Exponent

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September 28, 2022

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Subject: GRAS Notice for the Use of Shea Stearin in Select Foods

Dear Sir/Madam:

In accordance with 21 CFR part 170, subpart E, AAK USA Inc. hereby provides a notice of a claim that the food ingredient described in the enclosed document is excluded from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because the notifier has concluded such use to be generally recognized as safe (GRAS), based on scientific procedures.

The enclosed materials include Form 3667, one paper copy of the GRAS notice, and one compact disk (CD) with a complete electronic copy of the GRAS notice. If you have any questions or require additional information, please do not hesitate to contact me at 202-772-4953 or mmurphy@exponent.com.

Sincerely,

[redacted]

Mary M. Murphy, MS, RD
Senior Managing Scientist

2007430.000 - 5928

Generally Recognized As Safe (GRAS) Conclusion for the Use of Shea Stearin in Select Foods

SUBMITTED BY:

AAK USA Inc.
499 Thornall Street
Edison, NJ 08837

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
5001 Campus Drive
College Park, MD 20740

CONTACT FOR TECHNICAL OR OTHER INFORMATION:

Mary M. Murphy, M.S., RD
Exponent, Inc.
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Washington, DC 20036

September 28, 2022

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List of Acronyms

%	percent
°C	degrees Celsius
µg	microgram
CFR	Code of Federal Regulations
CFU	colony forming unit
cGMP	current good manufacturing practice
DHHS	U.S. Department of Health and Human Services
DM	dry matter
EC	European Commission
EDI	estimated daily intake
EFSA	European Food Safety Authority
EU	European Union
FARE	Foods Analysis and Residues Evaluation Program
FD&C	U.S. Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
FNDDS	Food and Nutrient Database for Dietary Studies
g	gram
GMP	good manufacturing practices
GRAS	generally recognized as safe
GRN	GRAS Notice
h	hour
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kcal	kilocalorie
kg	kilogram
kJ	kilojoule
L	liter
LOD	limit of detection
m	meter
mg	milligram
mL	milliliter
NaOH	sodium hydroxide
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
NOAEL	no observed adverse effect level
RBD	refined, deodorized, bleached
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

Part 1: Signed Statements and Certification

AAK USA Inc. (AAK) submits to the U.S. Food and Drug Administration (FDA) this generally recognized as safe (GRAS) notice in accordance with 21 CFR part 170, subpart E.

Name and Address of Notifier

Jeffrey B. Fine, Ph.D.
Benjamin C. Schwartz
AAK USA Inc.
499 Thornall Street
Edison, NJ 08837

Name of GRAS Substance

The substance that is the subject of this GRAS notice is shea stearin.

Intended Conditions of Use

The intended use of shea stearin is use at a maximum level of 3.5 g to 45 g per 100 g in select foods, namely, plant-based meat & poultry analogues including burgers/ground meat and sausages; plant-based dairy alternatives and dairy analogues (including butter, cheese, cream cheese, creamers, frozen desserts, milks, sour cream, and yogurt); fillings for cookies & wafers and confectionery; nut/seed spreads and butters; margarines/spreads; and bakery products including bars, biscuits, cakes, cookies, laminated dough products (e.g., Danish pastry/croissants), muffins, and pie crust.

Basis for Conclusion of GRAS Status

AAK's conclusion of GRAS status for the intended use of shea stearin in select foods is based on scientific procedures in accordance with 21 CFR §170.30(a) and (b).

Pre-Market Approval Exclusion Claim

The intended use of shea stearin in select foods is not subject to the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because AAK has concluded that such use is GRAS through scientific procedures.

Availability of Information

The data and information that serve as the basis for this GRAS conclusion, as well as the information that has become available since the GRAS conclusion, will be sent to the FDA upon

request, or are available for the FDA's review and copying during customary business hours at the office of Exponent, Inc., located at 1150 Connecticut Ave, NW, Washington, DC 20036.

Exemptions from Disclosure

It is our view that none of the data and information in Parts 2 through 7 of the GRAS notice are exempt from disclosure under the Freedom of Information Act (FOIA).

Certification Statement

On behalf of AAK, I hereby certify that, to the best of my knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, known to me and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

[redacted]

Jeffrey B. Fine, Ph.D.

Sept. 28, 2022

Date

Part 2. Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Common or Usual Name

The common or usual name of the subject of this dossier is "shea stearin," a fractionated solid derivative of shea butter.

Identity

Overview of Shea-Derived Products

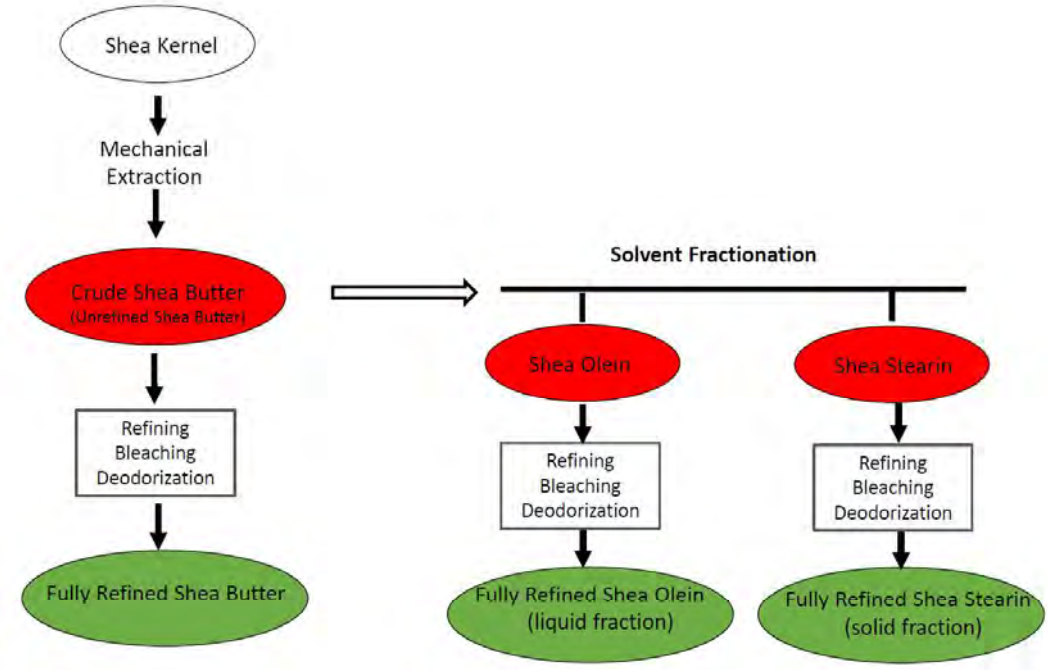
Shea (*Vitellaria paradoxa C.F. Gaertn;* synonyms*: Butyrospermum paradoxum, Butyrospermum parkii*) is an agro-managed tree crop indigenous to Africa from the Sapotaceae family that is found in the wild, growing in parklands in large parts of Sub-Saharan Africa and savannah ecosystems, from Gambia in the west to Uganda in the east. The shea tree provides fruits for direct consumption and has historically been a traditional African food plant. Shea seeds, known as the sheanut or kernels, are isolated from the fruit bodies. Kernels may be sold for further processing into crude or unrefined shea butter. Shea butter exported from Africa is refined and used primarily in food products and the balance is used in the cosmetic sector (Honfo *et al.*, 2014). Shea butter is used extensively for food in Africa (Honfo *et al.*, 2014). Shea stearin is a fractionated product derived from shea butter and solid at room temperature.

