

Description

Ibuprofen sodium dihydrate (ibuprofen sodium) is a water-soluble form of ibuprofen USP. It is useful for the production of solutions, and fast-dissolving and fast-acting tablets. Ibuprofen sodium is a nonsteroidal anti-inflammatory drug that is extremely effective in controlling pain and inflammation without serious gastrointestinal side effects.

Target Specification

	Limit
Appearance	White to off-white powder
Identification	
Infrared spectrum	Matches reference spectrum
HPLC	Matches reference spectrum
Sodium	Yellow flame test
Specific optical rotation (degree)	+0.050 to -0.050
Water, wt%	15.0
Heavy metals, ppm	10
Assay by Titration, wt% (anhydrous basis)	> 98.5
Related substances	
Largest specified impurity, wt%	0.30
Total unknown impurities, wt%	0.25
Total impurities, wt%	0.50
Solvent hexanes, ppm	290

Other Properties
Particle Size (Sieve method)

Lower quartile, microns	50
Median, microns	80
Upper quartile, microns	180

Microbiological

Total viable microbial count, Colony Forming Units/gram	< 100
Total viable yeasts count, Colony Forming Units/gram	< 50

Shipping Information

Container Information

50 kg and 25 kg (net) fiber drums

Shipping Classifications

Proper shipping name: Not regulated for transportation

Caution: Federal law prohibits dispensing ibuprofen in the U.S.A. without appropriate Food and Drug Administration (FDA) approval. For manufacturing, processing or repacking only.

Safety and Handling Information

Ibuprofen requires no special safety measures. As with all chemicals, typical precautions should be taken and the product should be handled with care to prevent contamination of the environment. For specific information on the safe handling of this product, please refer to the material safety data sheet. Copies are available upon request.

Chemical Registration Numbers

CAS: 31121-93-4

The information presented herein is believed to be accurate and reliable, but is presented without guarantee or responsibility on the part of Albemarle Corporation and its subsidiaries. It is the responsibility of the user to comply with all applicable laws and regulations and to provide for a safe workplace. The user should consider any health or safety hazards or information contained herein only as a guide, and should take those precautions which are necessary or prudent to instruct employees and to develop work practice procedures in order to promote a safe work environment. Further, nothing contained herein shall be taken as an inducement or recommendation to manufacture or use any of the herein materials or processes in violation of existing or future patent.



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