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Review

Safety assessment of kola nut extract as a food ingredient

George A. Burdock a,*, Ioana G. Carabin b, Christine M. Crincoli a

- a Burdock Group, 801 N. Orange Ave Suite 710, Orlando, Fl. 32829, United States
- ^b Women in Science, 3785 7th Lane, Vero Beach, FL 32968, United States

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ABSTRACT

Kola nut extract is used in the food industry as a flavoring ingredient. Kola nut extract is derived from the seeds of primarily two tropical *Cola* species (*Cola nitida* (Vent.) Schott *et* Endl. or *Cola acuminata* (Beauv.) Schott *et* Endl.) of the Family, Sterculiaceae. Present day consumption of kola nut extract is 0.69 mg/kg/day. Caffeine and theobromine are two important constituents of kola nuts. Although limited biological data are available for kola nut extract specifically, the published data of the major constituents of kola nuts suggest the pharmacological/toxicological properties of kola nut extract, parallel to those of a roughly equivalent dose of caffeine. Frank developmental/reproductive effects have not been reported and changes in offspring cannot be extrapolated to humans. A NOEL/NOAEL cannot be defined for repeated oral exposure to kola nut extract from available data. Notwithstanding the foregoing, U.S. consumers have a history of safe consumption of cola-type beverages containing kola nut extract that dates at least to the late 19th Century, with a significant global history of exposure to the intact kola nuts that date centuries longer.

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1. Introduction

Kola nut extract (CAS No. 68916–19-8) consists of an extract of the nuts (or seeds) from the pods of primarily two species of the *Cola* plant (Family, Sterculiaceae). In the food industry, kola nut extract is used as a flavoring ingredient and is approved for food uses by the Council of Europe (CoE), US Food and Drug Administration (FDA), the Flavor and Extract Manufacturers' Association (FEMA), and the International Organisation of Flavor Industries (IOFI). This review evaluates the safety-in-use of kola nut extract as a food ingredient.

1.1. Historical perspective

There is evidence that intra-African trade in kola nuts dates back to at least the 14th Century, with firm written records of Afri-

Abbreviations: CAS, chemical abstracts service; CFR, code of federal regulations; CoE, Council of Europe; DINFO, daily intake via natural food occurrence; EC, European Community; EU, European Union; FCC, Food Chemicals Codex; FEMA, Flavor and Extract Manufacturers' Association; FDA, Food and Drug Administration; GRAS, generally recognized as safe; IARC, International Agency for Research on Cancer; IOFI, International Organization of Flavor Industries; MRCA, Market Research Corporation of America; MSDI, maximum survey-derived daily intake; NACGM, National Association of Chewing Gum Manufacturers; NAS, National Academy of Sciences; NOEL/NOAEL, no observed (adverse) effect level; OTC, overthe-counter; PADI, possible average daily intake; PMDI, possible maximum daily intake; USDA, United States Department of Agriculture.

* Corresponding author. Tel.: +1 407 802 1400; fax: +1 407 802 1405. E-mail address: gburdock@burdockgroup.com (G.A. Burdock). can exports to England and the U.S. which date to the mid-19th Century. It was in 1886 that the druggist, John S. Pemberton, from Atlanta, Georgia, invented the popular soft drink, Coca-Cola®, by combining coca and kola extracts for use as a headache and hangover remedy (Kiple and Ornelas, 2000b). In its 1977 survey of industry on food additives in the U.S., the US National Academy of Sciences (NAS) indicated that the first reported use of kola nut extract was in 1935 (NAS, 1979).

The kola nut's primary social and economic significance lies in its being a very concentrated source of the central nervous system (CNS) stimulant, caffeine, with one nut containing more caffeine than two large cups of American coffee (Kiple and Ornelas, 2000b). Kola nuts have been, by one author's expression, "...the indispensable tonic of the west (*sic*) African people from time immemorial" (Arctander, 1960). Even today, chewing of fresh kola nut remains a 'social lubricant', with strong cultural significance for many indigenous West African people, particularly those of Islamic faith who are forbidden to consume alcohol (Blumenthal, 2000).

