ORIGINAL SUBMISSION

GENERALLY RECOGNIZED AS SAFE
GRAS
ASSOCIATES, LLC

GRAS Associates, LLC
27499 Riverview Center Blvd.
Bonita Springs, FL 34134
T: 239.444.1724 | F: 239.444.1723
www.gras-associates.com

GRN 000654

4/12/2016

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-255)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Attention: Dr. Paulette Gaynor
Re: GRAS Notification – Coberine™ N707 (Cocoa Butter Equivalent (eCBE))

Dear Dr. Gaynor:

On behalf of IOI Loders Croklaan, USA, LLC, we are submitting for FDA review Form 3667 and the enclosed CD, free of viruses, containing a GRAS notification for *Coberine™ N707 (Cocoa Butter Equivalent (eCBE))*. An Expert Panel of qualified persons was assembled to assess the composite safety information of the subject substance with the intended use in infant formula. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email.

We look forward to your feedback.

Sincerely

(b) (6)

Cheryl R. Dicks, MS, RAC
Director of Operations
GRAS Associates, LLC
27499 Riverview Center Blvd., Suite 212
Bonita Springs, FL 34134
540-272-3254
dicks@gras-associates.com

Enclosure: GRAS Notification for IOI Loders Croklaan, USA, LLC – *GRAS Assessment Of Cocoa Butter Equivalent (eCBE) Coberine™ N707 Food Usage Conditions for General Recognition of Safety*

cc Robert S. McQuate, PH.D. mcquate@gras-associates.com

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cc Robert S. McQuate, PH.D. mcquate@gras-associates.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
000654	RECEIVED JUN 1 2016 OFFICE OF FOOD ADDITIVE SAFETY
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☒ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position
Dr Luisa Gambelli	Regulatory&Nutritional Affairs Manager

Company *(if applicable)*: IOI Loders Croklaan, USA, LLC

Mailing Address *(number and street)*: 24708 W. Durkee Road

City	State or Province	Zip Code/Postal Code	Country
Channahon	Illinois	60410	United States of America

Telephone Number	Fax Number	E-Mail Address
+31 (0)75 629 2589		Luisa.Gambelli@ioiloders.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Cheryl R. Dicks	Director of Operations

Company *(if applicable)*: GRAS Associates, LLC

Mailing Address *(number and street)*: 27499 Riverview Center Blvd.

City	State or Province	Zip Code/Postal Code	Country
Bonita Springs	Florida	34134	United States of America

Telephone Number	Fax Number	E-Mail Address
239-444-1724	239-444-1723	lewis@gras-associates.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statement)

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Mailing Address *(number and street)*
24708 W. Durkee Road

City	State or Province	Zip Code/Postal Code	Country
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Telephone Number	Fax Number	E-Mail Address
+31 (0)75 629 2589		Luisa.Gambelli@ioiloders.com

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Cheryl R. Dicks	Director of Operations

Company *(if applicable)*
GRAS Associates, LLC

Mailing Address *(number and street)*
27499 Riverview Center Blvd.

City	State or Province	Zip Code/Postal Code	Country
Bonita Springs	Florida	34134	United States of America

Telephone Number	Fax Number	E-Mail Address
239-444-1724	239-444-1723	lewis@gras-associates.com

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

Coberine™ N707 (Cocoa Butter Equivalent; and Cocoa Butter Substitute)

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission Gateway

☒ Electronic files on physical media with paper signature page

☐ Paper

If applicable give number and type of physical media

_____

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☐ Yes *(Proceed to Item 5)* ☒ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*

☐ a) GRAS Notice No. GRN _____

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

☐ e) Other or Additional *(describe or enter information as above)* _____

6. Statutory basis for determination of GRAS status *(Check one)*

☒ Scientific Procedures *(21 CFR 170.30(b))* ☐ Experience based on common use in food *(21 CFR 170.30(c))*

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 8)*

☒ No *(Proceed to Part IV)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).*

intended to be used in the following food categories at levels not to exceed current good manufacturing practice: Confections and Frostings as defined in 21 CFR 170.3(n)(9); Coatings of Soft Candy, as defined in 21 CFR 170.3(n)(38); and Sweet Sauces, Toppings, as defined in 21 CFR 170.3(n)(43); except that the ingredient will not be used in a standardized food unless permitted by the standard of identity.

Coberine™ N707 is intended to be used in food in accordance with 21 CFR 184.1(b)(1) at levels not to exceed good manufacturing practice. The individual proposed uses and use levels of Coberine™ N707 are given in Section IV.

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

☐ Yes ☒ No

PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
1	Cocoa Butter Equivalent; Cocoa Butter Substitute (Coberine™ N707)	2190-25-2			
2					
3					

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (1 - 3) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)* and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s)),* and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source)*, and include any known toxicants that could be in the source.

Coberine™ N707 is the product of the enzymatic interesterification of palm oil and stearic acid. Detailed description of the composition of the combination appear in Section III.

3. Synonyms

Provide as available or relevant:

1	Enzymatically-Produced Cocoa Butter Equivalent
2	Cocoa Butter Equivalent
3	Cocoa Butter Substitute

PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- ☐ Any additional information about identity not covered in Part V of this form
- ☒ Method of Manufacture
- ☒ Specifications for food-grade material
- ☐ Information about dietary exposure
- ☐ Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- ☐ Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- ☒ Comprehensive discussion of the basis for the determination of GRAS status
- ☒ Bibliography

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☒ Yes ☐ No

Did you include this other information in the list of attachments?