Definitions of common terms used for shea-derived substances are summarized below in Table 1. Figure 1 below illustrates the relationship among these products derived from the sheanut. As shown in Figure 1, along with shea stearin, shea olein also is a fractioned product derived from shea butter.

Table 1. Common shea terminology

Term	Definition
Shea butter	Fat extracted from the shea kernel; may be raw or refined
Shea olein	Liquid fraction of shea butter; oleic acid is predominant fatty acid
Shea stearin	Solid fraction of shea butter; stearic acid is predominant fatty acid
Sheanut oil	Used in 21 CFR §184.1702 to represent the solid fraction
Shea sterols/ triterpenes	Primary form of unsaponifiables in shea, including sterols (largely butyrospermol, α-spinasterol and Δ7-stigmastenol), and triterpene alcohols (largely α-amyrin, lupeol, and β-amyrin)

Figure 1. Shea stearin and other shea-derived products



Composition of Shea Stearin

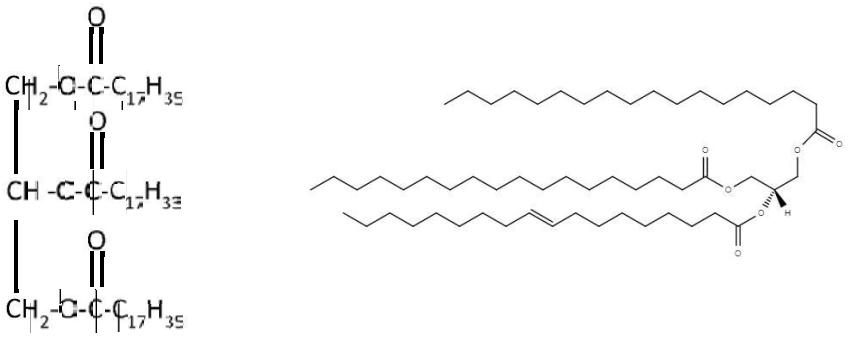
Shea butter can be separated into solid (shea stearin) and liquid (shea olein) fractions. Similar to other food-grade vegetable oils, shea stearin is composed of triglycerides, primarily comprising stearic and oleic acids, and unsaponifiable matter including triterpene alcohols, sterols, phenols, and tocopherols.

Main Components of Shea Stearin

Shea stearin is composed of triglycerides comprising primarily stearic and oleic acids, with lesser amounts of palmitic acid, linoleic acid, and other fatty acids. Natural variability in the fatty acid profiles is common, in part due to location in which the shea trees are grown (Honfo *et al.*, 2014). The predominant triglyceride present in shea stearin is 1,3-distearoyl-2-oleoylglycerol (StOSt), which accounts for roughly 75% of the triglycerides by weight. 1-Stearoyl-2,3-dioleoylglycerol (StOO) and 1-palmitoyl-2-oleoyl-3-stearoylglycerol (POSt) account for an additional 10% of triglycerides by weight (Zhang *et al.*, 2017). Stearic acid is typically found in the 1- and 3-positions in these triglycerides. StOSt, StOO, and POSt are described as shown in Tables 2 through 4 below, summarized from the European Inventory of Existing Commercial Chemical Substances “Nomenclature of Shea butter”.

1,3-Distearoyl-2-oleoylglycerol (StOSt)

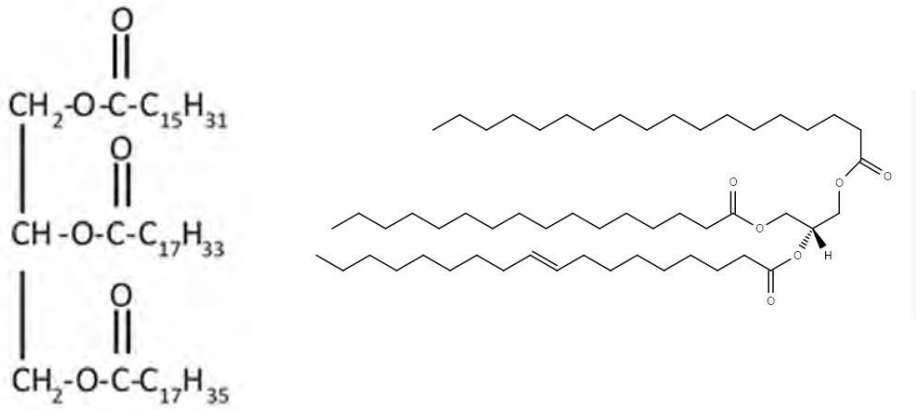
Table 2. Description of 1,3-distearoyl-2-oleoylglycerol (StOSt)

Parameter	Description
CAS Number:	2846-04-0
Structure:	
Empirical Formula:	$C_{57}H_{108}O_6$
Molecular Weight:	889.464 g/mol
Synonyms:	1,3-bis(octadecanoyloxy)propan-2-yl (9Z)-octadec-9-enoate, 1,3-bis(stearoyloxy)-2-propanyl (9Z)-9-octadecenoate, 1,3-bis(stearoyloxy)propan-2-yl (9Z)-octadec-9-enoate, 1,3-distearo-2-olein
Physical Characteristics:	Physical state (20°C and 101.3 KPa): Solid Melting/freezing point: 44.0°C (β'-form) Color: White to very faint yellow Density: 0.9±0.1 g/cm3 Boiling point: 817.6±35.0 °C at 760 mmHg
Found in (mol %):	shea butter (40.9%), cocoa butter (25.2%), illipe fat (44%), tallow (4.8%)

Data sources: Berry, 2009; Di Vincenzo *et al.*, 2005; Padley *et al.*, 1986

1-Palmitoyl-2-oleoyl-3-stearoylglycerol (POSt)

