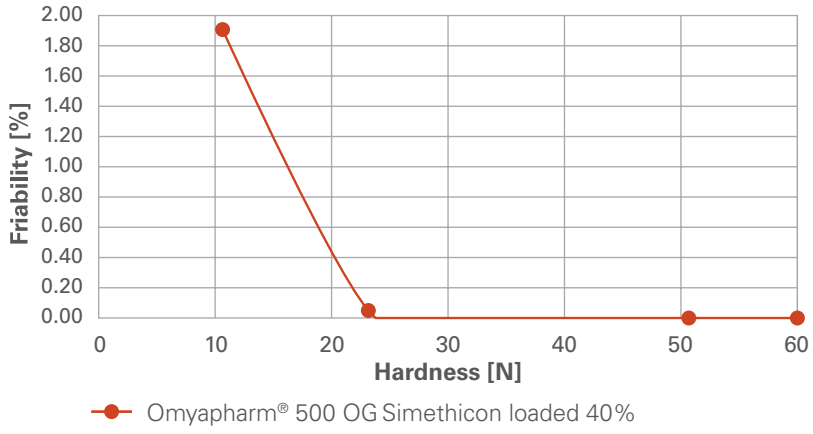
Tableting Performance

Compactability



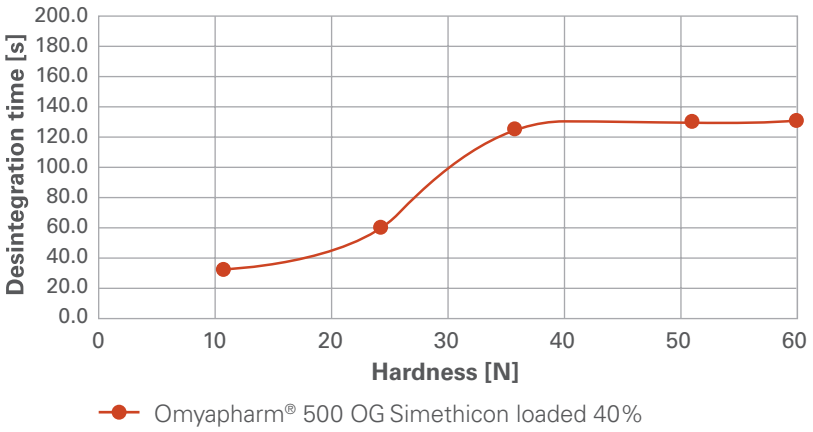
Omyapharm® is an excellent compressible carrier, compactability is significantly better than for other excipients.

Friability



Friability decreases with increasing loading percentage. At 40 % loading friability is below 0.1% for 25 N hard tablets.

Disintegration time



Disintegration time increases with increasing loading percentage but remains below 140 seconds.

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