1.2. Description, natural occurrence and sources

Kola nut extract is an aqueous or ethanolic extract of the dried cotyledons (*i.e.*, embryo leaves from the seeds contained in a seed or nut pod) of the *Cola* plant (Family, Sterculiaceae). Referred to generically in some references by the Latin, '*Colae semen*', the nuts for the commercial extract are derived, almost exclusively, from two species of *Cola*, either *Cola nitida* (Vent.) Schott *et* Endl. or *Cola*

acuminata (Beauv.) Schott et Endl; three additional species of minor importance are listed in the table (Table 1). Cola extract may be fluid, soft, or dried, and may be produced as tannin free. It should be noted that in the literature, 'Kola' and 'Cola' are frequently interchanged; the spelling and name, 'Kola nut extract', will be used in this review (Bradley, 1992; Burdock, 1997; Blumenthal, 2000; Burdock, 2005). Synonyms and other descriptive characteristics of kola nut extract are provided in Table 2.

The Cola species of interest originated in western Africa (the plant is indigenous of Togo, Sierra Leone and Angola), but is now extensively cultivated in other tropical areas of Africa and Central and South America. Most sources describe the source plant as an evergreen tree of moderate height (40-60 feet), with greenish-yellow or white flowers spotted with purple, and leaves that are six to eight inches long, elliptoid to ovate and pointed at both ends. The star-shaped fruits (Fig. 1) consist of follicles, or green wrinkled pods, that contain 1–10 bean-like seeds (PDR Herbal, 2004). The cotyledons, or cola nuts, comprise the bulk of the seed; they generally are two in number, but may be as many as five. The cola nuts are brownish, about the size of a chestnut, and have a bitter, astringent taste when fresh. After drying, however, the taste becomes milder and faintly aromatic, with an odor that hints of nutmeg. Of the two species, *C. nitida* is reported to be the most important and valuable, though the literature provides no more basis for this assessment than that this species grows cola nuts that are large in comparison to the small cola nuts of *C. acuminata* (Felter and Lloyd, 1898; Arctander, 1960; Grieve, 1971; Burdock, 1997; Blumenthal, 2000; Kiple and Ornelas, 2000a; Burdock, 2005).

In addition to being a significant source of caffeine, as noted above, kola nuts also contain modest amounts of the related methylxanthine, theobromine. Flavonoids, anthocyanins, and tannins (all of which are various permutations of plant phenolic compounds) have also been reported to be present in significant amounts (Harborne et al., 1999a,b,c; Burdock, 2005). Some specific chemical constituents of the *C. acuminate* kola nut that has been quantified and/or identified were reported by Duke (1992) (Table 3); some representative structures are provided in (Fig. 2). In fresh kola nuts, the caffeine is largely complexed through hydrogen bonding to the abundant catechins and tannins; whereas, in the dried nuts, oxidative degradation and polymerization of low molecular weight polyphenolics results in liberation of the caffeine unless the material is stabilized (Bradley, 1992; Evans, 1996).

1.2.1. Specifications

Specifications of kola nut extract for use as an ingredient for addition to food have not been published by any relevant authoritative body. Herbal medicinal preparations of kola nut extract are typically standardized for methylxanthine (e.g., caffeine and theo-

Table 1Cola spp. (http://www.itis.gov/servlet/SingleRpt/SingleRpt?search_topic = TSN& search_value = 500687).