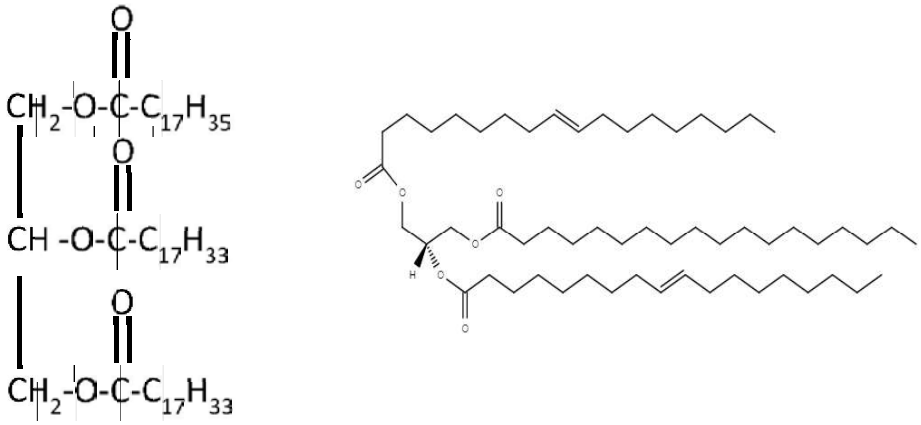
Table 3. Description of 1-palmitoyl-2-oleoyl-3-stearoylglycerol (POSt)

Parameter	Description	
CAS Number:	2190-27-4-1	
Structure:		
Empirical Formula:	$C_{55}H_{104}O_6$	
Molecular Weight:	861.41 g/mol	
Synonyms:	1-palmito-3-stearo-2-olein; 1-(((1-oxohexadecyl)oxy)methyl)-2-((1-oxooctadecyl)oxy)ethyl (Z)-9-octadecenoate; 1-palmitoyl-2-oleoyl-3-stearin; 2-oleo-3-palmito-1-stearin; 2-oleo-3-stearo-1-palmitin; 2-oleopalmitostearin; 9-octadecenoic acid (Z)-, 1-(((1-oxohexadecyl)oxy)methyl)-2-((1-oxooctadecyl)oxy)ethyl ester	
Physical Characteristics:	Physical state (20°C and 101.3 KPa)	Solid
	Melting/freezing point	37.1°C (β-form)
	Color	White to very faint yellow
	Density	0.915g/cm3
	Boiling point	800.3°C at 760 mmHg
Found in (mol %):	Cocoa butter (46%), shea butter (5.3%), palm oil (5.1%)	

Data sources: Berry, 2009; Di Vincenzo *et al.*, 2005; Padley *et al.*, 1986

1-Stearoyl-2,3-dioleoylglycerol (StOO)

Table 4. Description of 1-stearoyl-2,3-dioleoylglecerol (StOO)

Parameter	Description
CAS Number:	-
Structure:	
Empirical Formula:	$C_{57}H_{106}O_6$
Molecular Weight:	887.4 g/mol
Synonyms:	1,2-dioleoyl-3-stearoyl-rac-glycerol, 1,2-di(cis-9-octadecenoyl)-3-octadecanoyl-rac-glycerol, glycerol 1,2-di-(9Z-octadecenoate) 3-octadecanoate, 1-O-stearoyl-2-O,3-O-bis[(E)-9-octadecenoyl] glycerol
Physical Characteristics:	Physical state (20°C and 101.3 KPa): Liquid Melting/freezing point: 22.35°C in the ß form Color: Colorless to very faint yellow Density: 0.917g/cm3 Boiling point: 819.5°C at 760 mmHg
Found in (mol %):	shea butter (26.8%), illipe fat (6.0%), tallow (5.9%), lard (6.1%), olive oil (3-7%), cocoa butter (4.9%), and butter (1.2%)

Data sources: Berry, 2009; Di Vincenzo *et al*., 2005; Gunstone and Harwood, 2007; Padley *et al*., 1986

Fatty Acid Profile of Shea Stearin

The fatty acid composition of shea stearin is summarized in Table 5, as reported in the literature for an industrially produced product (Danthine *et al*., 2015) along with analytical data for fatty acids in representative batches of the AAK product. The predominant fatty acids in shea stearin are stearic acid and oleic acid, with these two fatty acids typically accounting for approximately 57% and 32% of total fatty acids, respectively. Palmitic acid and linoleic acid are present in concentrations from approximately 3-6% in shea stearin, while other fatty acids (e.g., arachidic acid) are present at less than 2% of total fatty acids.

