



## **Ibuprofen**

For over 25 years, we have been manufacturing ibuprofen at our site in **Bishop**, **Texas**. We offer a wide portfolio consisting of four powder grades, a direct compressible grade, and two fast-acting grades. As an experienced and collaborative partner, we offer world-class regulatory, quality, and technical service support with a global and regional presence.







75+ years experience in APIs



Eco-friendly process

High-quality product





Manufactured by the largest Western producer in the USA\*

\* by volume capacity

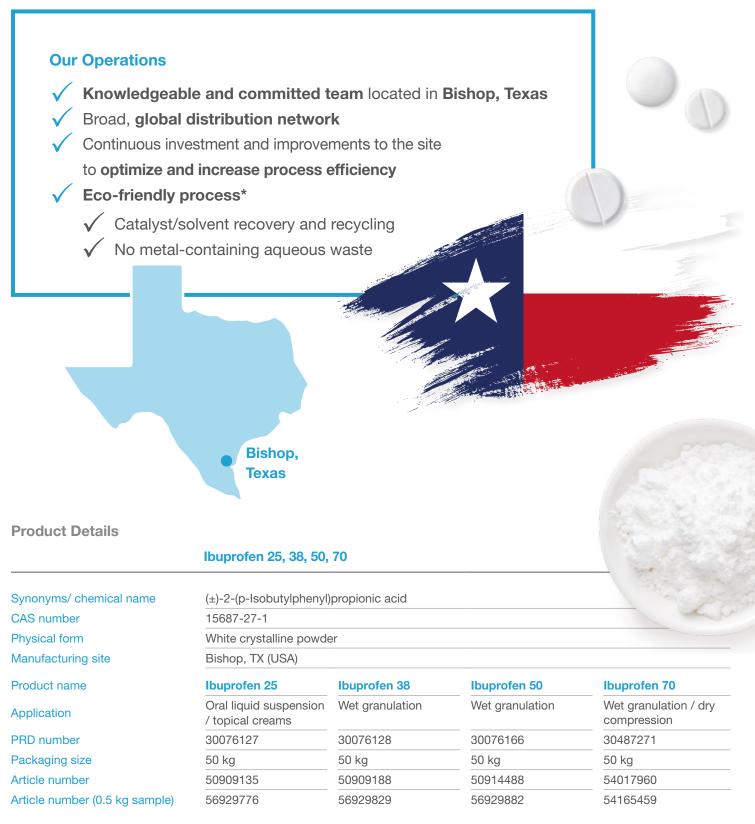
20+ years experience in environmental footprint calculations





## Ibuprofen 25, 38, 50, 70

Four powder grades with different particle size distributions for your formulation needs





**Available Regulatory Information**: Ibuprofen meets the current Ph. Eur., USP, JP and IP monographs. DMFs and CEPs are available upon request.

<sup>\*</sup> Product carbon footprint information from reviewed LCA methodology according to ISO standards is available upon request.

# **Ibuprofen DC 85 W**

Direct compressible grade for improved processibility

#### **Tableting Made Simple**

- √ No need for expensive wet granulation and compaction processing steps
- ✓ Better flowability compared to standard grades
- ✓ Patented formulation minimizes stickiness during production
- ✓ Enables reliable, fault-free tableting with higher output rates
- √ High drug concentration allows for reduced excipient costs and smaller tablets



Typical tablet defect with standard grades

Tablet containing Ibuprofen DC 85 W

#### **Product Details**

#### **Ibuprofen DC 85 W**

Synonyms/ chemical name	(±)-2-(p-IsobutyIphenyI)propionic acid	
Composition	Ibuprofen 50, Microcrystalline cellulose, Colloidal silicon dioxide, Croscarmellose Sodium	
CAS number	15687-27-1 (ibuprofen)	
Physical form	White granules, free flowing, homogeneous material	
Manufacturing site	Holland, MI (USA)	
PRD number	30526498	
Article number	50192890	50192933
Packaging size	50 kg	2 kg



Improved flowability of Ibuprofen DC 85 W



**Available Regulatory Information**: The Ibuprofen used to manufacture Ibuprofen DC 85 W meets the current Ph. Eur., USP, JP and IP monographs. A Technical Package and a US-DMF are available upon request.



