Harnessing the power of HMOS

GlyCare[™] Human Milk Oligosaccharides^{*}

The next generation nutrient supporting gut health for the dietary supplements market.

*not from human milk



Consumer demand for gut health is on the rise

Driven by lifestyle disruptions in a fast-paced, ever-changing world, consumers are seeking digestive health solutions more than ever. And most consumers want to support and improve their gut health through diet and supplements.

This strong consumer pull creates an opportunity for brands to leverage emerging science to bring new and innovative gut health solutions.





Consumer **interest in gut health has increased threefold** in the last five years¹





products that enhance digestion²



said they'd **purchase a dietary supplement with HMOs** after learning about their health benefits³

Differentiate your next gut health innovation

HMOs are unique, gut-strengthening nutrients found in infant nutrition, *scientifically shown to better equip the gut and thus support immune function, digestive health and an active lifestyle.*⁴

While the utilization of HMOs in infant formula and food products is a recent innovation, HMOs have been scientifically studied for over 130 years. Thanks to advancements in science, the gut-strengthening benefits of HMOs can now be leveraged throughout life!



DSM GlyCare[™] HMOs do *more* to build a stronger gut

DSM is pioneering the oligosaccharides market with GlyCare[™] HMOs by delivering innovations for all of life's ages and stages and enabling consumers to do more to stay healthy, active and resilient throughout life.

DSM GlyCare[™] HMOs help build a **stronger gut through Triple Action:**



good bacteria so they can flourish Fosters a thriving community in the gut from the very start

Builds a sturdier house for good bacteria to live

Plus... they support the role of probiotics in the gut by both nourishing <u>and</u> protecting good bacteria.⁴

Uniquely designed to mimic the bioactive components of breastmilk, DSM GlyCare[™] HMOs are the building blocks for optimal digestive health, immunity and active nutrition. They also feature key attributes that today's consumers seek:



** Except milk

The most comprehensive HMO portfolio worldwide

With the broadest commercial HMO portfolio in the market, GlyCare[™] HMOs are nature-identical, suitable for a wide variety of applications, and carry a *5-year shelf life*.

The portfolio offers science-backed health benefits across a wide range of products. This is based on scientific exploration around three key areas of human health: gut, brain, and immune health.



Clinical data in adults
Observational and/or wide variety of mechanistic data
No or limited mechanistic data

Leading the way with regulatory approvals

We are leading the number of global regulatory approvals on HMOs and are continuously expanding our global footprint to make HMOs easily available to our partners. Six single-ingredient or blend HMOs are currently authorized as Novel Foods in the EU and are notified to the U.S. FDA as GRAS, with more to come from our innovation pipeline.

Unites States Regulatory Landscape			
нмо	GRAS Notice	Intended Use	GRAS Uses
2'FL	650	Children⁺ Adults	Children's formulas: 2.4 g/L Beverages: Up to 5 g/L Foods: Up to 40 g/kg
LNnT	659	Children⁺ Adults	Children's formulas: 0.6 g/L Beverages: Up to 2.5 g/L Foods: Up to 20 g/kg
3'SL	880	Children⁺ Adults	Children's formulas: 0.15-0.20 g/L Beverages: Up to 0.5 g/L Foods: Up to 5 g/kg
6'SL	881	Children⁺ Adults	Children's formulas : 0.3-0.4 g/L Beverages : Up to 1.0 g/L Foods : Up to 10 g/kg
2'FL/ DFL	815	Children⁺ Adults	Children's formulas : 1.2–1.6 g/L Beverages : Up to 4 g/L Foods : Up to 40 g/kg
LNT	833	Children⁺ Adults	Children's formulas: 0.6 g/L Beverages: Up to 2.0 g/L Foods: Up to 20 g/kg

Expanding the possibilities around applications

Completed work with 2FL and LNnT includes:

• Fast dissolving tablet⁺⁺

● Gummies⁺⁺

- Soft chew⁺⁺
- Stick pack⁺⁺
- Chewable tablets⁺⁺
- Beverages, medical nutrition, and more