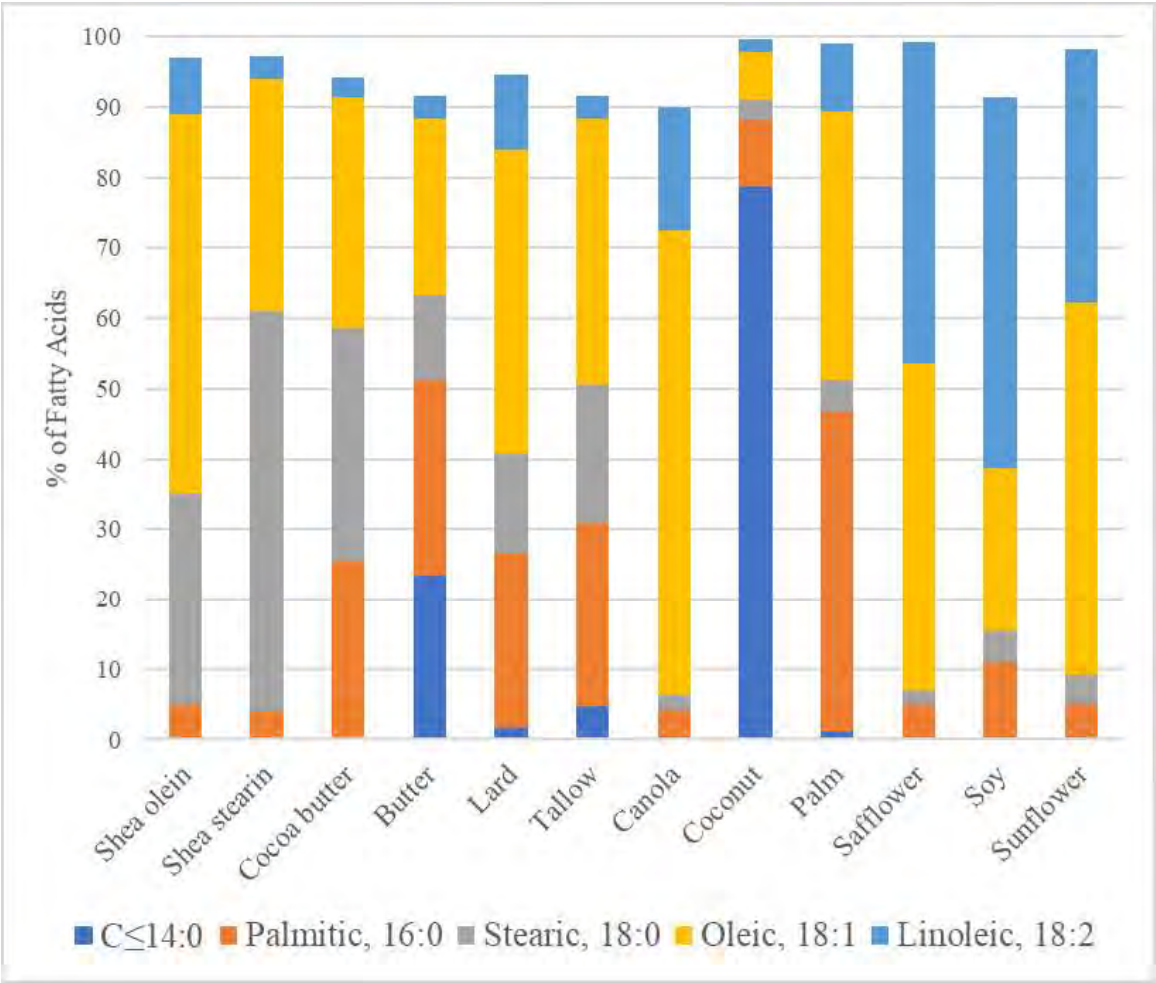
Table 5. Fatty acids in shea stearin

Fatty Acid	Percent of Total Fatty Acids			
	Industrial Product[a]	Batch A[b]	Batch B	Batch C[b]
Palmitic, 16:0	2.9	6.2	4.5	4.3
Stearic, 18:0	60.9	55.8	57.1	57.8
Oleic, 18:1	31.3	31.8	32.2	31.8
Linoleic, 18:2	2.7	3.4	3.5	3.4
Arachidic, 20:0	1.8	1.8	1.8	1.8
Other	0.4	1.0	0.9	0.9

[a] As reported in Danthine *et al*., 2015.
[b] Analytical data from AAK.

The fatty acid compositions of fats/oils commonly consumed in the United States are compared with the primary fatty acids of shea stearin and shea olein in Figure 2 below. As shown by the compositional data, stearic acid, oleic acid, palmitic acid, and linoleic acid are present in varying concentrations in commonly consumed vegetable oils and animal fats. The fatty acid profile of shea stearin is similar to the profile of cocoa butter. Animal fats (i.e., butter, lard, and tallow) are relatively concentrated sources of both stearic acid and oleic acid, while oleic acid is among the predominant fatty acids in many vegetable oils. Of note, the fatty acids in shea stearin are all present in the food supply, with oleic, palmitic, and stearic being among the most common fatty acids consumed in the diet.

Figure 2. Fatty acid composition of shea stearin vs other shea products and commonly consumed oils and fats



Source: Results from analytical data from AAK for shea stearin; data for shea olein from GRN 850; data for all other oils and fats from USDA Legacy Database.

Minor Components of Shea Stearin: Unsaponifiables

The unsaponifiable fraction of an oil includes all of its non-polar components that are petroleum ether-extractable following alkaline hydrolysis (i.e., saponification). Unsaponifiable matter is a common feature of all fats and oils, including those obtained from shea kernels (Honfo *et al.*, 2014). The unsaponifiable content of refined shea butter is approximately 8%, though the concentration may range from 1% to 18% depending on factors such as ripeness of the fruit and growing conditions (Honfo *et al.*, 2014).

Relative to the shea butter from which it is derived, shea stearin contains unsaponifiable matter at a reduced level. The shea stearin that is the subject of this notice contains up to 3% w/w unsaponifiable matter. The concentration of total sterols/triterpenes in shea butter is approximately 3.5 g per 100 g, while concentrations of total sterols/triterpenes in the stearin and olein fractions are approximately 0.5 g and 5.5 g per 100 g, respectively. Analytical data on the shea materials (Table 6) indicate that total sterols/triterpenes account for approximately 50% of total unsaponifiable matter in shea butter and shea stearin (i.e., 3.5 g of 7 g and 0.5 g of 1 g, respectively, in 100 g shea butter or shea stearin) and approximately 90% of total unsaponifiable matter in shea olein (i.e., 5.5 g of 6 g in 100 g shea olein). The sterols/triterpenes from shea butter are therefore concentrated in the olein fraction, and the concentration of sterols/triterpenes in shea stearin is substantially lower relative to concentrations in shea olein and shea butter. The concentration of sterols/triterpenes in shea stearin is 0.5 g per 100 g, or approximately 1/11th (i.e., 9%) the concentration of 5.5 g per 100 g in shea olein. The concentration of the remaining components of the total unsaponifiable matter is similar in both the stearin and olein fractions at approximately 0.5 g per 100 g.

Characteristic of shea butter, and its fractions, is its high proportion of pentacyclic triterpenoids, with 4,4-dimethyltriterpenols accounting for the majority of non-sterol unsaponifiable components, while the balance of unsaponifiables is composed of 4,4-dimethylsterols, 4-desmethylsterols, and 4-α-methylsterols (Baldrick *et al.*, 2001).

Data in Table 6 show that α-amyrin, butyrospermol, lupeol, and β-amyrin account for the majority of sterols/triterpenes in the shea-derived substances. The data also demonstrate that normalized percentages of sterols/triterpenes are comparable in shea butter, shea stearin, and shea olein.

Table 6. Unsaponifiables and sterols/triterpenes in shea butter, shea stearin, and shea olein

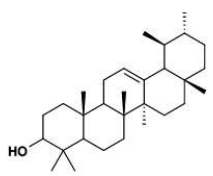
Sterols/Triterpenes	Molecular Structure	Shea Butter[a]	Shea Stearin[b]	Shea Olein[c]
		Concentration, g per 100		
Sterols/triterpenes	-	3.5	0.5	5.5
Total unsaponifiables	-	7	1	6
		Normalized %		
α-Amyrin	triterpene	40.9	35.7	38.6
Butyrospermol	sterol	18.0	20.6	22.2
Lupeol	triterpene	15.7	18.8	19.7
β-Amyrin	triterpene	11.0	10.5	7.0
Taraxasterol	triterpene	7.1	4.8	3.9
Δ7-Stigmastenol	sterol	2.0	3.4	2.9
24-Methylene cycloartenol	sterol	0.6	0.9	1.1
Psi-Taraxasterol	triterpene	0.0	0.4	0.8
Others	-	4.8	4.9	4.0

[a] Single analysis for sterols/triterpenes normalized percentage distribution; data as reported in Appendix A. Total unsaponifiable value represents mean of 4 batches; data as reported in Appendix A.
[b] Mean of 3 batches; data as reported in Appendix A.
[c] Mean of 3 batches as presented in GRN 850.

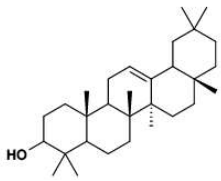
Triterpene Alcohol Compounds

The main components of the unsaponifiable fraction of shea stearin (Table 6) are triterpene alcohols and their acetic and cinnamic acid esters (Akihisa *et al.*, 2010a, 2010b), which is similar to those in the parent material, shea butter. Approximately 95% of total triterpene alcohols are composed of α-amyrin, lupeol, β-amyrin, and taraxasterol (Ito *et al.*, 1974; Itoh *et al*, 1980; Padley *et al.*, 1986; Akihisa *et al.*, 2010b, 2011). The structures of the major triterpene alcohols in shea stearin and the parent material, shea butter, are shown in Figure 3.

