Shellac

1 Nonproprietary Names

BP: Shellac
JP: Purified shellac, White shellac
PhEur: Lacca
USPNF: Shellac

2 Synonyms

Bleached shellac; *CertiSeal*; dewaxed orange shellac; E904; lac; *Mantrolac R-49*; orange shellac; refined bleached shellac; regular bleached shellac; *Swanlac*.

3 Chemical Name and CAS Registry Number

Shellac [9000-59-3]

4 Empirical Formula Molecular Weight

Shellac is a naturally occurring material consisting of a complex mixture of constituents that may be obtained in various refined or modified forms; *see* Section 13.

The PhEur 2002 defines four types of shellac depending on the nature of the treatment of the crude shellac (seed lac): wax-containing shellac; bleached shellac; dewaxed shellac; and bleached dewaxed shellac. The USPNF 20 similarly defines four types of shellac: orange shellac; dewaxed orange shellac; regular bleached (white) shellac; and refined bleached shellac. The JP 2001 defines two types: purified shellac and white shellac (bleached).

Elementary analysis reveals that shellac contains carbon, hydrogen, oxygen, and a negligible amount of ash. A formula of $C_{60}H_{90}O_{15}$ and an average molecular weight of 1000 is assigned to shellac. Although its composition has not been fully elucidated, the main component of shellac (about 95%) is a resin that gives a mixture of aliphatic and alicyclic hydroxy acids and polyesters on mild basic hydrolysis. Some of the compounds identified and named include aleuritic, butolic, kerrolic, and shellolic acids. The major component of the aliphatic fraction is aleuritic acid, while the major component of the alicyclic fraction is shellolic acid.

Shellac also contains about 5–6% wax along with gluten, other impurities, and a small amount of pigment. The exact composition of shellac may vary depending upon the country of origin and method of manufacture.[1,2]

5 Structural Formula

See Section 4.

6 Functional Category

Coating agent.

7 Applications in Pharmaceutical Formulation or Technology

Shellac has been used in pharmaceutical formulations for the enteric coating of tablets and beads,[3] the material usually being applied as a 35% w/v alcoholic solution; *see also* Section 18.

It is a primary ingredient of pharmaceutical printing inks for monogramming capsules and tablets, and can be applied as a 40% w/v alcoholic solution. It has also been used to apply one or two sealing coats to tablet cores to protect them from moisture before being film- or sugar-coated.

Shellac may also be used in food products and cosmetics.

8 Description

Shellac is a naturally occurring material that may be obtained in a variety of refined or modified forms; *see* Sections 4 and 13.

Generally, shellac occurs as hard, brittle, transparent, pale lemon-yellow to brownish orange-colored flakes of varying size and shape; it is also available as a powder. Shellac is tasteless and odorless, or may have a faint odor.

9 Pharmacopeial Specifications

see Table I.

Table I: Pharmacopeial specifications for shellac.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	—	+	+
Characters	—	+	—
Heavy metals	⩽10 ppm	⩽10 ppm	⩽0.001%
Arsenic	⩽5 ppm	⩽3 ppm	—
Ethanol-insoluble substances	⩽2.0%	—	—
Rosin	+	—	+
Total ash	⩽1.0%	—	—
Acid value (on dried basis)	60–80	65–95	+
Dewaxed orange shellac	—	—	71–79
Orange shellac	—	—	68–76
Refined bleached shellac	—	—	75–91
Regular bleached shellac	—	—	73–89
Loss on drying	⩽2.0%	+	+
Dewaxed orange shellac	—	—	⩽2.0%
Orange shellac	—	—	⩽2.0%
Refined bleached shellac	—	—	⩽6.0%
Regular bleached shellac	—	⩽6.0%	⩽6.0%
Unbleached shellac	—	⩽2.0%	—
Wax	⩽20 mg	—	+
Dewaxed orange shellac	—	—	⩽0.2%
Orange shellac	—	—	⩽5.5%
Refined bleached shellac	—	—	⩽0.2%
Regular bleached shellac	—	—	⩽5.5%

10 Typical Properties

Alcohol-insoluble matter: ⩽1.0%
Ash: ⩽1.0%
Density: 1.035–1.140 g/cm^3
Hydroxyl value: 230–280
Iodine number: 10–18
Melting point: 115–120°C
Refractive index: n_D^{20} = 1.5210–1.5272

Saponification value: 185–210
Solubility: *see* Table II.

Table II: Solubility of shellac.

Solvent	Solubility at 20°C
Alkalis	Soluble
Aqueous ethanolamine solution	Soluble
Benzene	1 in 10
Ethanol	1 in 2
Ethanol (95%)	1 in 1.2 (very slowly soluble)
Ether	1 in 8
Hexane	Practically insoluble
Propylene glycol	1 in 10
Water	Practically insoluble

11 Stability and Storage Conditions

After long periods of storage, shellac becomes less readily soluble in alcohol, less fluid on heating, and darker in color. Shellac-coated tablets may have increased disintegration times following prolonged storage owing to changes in the physical characteristics of the coating; *see* Section 18.[4]

Shellac should be stored in a well-closed container at temperatures below 27°C. Wax-containing grades should be mixed before use to ensure uniform distribution of the wax.

