

Product Information

Product Data Sheet

Vitamin B12 Crystalline

Product code: 0429155

Description

Vitamin B12 Crystalline is a red to purplish-red, crystalline powder. It is highly hygroscopic and practically odorless and begins to darken at about 200 °C without melting. It is produced by fermentation using a genetically modified micro-organism (GMM) under containment.

Product identification

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Chemical name: Co α -[α -(5,6-Dimethylbenzimidazolyl)]-Co β -cyanocobamide

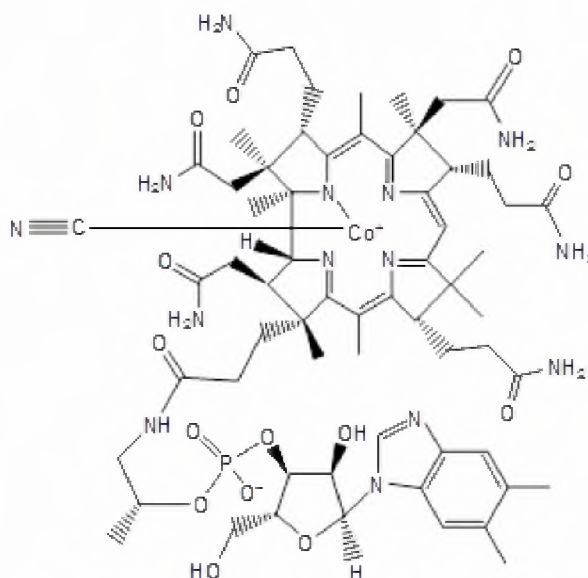
Synonyms: cyanocobalamin; cobalamin; vitamin B₁₂

CAS No.: 68-19-9

EINECS No.: 200-680-0

Empirical formula: C₆₃H₈₈CoN₁₄O₁₄P

Molecular mass: 1355.42 g/mol



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Specification

Appearance:	Red to purplish-red powder
Identification A (Spectrophotometry):	Complies
Absorbance ratio:	
A₃₆₁/A₂₇₈ nm	1.70-1.90
A₃₆₁/A₅₅₀ nm	3.15-3.40
Identification B (UHPLC):	Complies
Loss on drying:	Max. 12.0 % ⁽¹⁾
Assay:	96.0-100.5 % (on dry material)
Related substances:	
7B, 8B-lactocyanocobalamin (Ph. Eur. imp. A)	Max. 0.7%
50-carboxycyanocobalamin (Ph. Eur. imp. B)	Max. 0.5%
34-methylcyanocobalamin (Ph. Eur. imp. C)	Max. 1.5%
32-carboxycyanocobalamin (Ph. Eur. imp. D)	Max. 0.5%
8-epi-cyanocobalamin (Ph. Eur. imp. E)	Max. 0.5%
Cyanocobalamin isomer (Ph. Eur. imp. F)	Max. 0.5%
Any unspecified impurity each, max. 0.2%	Complies
Total impurities	Max. 3.0%
Residual Solvents:	
Acetone	max. 5000 ppm

Solubility

Vitamin B12 Crystalline is sparingly soluble in water, slightly soluble in alcohol, and insoluble in acetone, chloroform and ether.

⁽¹⁾ The beforementioned specification limit of max. 12.0 % refers to the Cyanocobalamin monographs of the US Pharmacopoeia (USP) and the European Pharmacopoeia (Ph. Eur.). An additional tighter limit of max. 3.0% is used for product release, the latter limit is reported on the batch certificate of analysis.

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Stability and storage

Vitamin B12 Crystalline is relatively stable to air and heat if protected from humidity but is sensitive to light. The product is very hygroscopic. Vitamin B12 Crystalline may be stored for 60 months from the date of manufacture in the unopened original container and at a temperature below 25 °C. The “expiry date” is printed on the label. Aqueous solutions are sensitive to alkalis, strong acids and light.

Uses

For use as ingredient in dietary/food supplements, in food and beverage applications, and in pharmaceutical preparations.

This product is not intended for use in the manufacture of sterile drug products. The purchaser assumes all responsibility for additional processing, testing, labelling and registration required for such use.

Compendial compliance

Vitamin B12 Crystalline meets all requirements of the USP, FCC, JP and Ph. Eur when tested according to these compendia.

Safety

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene.

For full safety information and necessary precautions, please refer to the respective DSM Material Safety Data Sheet.

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Additional information

To find out more about our ingredients, please contact your nearest DSM Nutritional Products office.

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