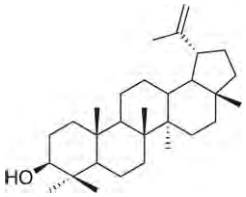
Figure 3. Structure of major triterpene alcohols of shea stearin and shea butter



α-amyrin



β-amyrin

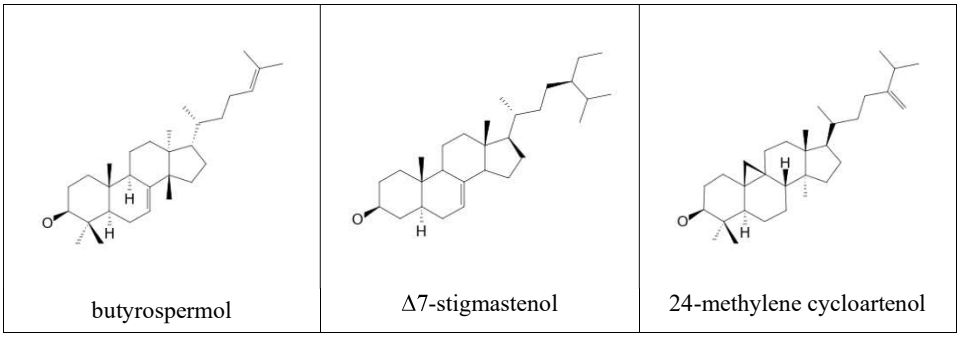


lupeol

Sterol Compounds

The primary sterols component of the unsaponifiable fraction of shea stearin and also the parent material shea butter, are butyrospermol, Δ7-stigmastenol, and 24-methylene cycloartenol (Figure 4).

Figure 4. Structure of major sterols of shea stearin and shea butter



4-Desmethylsterols and Other Components

The compositional analysis of sterols (4,4-dimethylsterols, 4-desmethylsterols) and triterpenes (i.e., 4,4-dimethyltriterpenols) in representative samples of AAK's shea stearin is shown in Table 7 (mean normalized percentages were shown in Table 6); the analytical reports are presented in Appendix A. The average concentration of sterols/triterpenes is approximately 502 mg per 100 g shea stearin (i.e., 0.5%).

Table 7. Sterol and triterpene alcohol composition of shea stearin

	Concentration of sterols/triterpenes							
	mg/100 g sample				Normalized %			
Sterols/Triterpenes	Mean	Batch A	Batch B	Batch C	Mean	Batch A	Batch B	Batch C
α-Amyrin	179.3	167.8	183.4	186.7	35.7	35.3	36.0	35.9
Butyrospermol	103.1	99	103.4	106.8	20.6	20.9	20.3	20.5
Lupeol	94.2	89	95.4	98.2	18.8	18.7	18.7	18.9
β-Amyrin	52.7	49.9	53.7	54.6	10.5	10.5	10.5	10.5
Taraxasterol	24.3	22.3	24.9	25.7	4.8	4.7	4.9	4.9
Δ7-Stigmastenol	16.9	16.6	16.2	17.8	3.4	3.5	3.2	3.4
24-Methylene cycloartenol	4.6	4.5	4.3	4.9	0.9	0.9	0.8	0.9
Psi-Taraxasterol	1.8	2.5	1.8	1.0	0.4	0.5	0.4	0.2
Others	24.7	23.1	26.2	24.9	4.9	4.9	5.1	4.8
Total	501.5	474.6	509.4	520.6	100	100	100	100

Data as reported in Appendix A.

The predominant sterols/triterpenes in shea stearin, shea olein, and shea butter are also present, albeit in lower concentrations, in commonly consumed vegetable oils (Table 8).

Table 8. Sterols/triterpenes composition of some vegetable oils compared to AAK's shea stearin

	Concentration of sterols/triterpenes (mg per 100 g product)						
Sterols/ Triterpenes	AAK's shea stearin[a]	BUNGE shea olein[b]	Shea butter[c]	Olive oil[c]	Palm kernel oil[c]	Safflower oil[c]	Soybean oil[c]
α-Amyrin	179	2138	1760	-	21	8	-
Butyrospermol	103	1229	995	10	7	-	14
Lupeol	94	1091	612	30	9	-	24
β-Amyrin	53	386	306	22	3	8	13
24-Methylene cycloartenol / cyclobranol	5	61	38	14	-	2	-
Taraxasterol	24	212					
Psi-Taraxasterol	2	44					
Others	25	223	115	68	32	47	35
TOTAL	502[d]	5541[d]		~145	~70	~35	~85

[a] AAK Analytical data, average of 3 samples (Table 7 and Appendix A), sterol esters and triterpene esters detected as alcohols.
[b] GRN 850; mean values from analytical data reported in Appendix 1.
[c] Gunstone *et al.*, 2007 as cited in GRN 850.
[d] Includes Δ7-Stigmastenol as shown in Table 7 and GRN 850 Appendix 1.

Production Process

Shea stearin is produced using conventional refining, bleaching, and deodorization operations common throughout the edible oil industry. A flowchart depicting the production of shea stearin from shea kernels is shown in Figure 5.

Incoming shea kernels are visually inspected for mold and other physical defects. Broken, cracked, or moldy kernels and kernels containing >12% moisture are eliminated. Following cleaning and steaming, the oil in the kernels is mechanically extracted by expeller pressing, yielding unrefined shea oil known as raw or crude shea oil ("CRD shea oil" in Figure 5) and shea meal. Residual oil in the meal is extracted with hexane and combined with the expeller pressed oil. Hexane used in the extraction is a non-polar solvent commonly used in the production of edible oils.

The crude oil is caustic refined (also referred to as chemical refining) using sodium hydroxide (21 CFR §184.1763). The main purpose of this step is to remove free fatty acids by converting them into insoluble soaps that are easily removed from the oil. The end product of caustic refining is neutralized shea oil ("N shea oil" in Figure 5).

The neutralized shea oil is subsequently fractionated by mixing with a non-polar solvent (e.g., hexane), and cooling. The slurry is filtered using a band filter and the shea stearin crystals ("FR shea stearin" in Figure 5) are collected. By this process, shea stearin crystals are separated from the liquid olein fraction.

