Dibutyl Sebacate

1 Nonproprietary Names

USPNF: Dibutyl sebacate

2 Synonyms

Butyl sebacate; decanedioic acid, dibutyl ester; dibutyl decanedioate; dibutyl 1,8-octanedicarboxylate; *Kodaflex DBS*.

3 Chemical Name and CAS Registry Number

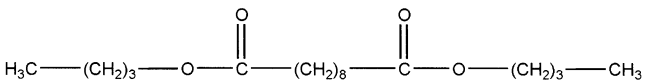
Decanedioic acid, di-*n*-butyl ester [109-43-3]

4 Empirical Formula Molecular Weight

$C_{18}H_{34}O_4$ 314.47

The USPNF 20 describes dibutyl sebacate as consisting of the esters of *n*-butyl alcohol and saturated dibasic acids, principally sebacic acid.

5 Structural Formula



6 Functional Category

Plasticizer.

7 Applications in Pharmaceutical Formulation or Technology

Dibutyl sebacate is used in oral pharmaceutical formulations as a plasticizer for film coatings on tablets, beads, and granules, at concentrations of 10–30% by weight of polymer.[1,2] It is also used as a plasticizer in controlled-release tablets and microcapsule preparations.[3,4]

Dibutyl sebacate is also used as a synthetic flavor and flavor adjuvant in food products; for example, up to 5 ppm is used in ice cream and nonalcoholic beverages.

8 Description

Dibutyl sebacate is a clear, colorless, oily liquid with a bland to slight butyl odor.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for dibutyl sebacate.

Test	USPNF 20
Specific gravity	0.935–0.939
Refractive index	1.429–1.441
Acid value	≤0.1
Saponification value	352–357
Assay (of $C_{18}H_{34}O_4$)	≥92.0%

10 Typical Properties

Acid value: 0.02
Boiling point: 344–349°C
Flash point: 193°C
Melting point: −10°C
Refractive index: n_D^{25} = 1.4401
Solubility: soluble in ethanol, isopropanol, and mineral oil; practically insoluble in water.
Specific gravity: 0.937 at 20°C
Vapor density (relative): 10.8 (air = 1)
Vapor pressure: 0.4 kPa (3 mmHg) at 180°C

11 Stability and Storage Conditions

Dibutyl sebacate is stable. It is not reactive with water and hazardous polymerization does not occur. Dibutyl sebacate should be stored in a closed container in a cool, dry location.

12 Incompatibilities

Dibutyl sebacate is incompatible with strong oxidizing materials and strong alkalis.

13 Method of Manufacture

Dibutyl sebacate is manufactured by the esterification of *n*-butanol and sebacic acid in the presence of a suitable catalyst, and by the distillation of sebacic acid with *n*-butanol in the presence of concentrated acid in benzene solution.

14 Safety

Dibutyl sebacate is used in cosmetics, foods, and oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. Following oral administration, dibutyl sebacate is metabolized in the same way as fats. In humans, direct eye contact and prolonged or repeated contact with the skin may cause very mild irritation. Acute animal toxicity tests and long-term animal feeding studies have shown no serious adverse effects to be associated with orally administered dibutyl sebacate.

LD_{50} (rat, oral): 16 g/kg[5]

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. It is recommended that eye

protection be used at all times. When heating this product, it is recommended to have a well-ventilated area, and the use of a respirator is advised.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (oral capsules and tablets).

17 Related Substances

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18 Comments

As dibutyl sebacate is an emollient ester, the personal care grade is recommended for use in cosmetics, hair products, lotions, and creams.

The EINECS number for dibutyl sebacate is 203-672-5.

19 Specific References

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4 Zhang ZY, Ping QN, Xiao B. Microencapsulation and characterization of tramadol-resin complexes. *J Control Release* 2000; **66**: 107–113.

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20 General References

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Ozturk AG, Ozturk SS, Palsson BO, *et al.* Mechanism of release from pellets coated with an ethylcellulose-based film. *J Control Release* 1990; **14**: 203–213.

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21 Authors

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22 Date of Revision

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