TECHNICAL DATA SHEET

PINHONBIO® 4-Butylresorcinol

Cosmetic-grade 4-butylresorcinol is supplied as white crystals for use in skin care formulations designed to improve the appearance of uneven skin tone.

INCI name	4-BUTYLRESORCINOL
Chemical name	4-Butylbenzene-1,3-diol (4-n-butylresorcinol)
CAS number	18979-61-8
Molecular formula / molar mass	$C_{10}H_{14}O_2$ / 166.22 g/mol

Release specifications

Test	Acceptance criterion
Purity by HPLC	≥99%
Identification by HPLC	Sample peak retention time matches the reference standard.
Appearance / odour	White crystals with a characteristic odour
Resorcinol	≤0.2%
Melting range	49–53 °C
Arsenic / lead	≤2.0 ppm each
Mercury / cadmium	≤1.0 ppm each
Total plate count	≤1,000 CFU/g
Yeasts and moulds	≤100 CFU/g
Diarrheagenic Escherichia coli	Absent in 1 g
Salmonella	Absent in 1 g

Interpreting the analytical specification

The HPLC identification compares the sample peak with the 4-butylresorcinol reference standard. Resorcinol is a separately controlled impurity. For incoming inspection, compare the lot certificate with both limits and check the melting range independently.

Packaging, storage and shelf life

Two inner plastic bags in a plain fibre drum. Keep the liners closed in a cool, dry place protected from light. Reseal promptly after sampling. The shelf life of the raw material is 24 months when properly stored.

Formulation development

4-Butylresorcinol has been studied for its effect on human tyrosinase, an enzyme involved in melanin formation [1]. A vehicle-controlled study evaluated a cream containing 0.1% 4-butylresorcinol [2]. That concentration describes the tested cream. Select the level for a new formulation from its stability, safety assessment and intended market requirements.

Choosing a vehicle and incorporating the crystals

Formulation question	Practical approach
Which solvent should be screened first?	For an alcohol-containing serum, an ethanol–water premix is a documented starting point [3]. Test the actual ethanol-to-water ratio at the intended loading. Additional water or loss of ethanol can change whether the active remains dissolved.
How should an alcohol-free emulsion be evaluated?	Screen the selected emollient or cosolvent separately, using the concentration it must carry in that phase. Record clarity after mixing and cooling before adding the premix to the emulsion.
How concentrated must the premix be?	For a 1 kg trial containing 0.10% raw material, weigh 1.00 g of crystals. If the premix is 50.0 g in total, combine 1.00 g of crystals with 49.0 g of vehicle. The premix must hold 2.00% w/w. This example calculates the loading to test.
How do I check for recrystallisation?	Inspect the premix at ambient temperature and after dilution into the finished base. For clear liquids, look for haze or sediment. For opaque emulsions, examine a thin sample under a microscope. Compare with a sample of the base without the active.

Stability checks in the finished product

Cooling and storage Set aside samples after manufacture and compare them at ambient and low temperature over the intended test interval. Record crystals, colour and any change in emulsion texture. The raw-material melting range of 49–53 °C alone cannot establish a mixing temperature or guarantee solubility after cooling.

Light and packaging Compare samples in the intended pack with a light-protected control. Record changes in colour and odour. Where active retention is critical, measure 4-butylresorcinol at baseline and during storage using an HPLC method verified for the finished matrix.

pH and compatibility Record the final pH of water-containing products and check it again during stability testing. Establish a working pH range and compatible solvent system for the particular base.

Technical references

[1] Kolbe L et al. Human tyrosinase inhibition by 4-n-butylresorcinol. J Eur Acad Dermatol Venereol. 2013. doi.org/10.1111/jdv.12051

[2] Huh SY et al. Vehicle-controlled study of a 0.1% 4-n-butylresorcinol cream. Ann Dermatol. 2010. pubmed.ncbi.nlm.nih.gov/20548876/

[3] External skin preparation and production method of same. US 2014/0023604 A1. Formulation examples, Composition B. patents.google.com/patent/US20140023604A1/en

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