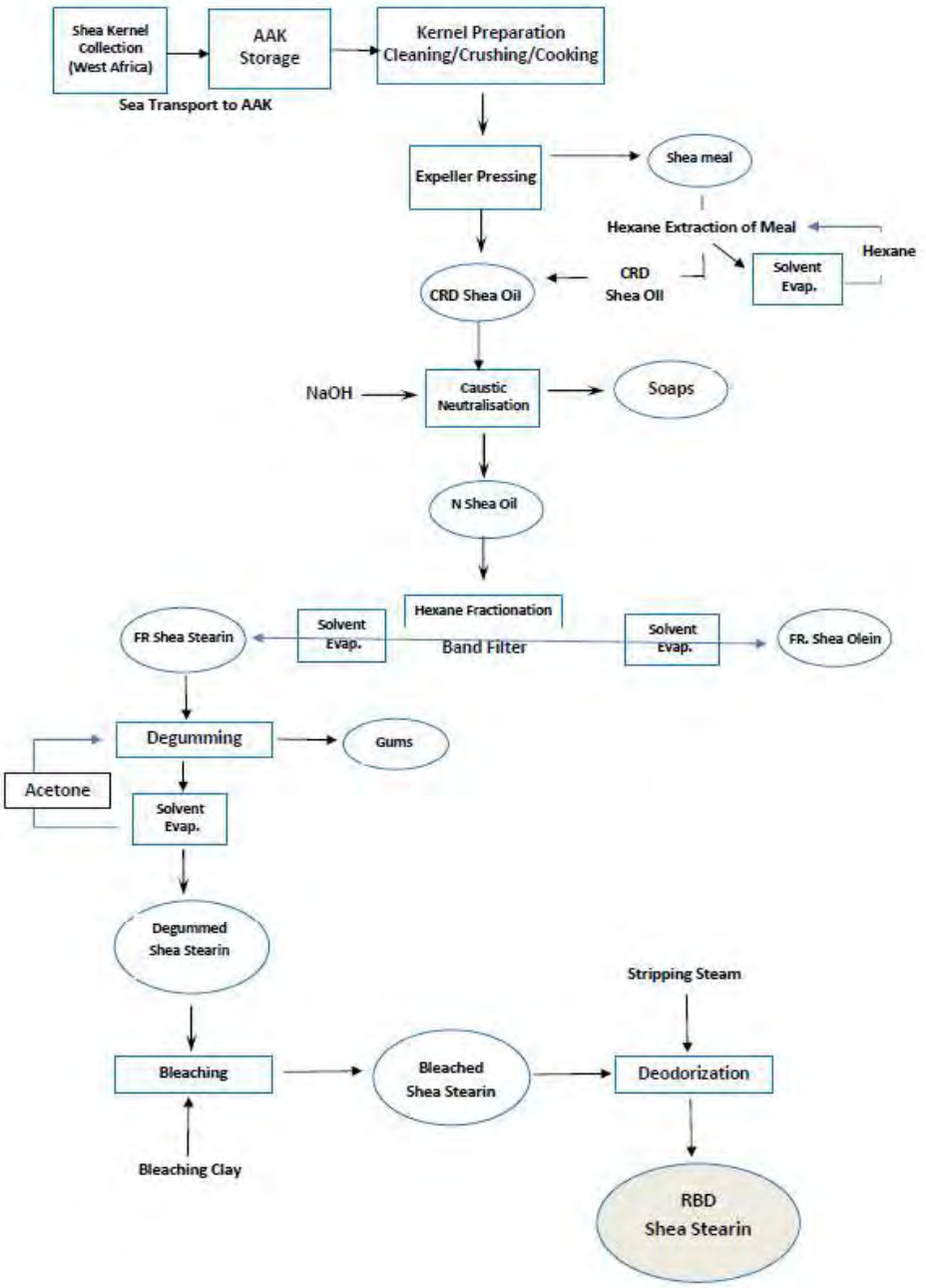
The shea stearin obtained by solvent fractionation is then "degummed" with acetone to remove viscous high-molecular weight unsaturated hydrocarbon material found in shea. This is followed by conventional bleaching of the degummed shea stearin with bleaching earth (21 CFR §184.1155). This is a form of "adsorptive purification" which acts to remove trace metals, oxidation products, residual soaps, and color bodies.

In the final step, the degummed, bleached shea stearin is deodorized using industrial vacuum steam distillation equipment. This process, utilizing vacuum, steam and heat, removes volatile compounds such as aldehydes and ketones and eliminates peroxides by thermal decomposition, yielding a relatively "clean" tasting product, free of undesirable odors and flavors. Removal of hexane and acetone from the product is facilitated by deodorization at high temperature, which is approximately 200°C.

The final product of this complete process is refined, bleached, deodorized shea stearin, commonly referred to as a RBD shea stearin. The specifications for AAK's RBD shea stearin, produced as described, are given in Table 9.

All processing materials used in the manufacture of refined shea butter are appropriate for food-use. AAK USA has certified all production materials as food grade; documentation of compliance with requirements of food safety management systems is provided in Appendix B.

Figure 5. Shea stearin processing flow chart



Abbreviations: CRD – crude; FR – fractionated; N – neutralized; NaOH - sodium hydroxide; RBD – refined, bleached, deodorized

Specifications

AAK's Shea Stearin Specifications

AAK's shea stearin is an ivory to straw-colored (off-white), brittle solid at room temperature. The use of shea stearin would not impart any color to a food product containing it. Product specifications for AAK's shea stearin, along with methods of analysis for each parameter, are presented in Table 9 below. Stearic acid accounts for ≥50% of total fatty acids and oleic acid accounts for no more than 40%. Unsaponifiables account for no more than 3% of shea stearin.

Table 9. Product specifications for shea stearin

Parameter	Specification	Method of Analysis
Color, Lovibond Red	≤5	AOCS Cc13e-92
Odor and Taste	Neutral	Sensory
Peroxide value, meq/kg	≤10	AOCS Cd8b-90
Free fatty acid as oleic acid, %	≤1.0	AOCS Ca 5a-40
Unsaponifiable matter, %	≤3	DIN EN ISO 3596
Stearic acid, %	≥50	AOCS Cd 16b-93
Oleic acid, %	≤40	AOCS Cd 16b-93
Trans fatty acid	≤1.0	ISO 12966, mod
Iron, mg/kg	≤ 1.5	DIN EN 15763, mod
Copper, mg/kg	≤ 0.1	DIN EN 15763, mod
Lead, mg/kg	≤ 0.1	DIN EN 15763, mod
Arsenic, mg/kg	≤ 0.1	DIN EN 15763, mod
Cadmium, mg/kg	≤ 0.02	DIN EN 15763, mod
Mercury, mg/kg	≤ 0.1	DIN EN 15763, mod
Hexane, mg/kg	≤1	Headspace, GC-FID
Acetone, mg/kg	≤1	Headspace, GC-FID

Analytical data from three non-consecutive, representative lots of the subject material demonstrate that AAK's shea stearin product can consistently be manufactured so as to meet the established specifications (Table 10). Representative data indicate that the concentration of unsaponifiable matter in the shea stearin is typically 1% given current production processes.