# Racemic Ibuprofen Lysinate (RIBL) & Ibuprofen Sodium Dihydrate

Functionality to add diversity to your portfolio

#### **Fast-Acting Ibuprofen Grades**

#### Racemic Ibuprofen Lysinate (RIBL) vs. Conventional Ibuprofen

√ Higher solubility in water¹

✓ More rapidly absorbed in the intestinal tract²

#### Ibuprofen Sodium Dihydrate vs. Conventional Ibuprofen

✓ Dissolves more quickly in vitro and is absorbed into blood plasma more quickly³

Comparable tolerability and safety profile<sup>3</sup>

#### **Product Details**

#### Racemic Ibuprofen Lysinate (RIBL) **Ibuprofen Sodium Dihydrate** Synonyms/ chemical name (±)-2-(p-IsobutyIphenyI)propionic acid lysinate 2-(4-isobutylphenyl)-propionate sodium dihydrate CAS number 57469-86-8 31121-93-4 White to almost-white powder White to almost-white powder **Appearance** Minden, Germany Bishop, TX (USA) Manufacturing site PRD number 30081848 30260589 Packaging size 25 kg 50 kg 51224063 Article number 56477527 Article number sample 51287979 (0.1 kg) 51217385 (0.5 kg) Regulatory status E-DMF is available upon request E-DMF and US-DMF are available upon request



<sup>&</sup>lt;sup>1</sup> Ibuprofen, Rainsford, K.D., Taylor & Francis Ltd. London, UK. 1999;



<sup>&</sup>lt;sup>2</sup> Hermann, T.W., Gtowka, F.K., Garrett, E.R., J. Pharm. Sci. 82(11):1102-11, 1993;

<sup>&</sup>lt;sup>3</sup> Soergel, F., et al. Int. J. Clin. Pharmacol. Ther. 43(3):140-149, 2005;

#### **Exceptional Quality & Regulatory Support**



The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high-quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality-related questions.

A regional footprint secures quick and regional-specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations, we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

Access to standard quality and regulatory documentation is now more efficient than ever. Retrieve your documents 24/7 from your World account or sign-up for new RegXellence®, your free online Quality & Regulatory Assistant that provides a unified platform for compliance documents, filing assistance and audit information.



### Sign-up today at: https://info-mypharma.basf.com

#### Contact us for pricing. pharma-solutions@basf.com

This document, or any information provided herein does not constitute a legally binding obligation of BASF and has been prepared in good faith and is believed to be accurate as of the date of issuance. Unless expressly agreed otherwise in writing in a supply contract or other written agreement between you and BASF

- (a) To the fullest extent not prohibited by the applicable laws, BASF EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY FACT OR LAW, INCLUDING ANY IMPLIED WARRANTIES, REPRESENTATIONS OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, NON-INFRINGEMENT, AND ANY REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES, ARISING FROM STATUTE, COURSE OF DEALING OR USAGE OF TRADE and BASF HEREBY EXPRESSLY EXCLUDES AND DISCLAIMS ANY LIABILITY RESULTING FROM OR IN CONNECTION WITH THIS DOCUMENT OR ANY INFORMATION PROVIDED HEREIN, including, without limitati any liability for any direct, consequential, special, or punitive damages relating to or arising therefrom, except in cases of (i) death or personal injury to the extent caused by BASF's sole negligence, (ii) BASF's willful misconduct, fraud or fraudulent misrepresentation or (iii) any matter in respect of which it would be unlawful for BASF to exclude or restrict liability under the applicable laws;
- (b) Any information provided herein can be changed at BASF's sole discretion anytime and neither this document nor the information provided herein may be relied upon to satisfy from any and all obligations you may have to undertake your own inspections and evaluations;
- (c) BASF rejects any obligation to, and will not, automatically update this document and any information provided herein, unless required by applicable law; and (d) The user is responsible for confirming that the user has retrieved the most current version of this document from BASF as appropriate

RegXellence® is a registered trademark of BASF. © 2021 BASF Corporation. All Rights Reserved.

#### **Inspiring Medicines for Better Lives**





BASF\_Pharma in BASF Pharma Solutions

www.pharma.basf.com