12 Incompatibilities

Shellac is chemically reactive with aqueous alkalis, organic bases, alcohols, and agents that esterify hydroxyl groups. Therefore, shellac should be used with caution in the presence of such compounds.

13 Method of Manufacture

Shellac or lac is obtained by purification of the resinous secretion of the insect *Laccifero* (Tachardia) lacca Kerr (Homoptera, Coccidae). The insect lives on the sap of the stems of various trees; secretions are found most abundantly on the smaller branches and twigs, which are broken off and constitute sticklac. After scraping of the twigs and soaking in water, the water-soluble components are removed by treatment with dilute alkali. The resulting water-insoluble material is called seed lac.

Historically, seed lac was processed into shellac by melting the seed lac in a muslin bag suspended over a fire. Shellac could then be squeezed from the bag by hand and poured into molds to produce button shellac. Alternatively, the molten shellac was collected and allowed to cool as discs or wafer-thin sheets.

Today, most shellac is produced on a commercial scale using machine processes involving extraction from seed lac using steam heat or solvent extraction with hot ethanol. Shellac produced by the heat and solvent extraction processes cannot usually be differentiated by chemical tests.

Various different grades of modified or refined shellac are available, which may be broadly defined as either bleached or orange shellac. Orange shellac is essentially the crude shellac obtained from seed lac, as described above. It may retain most of its wax or be dewaxed, and may contain less of the natural color than was originally present. The quantities of wax, coloring material, and other impurities present may vary; the physical properties of orange shellac may therefore also vary depending upon its source or the processing methods used.

Bleached or white shellac is obtained by dissolving shellac in aqueous sodium carbonate, bleaching the solution with sodium hypochlorite, and precipitating the bleached shellac with 2 N sulfuric acid. Removal of wax by filtration results in a refined bleached shellac.

Most commercial shellac is produced in India and Thailand; smaller amounts come from Burma and Malaysia.

14 Safety

Shellac is used in oral pharmaceutical formulations, food products, and cosmetics. It is generally regarded as an essentially nonirritant and nontoxic material at the levels employed as an excipient. However, excessive consumption of shellac may be harmful.

15 Handling Precautions

Shellac may be harmful if ingested in large quantities. It is irritating to the eyes, and to the respiratory system if inhaled as dust. Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection, gloves, and a dust respirator are recommended. Shellac should be handled in a well-ventilated environment.

16 Regulatory Status

Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Aleuritic acid; pharmaceutical glaze; shellolic acid

Aleuritic acid

Empirical formula: $C_{16}H_{32}O_5$
Molecular weight: 304.42
CAS number: [533-87-9]
Synonyms: DL-*erythro*-9,10,16,-trihydroxyhexadecanoic acid; 9,10,16-trihydroxypalmitic acid; 8,9,15-trihydroxypentadecane-1-carboxylic acid.
Melting point: 100–101°C
Solubility: soluble in methanol.
Comments: component of shellac. The EINECS number for aleuritic acid is 208-578-8.

Pharmaceutical glaze

Comments: pharmaceutical glaze is a specially denatured alcoholic solution of shellac containing between 20% and 57% of anhydrous shellac. It may be prepared using either ethanol or ethanol 95% and may contain waxes and titanium dioxide as an opacifing agent.

Shellolic acid

Empirical formula: $C_{15}H_{20}O_6$
Molecular weight: 296.33
CAS number: [4448-95-7]
Synonyms: 10β,13-dihydroxycedr-8-ene-12,15-dioic acid; 2,3,4,7,8,8α-hexahydro-4-hydroxy-8-(hydroxymethyl)-8-methyl-1*H*-3α,7-methanoazulene-3,6-dicarboxylic acid.
Melting point: 204–207°C
Comments: component of shellac.

18 Comments

Shellac is insoluble in acidic conditions but is soluble at higher pH; it therefore appears to be a suitable enteric-coating material. However, in practice, delayed disintegration and drug release may occur *in vivo* as shellac is insoluble in the slightly acidic environment of the upper intestine. Additives such as lauric acid may be added to plasticize and improve disintegration of shellac films, although shellac tends not to be used in new drug formulations as an enteric-coating agent.

Studies using the USP disintegration test for enteric-coated tablets have indicated that there is a marked increase in the disintegration time over a 6-month storage period for shellac-coated tablets.[4] It is likely that this effect is due to the polymerization of shellac, which occurs over storage periods of this duration.

The EINECS number for shellac is 232-549-9.

19 Specific References

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4 Luce GT. Disintegration of tablets enteric coated with CAP. *Manuf Chem Aerosol News* 1978; **49**(7): 50, 52, 67.

20 General References

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21 Authors

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22 Date of Revision

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