Table 10. Analytical data from non-consecutive batches of AAK's shea stearin

Parameter	Specification	Batch A	Batch B	Batch C
Color (Lovibond Red)	≤ 5	0.7	0.7	1.7
Odor and Taste	Neutral	Pass	Pass	Pass
Peroxide value, meq/kg	≤ 10	0.0[a]	0.0[a]	0.0[a]
Free fatty acid as oleic acid, %	≤ 1.0	0.05	0.06	0.05
Unsaponifiable matter, %	≤ 3	1.1	1.0	1.1
Stearic acid, %	≥ 50	55.8	57.1	57.8
Oleic acid, %	≤ 40	31.8	32.2	31.8
Iron, mg/kg	≤ 1.5	<0.2	<0.2	<0.2
Copper, mg/kg	≤ 0.1	<0.05	<0.05	<0.05
Lead, mg/kg	≤ 0.1	<0.01	<0.01	<0.01
Arsenic, mg/kg	≤ 0.1	<0.02	<0.02	<0.02
Cadmium, mg/kg	≤ 0.02	<0.005	<0.005	<0.005
Mercury, mg/kg	≤ 0.1	<0.01	<0.01	<0.01
Hexane, mg/kg	≤1	<0.5	<0.5	<0.5
Acetone, mg/kg	≤1	<0.5	<0.5	<0.5

[a]Value as reported. A limit of detection (LOD) is not provided for peroxide value; values determined with AOCS method Cd8b-90.

Monitoring of Potential Contaminants

To ensure a high-quality and suitable food ingredient, AAK routinely monitors shea stearin for the presence of potential contaminants as a component of its current good manufacturing practices (cGMP). Analytical data demonstrating that all tested compounds meet internal limits are provided in Appendix A. Contaminant levels are monitored quarterly by AAK.

Stability

Edible fats and oils generally contain only trace amounts of moisture and are considered anhydrous food substances. With no appreciable moisture, they have a low water activity (Aw) and are not susceptible to microbiological deterioration. Based on its relatively high level of saturated fat (60%) and its low level of polyunsaturated fat (3.5%), shea stearin can be considered a stable fat exhibiting good resistance to oxidative rancidity compared to other common vegetable oils already in the food supply and in wide use.

Physical or Technical Effect

AAK's shea stearin is intended to be used as a substitute for select uses of fats in conventional foods. Shea stearin contributes solid fat in the absence of hydrogenation.

Part 3. Dietary Exposure

Proposed Use and Level

Use of shea stearin as an ingredient is intended to provide a source of fat in select analogues of animal-based products, and a replacement for animal fats and vegetable oils in specified foods. Shea stearin is intended for use in plant-based meat & poultry analogues including burgers/ground meat and sausages; plant-based dairy alternatives and dairy analogues (including butter, cheese, cream cheese, creamers, frozen desserts, milks, sour cream, and yogurt); fillings for cookies & wafers and confectionery; nut/seed spreads and butters; margarines/spreads; and bakery products including bars, biscuits, cakes, cookies, laminated dough products (e.g., Danish pastry/croissants), muffins, and pie crust. The proposed use of shea stearin as an ingredient in select foods is detailed in Table 11, along with the maximum intended use of shea stearin in each food category.

Table 11. Intended use and use levels of AAK's shea stearin

Food Category	Proposed Food Use	Shea Stearin use Level (g) Per 100 g Product
Plant-based meat & poultry analogues	Burgers/Ground meat	14
	Sausages	14
Plant-based dairy alternatives and dairy analogues	Butter	45
	Cheese	25
	Cream Cheese	20
	Creamers	6
	Frozen Desserts	15
	Milks	3.5
	Sour Cream	12
	Yogurt	3.5
Fillings	Cookies & wafers	40
	Confectionery	35
Nut & seed products	Nut/Seed Spreads and Butters	45
Fats & oils	Margarines/Spreads	35
Bakery	Bars	15
	Biscuits	20
	Cakes	15
	Cookies	20
	Laminated dough products (Danish pastry/croissants)	16
	Muffins	15
	Pie Crust	20

Estimated Daily Intakes

Methods

Food Consumption Data

Estimates of shea stearin intake were developed from food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Survey (NHANES) conducted in 2015-2016 and 2017-2018 (NHANES 2015-2018). NHANES is a continuous survey that uses a complex multistage probability sample designed to be representative of the civilian U.S. population (CDC 2020). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the United States. Statistical weights are provided by the National Center for Health Statistics to adjust for the differential probabilities of selection and non-response.

As part of the examination, trained dietary interviewers collected detailed information on all foods and beverages consumed by respondents in the previous 24-hour time period (midnight to midnight). A second dietary recall was administered by telephone three to ten days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 13,666 individuals in the survey period 2015-2018 provided two complete days of dietary recalls. Only individuals providing two reliable dietary recalls were included in this analysis.

Representative NHANES Foods

The list of all food codes reported consumed in NHANES 2015-2018 was reviewed, and food codes corresponding to, or foods containing ingredients corresponding to a proposed use, were identified. The list of food codes used to process NHANES dietary recalls contain a limited number of codes for vegetable-based analogues of meat and poultry, plant-based dairy alternatives and dairy analogues. With the exception of "soymilk" (a milk alternative), the number of individuals reporting consumption of these products was small. To more completely capture the intended use of shea stearin, reported intakes of all burgers/ground meat, sausages, and all dairy products (other than plant-based beverages such as "soymilk" and other milk alternatives) represented by the plant-based analogues were used to develop estimates of intake. This represents an overestimate of intake for these plant-based analogues to ensure a robust safety assessment.

When only a component of the food corresponded to the proposed use, USDA's Food and Nutrient Database for Dietary Studies (FNDDS) was used to identify relevant ingredients in each food as grams per 100 g food. Identification of the weight of ingredients in foods allowed for the estimation of proposed food use of shea stearin that can be consumed as is or as a component in a food (e.g., the cheese and burger components of a cheeseburger). FNDDS version 2017-2018 (USDA, 2020) was used to process dietary recall data reported in NHANES 2017-2018 and FNDDS version 2015-2016 (USDA, 2018) for foods reported consumed only in NHANES 2015-2016. The list of all NHANES food codes (and their descriptions) included in the analysis to estimate intake of the proposed use of shea stearin is provided in Appendix C.

Analysis

Using the NHANES 2015-2018 consumption data, the 2-day average daily intake on a *per capita* and *per user* basis was estimated. *Per capita* estimates refer to the consumption based on the entire population of interest, whereas *per user* estimates refer to the consumption among those who reported consuming any of the foods of interest on either of the survey days. For each subject with a complete 2-day dietary recall, a 2-day average intake estimate was derived by multiplying the reported intake of foods from the 24-hour recall with the shea stearin use level and the cumulative sum over the two 24-hour recalls was divided by two. The mean and 90th percentile of 2-day average shea stearin intakes were calculated for the total U.S. population two years and older (2+ y) and subpopulations including children ages 2-5 years and 6-12 years, teenagers ages 13-18 years, and adults ages 19 years and older.