Kingdom	Plantae – plants
Subkingdom	Tracheobionta – vascular plants
Superdivision	Spermatophyta – seed plants
Division	Magnoliophyta – flowering plants
Class	Magnoliopsida – dicotyledons
Subclass	Dilleniidae-
Order	Malvales -
Family	Sterculiaceae – cacao family
Genus	Cola Schott & Endl. – cola
Species	Cola nitida (Vent.) A. Chev. – ghanja kola
Species	Cola acuminata (Beauv.) Schott & Endl abata cola
Species	Cola anomala Schumann – anomalous cola
Species	Cola pachycarpa Schumann – cola
Species	Cola verticillata (Thonn.) Stapf ex A. Chev – cola

bromine) content, usually 1.5–2.5% (Bradley, 1992; Blumenthal, 1998). However, reports of caffeine content can vary between 1.5% and 3.8%, depending on the variety of nut characterized, as well as the treatment of the kola nut. Treatments include fresh (raw) nuts, cured nuts (6 months), sun-dried nuts (sun dried for 40 days), and, milled and stored nuts (sun-dried nuts milled and stored for 12 months) (Atawodi et al., 2007).

1.2.2. Economic uses

Kola nut extract is used in the food industry as a natural flavoring agent (Ash and Ash, 1995; Burdock, 1997). The extract also finds use as a natural herbal preparation for the treatment of mental and physical fatigue (Bradley, 1992; Blumenthal, 1998). The nut itself is also exported worldwide for extraction and is used in the manufacture of methylxanthine-based pharmaceuticals (Blumenthal, 2000).

1.2.3. Regulatory history

Kola nut extract has been approved for use in food by CoE, FDA, FEMA, and the IOFI (Table 4). CoE has classified kola nut extract as Category 4, which is defined as "plants, animals and other organisms, and parts of these or products thereof, and preparations derived therefrom, not normally consumed as food items, herbs or spices in Europe, which contain defined 'active principles' or 'other chemical components' requiring limits on use levels" (CoE, 2000). The FDA and FEMA have determined kola nut extract to be GRAS for use as a flavoring ingredient. IOFI has classified the extract as, "natural flavor isolated by physical methods" (Clydesdale, 1997). The FDA has also approved kola nut extract for use as an inactive ingredient in certain oral and rectal pharmaceutical preparations (FDA, 2005). Kola extract is approved by German Commission E (Blumenthal, 1998).

Certain chemical constituents of kola nuts have also been approved in pure form for use in foodstuffs. Caffeine is regulated by FDA as GRAS for use in cola-type beverages up to a maximum use level of 0.02% (0.2 mg/mL) (21 CFR § 182.1180). Both caffeine (Flavouring Substances Registry, No. 16.016) and theobromine (No. 16.032) have been approved by the European Commission as flavoring substances for use in or on foodstuffs (EC, 2002a,b). Caffeine is also regulated as a drug by FDA, specifically as the only active ingredient approved for use in over-the-counter (OTC) stimulant drug products (21 CFR § 340); pre-existing uses in OTC weight control drug products have been disallowed as part of the Agency's ongoing OTC Drug Review (21 CFR § 310.545).

FEMA (Burdock, 2005) and the National Association of Chewing Gum Manufacturers (NACGM, 1977) reported food uses of kola nut extract which are provided in Table 5.

1.3. Consumption

Several methods can be applied to estimate the consumption of a substance in the diet (refer to Burdock and Carabin (2009) for a detailed explanation). For example, the *per capita* estimate of intake is based on "disappearance data" (i.e., production data) used for food and the differences between the two sources of data (NAS versus FEMA) are based on an estimate of how much is reported versus actual value (refer to Table 6). Production value estimated by NAS is 489,000 lbs for the year 1987 (NAS, 1989) for a per capita consumption of 41.42, or 0.69 mg/kg/day (for an average individual weighing 60 kg) and a possible methylxanthine intake of 0.6–1.5 mg/day. A production value of 48,400 lb reported by FEMA (Lucas et al. 1999) yields a per capita extract consumption of 2.88 or 0.05 mg/kg/day and a possible methylxanthine intake of 0.04–0.10 mg/day.

In contrast to the *per capita* method of estimation, the Theoretical Added Maximum Daily Intake (TAMDI) values such as FEMA

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