tt Patent filed. Country-specific



Europe Regulatory Landscape			
НМО	Intended Use	Food category and conditions of use (Commission Implementing Decision (EU) 2017/2470)	
2'FL	Children† Adults	Various levels in a wide selection of foods and beverages. According to patients needs in Foods for special medical purposes. 1.2–3.0 g/day in food supplements for young children and general population.	
LNnT	Children† Adults	Various levels in a wide selection of foods and beverages. According to patients needs in Foods for special medical purposes. 0.6–1.5 g/day in food supplements for young children and general population.	
LNT DSM holds exclusive authorization until 23.04.2025	Children* AdultsVarious levels in a wide selection of foods and beverages.According to patients needs in Foods for special medical purposes.2.0 g/day in food supplements.		
3'SL DSM holds exclusive authorization until 18.02.2026	Children* AdultsVarious levels in a wide selection of foods and beverages.AdultsAccording to patients needs in Foods for special medical purpose.0.5 g/day in food supplements (excluding young children).		
6'SL DSM holds exclusive authorization until 17.02.2026	SM holds exclusive authorization until Children ⁺ According to patients needs in Foods for special medical purposes. Up to 1.0 g/L in beverages, Up to 10 g/kg in foods. Up to 1.0 g/L in beverages, Up to 10 g/kg in foods.		
2'FL/DFL DSM holds exclusive authorization until 19.12.2024	Children† Adults	Various levels in a wide selection of foods and beverages. According to patients needs in Foods for special medical purposes. 4.0 g/day in food supplements.	

† Ages 3+

Scientific evidence supporting HMO's impact on gut health

Scientific evidence confirms that the gut microbiome plays an essential role in the overall health of the GI tract.⁵ In two clinical trials conducted in adults, HMOs were reported to stimulate the growth of beneficial bacteria, which may suggest a potential role in gut health.^{4,6}

- When ingested, HMOs resist digestion and reach the colon mostly intact.^{7,8}
- By selectively feeding the beneficial bacteria in the gut, HMOs enhance the growth of helpful bacteria like bifidobacteria, encouraging the dominance of organisms that positively impact human health.^{7,8}



• By-products of HMO metabolism – such as short chain fatty acids and other metabolites – work to create a community of healthy microbes in the GI tract.^{9,10}

Randomized controlled trial

Emerging clinical data demonstrates that supplementation with select HMOs – 2'FL and LNnT – can positively impact the gut microbiota and may reduce incidence or severity of symptoms related to irritable bowel syndrome (IBS).⁴

Open-label trial

The data from a 12-week, open-label, multi-center study in 317 adults with IBS, a mixture of 2'FL and LNnT suggests that significant improvements in stool consistency, IBS symptom severity[‡], and quality of life.¹¹

DSM is the only HMO provider that has a fully integrated and dedicated HMO production site that oversees the entire process - from product development, pre-clinical and clinical development, to regulatory and large-scale production. This allows us to make HMOs easily available to you, and to support you in getting to market with customerfocused science-backed quality and safety at the core.

DSM: Your innovative end-to-end partner in HMOs

Widest Portfolio with Legacy of Trust

With the widest portfolio of commercially available HMOs, our extensive history provides assurance of quality as a trusted source for infants, children, and adults

Expert Services to Support your Product Development

We can support your product launch with expertise in innovation and R&D, application development, regulatory and legal advice, scientific support and insights and marketing

Long shelf life and high purity

GlyCare[™] HMOs feature dry blend powder properties, longest shelf-life (5 years), and high purity

Streamline your product development process

The only manufacturer of HMOs with straight, premix capabilities and market-ready solutions under one roof

Largest market access – world's largest HMO facility

Available for use in more than 165 countries, the *largest market access* for HMOs worldwide, and in supply with the *world's largest HMO facility*

Pioneering the future of HMOs

Together with clinical partners, leading universities and external labs, we have supported over 20 studies to advance the understanding of HMOs and how they impact human health

Where others see products, we see purpose

At DSM, we know purpose can be the difference between just driving customer interest and differentiating your product on the store shelf. That's why we pour all our curiosity, insights, and innovation into every product we help develop. This takes more than ingredients. It takes a partner.

Partner with DSM for access to our broad portfolio of science-backed products, customized solutions, and expert services aimed at reliably supporting your entire product life cycle, from concept to consumer.

To get started on your next top-selling product featuring our innovative HMO product solutions, visit **PartnerWithDSM.com**.

YOUR END-TO-END PARTNER

PRODUCTS CUSTOMIZED SOLUTIONS EXPERT SERVICES

- 1 Google analytics
- 2 Lightspeed/Mintel; KuRunData/Mintel
- 3 Qualtrics Custom HMOs Survey, November 2020. n=417
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- 11 Palsson OS, Peery A, Seitzberg D, Amundsen ID, McConnell B, Simrén M. Human Milk Oligosaccharides Support Normal Bowel Function and Improve Symptoms of Irritable Bowel Syndrome: A Multicenter, Open-Label Trial. Clin Transl Gastroenterol. 2020;11(12):e00276.
- † As measured by the Bristol Stool Form Scale (BFBS)
- # Based on the IBS Symptom Severity Score (IBS-SSS)

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