The 2-day average intakes by each individual were estimated using Exponent's Foods Analysis and Residues Evaluation Program (FARE® version 14.02) software, which uses the statistically weighted values from the survey in analyses. The statistical weights compensate for variable probabilities of selection, adjusted for non-response, and provide intake estimates that are representative of the U.S. population.

Results

Shea Stearin Intake

Estimates of shea stearin intake from the proposed use are presented in Table 12. Among the total U.S. population ages 2 years and older and all subpopulations, 99% of individuals were estimated to consume a product that could contain shea stearin on one or both days of dietary recall. For the U.S. population ages 2 years and older, the per user estimated daily intake (EDI) of shea stearin from the proposed use is 25 g/person/day at the mean and 48 g/person/day at the 90th percentile of intake. On a bodyweight basis, per user intake by the U.S. population ages 2 years and older is 0.4 g/kg bw/day at the mean and 0.8 g/kg bw/day at the 90th percentile.

Table 12. Estimated daily intake of AAK's shea stearin from the proposed use, WWEIA/ NHANES 2015-2018

Population	n Total	n user	% User	Mean	90th Percentile	Mean	90th Percentile
				Per Capita		Per User	
				- - - g/day - - -			
U.S. 2+ y	12,717	12,532	99	25	47	25	48
Children 2-5 y	999	993	99	18	32	18	32
Children 6-12 y	1,744	1,729	99	24	44	24	44
Adolescents 13-18 y	1,433	1,416	99	25	48	25	48
Adults 19+ y	8,541	8,394	99	25	48	26	49
				- - - g/kg bw/day - - -			
U.S. 2+ y	12,717	12,532	99	0.4	0.8	0.4	0.8
Children 2-5 y	999	993	99	1.0	1.8	1.0	1.8
Children 6-12 y	1,744	1,729	99	0.7	1.4	0.7	1.4
Adolescents 13-18 y	1,433	1,416	99	0.4	0.8	0.4	0.8
Adults 19+ y	8,541	8,394	99	0.3	0.6	0.3	0.6

It is important to consider the factors contributing to the estimates. In calculating the estimates of intake, we have assumed that all foods in each proposed use category will contain the maximum intended use of shea stearin. In reality, manufacturers may not use the maximum intended use of shea stearin in products, and not all consumers may select products with shea stearin at all eating occasions.

As previously noted, reported intakes of vegetable analogue meats and plant-based dairy products in the NHANES dietary recall is limited, indicating that consumption of these products is not widespread at this time. Intakes of all ground meat, sausage, and dairy products were used to develop the estimates of intake. As such, the estimates may provide representative intakes of shea stearin per user of a particular application, though the estimates likely greatly overstate the proportion of the U.S. population that may consume products with shea stearin and the estimates may overstate cumulative estimates of shea stearin intake.

In reality, the availability of shea stearin is restricted due to agronomic and economic factors specific to the production of shea butter and shea derivatives. Relative to other oil seeds and fats, shea butter accounts for a small fraction of the total edible oils market and global supplies are insufficient to support the levels of shea stearin use modeled in these EDIs for the U.S. population. Therefore, the estimates of shea stearin intake are high. Additionally, given that the intended use is substitutional for other vegetable and animal fats with a comparable fatty acid profile, the intended use of shea stearin will not substantially alter overall fat intake or intake of specific fatty acids.

Sterols/Triterpenes Intake from Shea Stearin

Estimates of sterols/triterpenes intake can be derived from estimates of shea stearin intake. Analytical data of representative products demonstrate that the concentration of triterpene/sterols in AAK's shea stearin is approximately 0.5%, while the concentration of total unsaponifiable matter is approximately 1% (Table 6), thus indicating that sterols/triterpenes account for 50% of the unsaponifiable material. Assuming that shea stearin contains the maximum concentration of total unsaponifiables at 3% as permitted in the product specifications, the corresponding maximum concentration of sterols/triterpenes in shea stearin is 1.5%.

Based on the estimated intakes of shea stearin (Table 12) and the maximum concentration of 1.5% sterols/triterpenes in shea stearin, the EDI of sterols/triterpenes from the proposed use is 0.38 g/person/day at the mean and 0.71 g/person/day at the 90th percentile of intake for the U.S. population ages 2 years and older or 6 and 12 mg/kg bw/day, respectively, as shown in Table 13. However, as previously noted, analytical data demonstrate that the concentration of sterols/triterpenes in shea stearin is 0.5%. Based on the estimated intakes of shea stearin shown in Table 12 and the measured concentration of sterols/triterpenes in shea stearin (0.5%), the estimated 90th percentile intake of sterols/triterpenes by the U.S. population ages 2 years and older is 0.24 g/person/day or 4 mg/kg bw/day from the maximum intended uses (i.e., 48 g shea stearin/day x 0.5 g sterols/triterpenes /100 g shea stearin, or 0.8 g shea stearin/kg bw/day x 0.5 g sterols/triterpenes /100 g shea stearin).

Table 13. Maximum estimated daily intake of sterols/triterpenes from the proposed use of AAK's shea stearin, WWEIA/NHANES 2015-2018

Population	n user	% User	Mean	90th Percentile	Mean	90th Percentile
			Per Capita		Per User	
			- - - g/day - - -			
U.S. 2+ y	12,532	99	0.37	0.71	0.38	0.71
Children 2-5 y	993	99	0.26	0.48	0.26	0.48
Children 6-12 y	1,729	99	0.36	0.66	0.36	0.66
Adolescents 13-18 y	1,416	99	0.38	0.73	0.38	0.73
Adults 19+ y	8,394	99	0.38	0.73	0.39	0.73
			- - - mg/kg bw/day - - -			
U.S. 2+ y	12,532	99	6	12	6	12
Children 2-5 y	993	99	15	27	15	27
Children 6-12 y	1,729	99	11	20	11	20
Adolescents 13-18 y	1,416	99	6	11	6	11
Adults 19+ y	8,394	99	5	9	5	9

Note: Calculated from estimated intake of shea stearin (Table 12) and assuming 1.5% sterols/triterpenes in shea stearin.

Part 4. Self-Limiting Levels of Use

The intended use of shea stearin in foods is self-limiting due to the inherent properties and functionality of the fat. Shea stearin is a hard, high melting fat (104°F) with greater than 80% fat solids at room temperature. These physical properties limit the use of shea stearin in foods. As an example, bakery fats are typically plasticized and viscoelastic in nature. Therefore, in most cases shea stearin will be combined with other selected GRAS fats to achieve specific mechanical properties and functionality for a given food. Exceeding the amounts prescribed in Table 11 will negatively affect the intended eating properties and quality of the food.

Additionally, the Dietary Guidelines for Americans (DGA 2020-2025) recommends limiting saturated fat to 10% of daily calories. Therefore, another factor limiting the use of shea stearin will be the desired amount of saturated fat in the final product. Given that shea stearin contains an appreciable amount of saturated fat, food manufacturers would likely restrict the use of shea stearin in order to meet targeted nutritional requirements.