☒ Yes ☐ No

PART VII – SIGNATURE

1. The undersigned is informing FDA that IOI Loders Croklaan, USA, LLC
(name of notifier)

has concluded that the intended use*(s)* of Coberine™ N707 (Cocoa Butter Equivalent; and Cocoa Butter Substitute)
(name of notified substance)

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. ☒ IOI Loders Croklaan, USA, LLC *(name of notifier)* agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

IOI Loders Croklaan, USA, LLC *(name of notifier)* agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

24708 W. Durkee Road Channahon, Illinois 60410 U.S.A.
(address of notifier or other location)

IOI Loders Croklaan, USA, LLC *(name of notifier)* agrees to send these data and information to FDA if FDA asks to do so.

OR

☐ The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No. ----------
(GRAS Affirmation Petition No.)

3. Signature of Responsible Official, Agent, or Attorney	**Printed Name and Title**	**Date (mm/dd/yyyy)**
Cheryl R. Dicks, MS, RAC Digitally signed by Cheryl R. Dicks, MS, RAC DN: cn=Cheryl R. Dicks, MS, RAC, o=GRAS Associates, LLC, ou=Director of Operations, Senior Regulatory Affairs Scientist, Project Manager, e=chd@gras-associates.com, c=US Date: 2016.05.22 15:08:29 -04'00'	Cheryl R. Dicks, MS, RAC Director of Operations	04/12/2016

PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Multiple appendices---Appendices A through Y	

OMB Statement: Public reporting burden for this collection of information is estimated to average 150 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

GRAS Assessment

of

Cocoa Butter Equivalent (eCBE)
Coberine™ N707
Food Usage Conditions for General Recognition of Safety

for

IOI Loders Croklaan, USA, LLC
Channahon, Illinois

Evaluation By

Richard C. Kraska, Ph.D., DABT
Robert S. McQuate, Ph.D.
Kara Lewis, Ph.D.

April 9, 2016

TABLE OF CONTENTS

FIGURES

TABLES

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I. GRAS EXEMPTION CLAIM

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)[1]

IOI Loders Croklaan has determined that its Coberine™ N707, meeting the specifications as described below, is Generally Recognized as Safe in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. This determination was made by experts qualified by scientific training and experience and is based on scientific procedures as described in the following sections. The evaluation accurately reflects the conditions of the intended use of this substance in foods.

Signed:

(b) (6)

Cheryl Dicks, MS, RAC Date: 3/25/2016
Director of Operations
GRAS Associates, LLC
27499 Riverview Center Blvd.
Suite 212
Bonita Springs, FL 34134
Email: dicks@gras-associates.com

B. Name and Address of Notifier

IOI Loders Croklaan, USA, LLC
24708 W. Durkee Road
Channahon, Illinois 60410
U.S.A.
http://northamerica.croklaan.com

As the notifier, IOI Loders Croklaan, USA, LLC accepts responsibility for the GRAS determination that has been made for Coberine™ N707, as described in the subject notification; consequently, the Coberine™ N707 preparations of sufficient purity which meet the conditions described herein, are exempt from premarket approval requirements for food ingredients.

[1] See 62 FR 18938, 17 April 1997. Accessible at www.gpo.gov/fdsys/pkg/FR-1997-04-17/pdf/97-9706.pdf.

C. Common Name and Identity of Notified Substance

Several common names may be used to declare the addition of Coberine™ N707 as an ingredient on food labels. Among them are Enzymatically-Produced Cocoa Butter Equivalent; Cocoa Butter Equivalent; and Cocoa Butter Substitute.

D. Conditions of Intended Use in Food

IOI Loders Croklaan intends to market Coberine™ N707 as a human food ingredient. Similar products (CBS in 21 CFR 184.1259 (CFR 2014a) and 21 CFR 172.861 (CFR 2014b), for CBS from coconut oil, palm kernel oil, or both oils) are already in commercial use in the U.S. In accordance with 21 CFR 184.1(b)(1), the ingredient is intended to be used in the following food categories at levels not to exceed current good manufacturing practice: Confections and Frostings as defined in 21 CFR 170.3(n)(9); Coatings of Soft Candy, as defined in 21 CFR 170.3(n)(38); and Sweet Sauces, Toppings, as defined in 21 CFR 170.3(n)(43); except that the ingredient will not be used in a standardized food unless permitted by the standard of identity.

Coberine™ N707 is intended to be used in food in accordance with 21 CFR 184.1(b)(1) at levels not to exceed good manufacturing practice. The individual proposed uses and use levels of Coberine™ N707 are given in Section IV.

E. Basis for GRAS Determination

Pursuant to 21 CFR 184.1259 Coberine™ N707 has been determined by GRAS Associates to be GRAS for the intended food use conditions noted above on the basis of scientific procedures in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. This GRAS determination is based on the data generally available in the public domain pertaining to the safety of the following:

- CBS;
- Other enzymatically-produced fats from palm oil;
- Purity specification of raw materials to manufacture Coberine™ N707;
- Standardized processing conditions applied to produce Coberine™ N707;
- Contaminants analysis of Coberine™ N707;

and on a consensus among a panel of experts (Richard Kraska, Ph.D., DABT, Kara Lewis, Ph.D., and Robert McQuate, Ph.D.) who are qualified by scientific training and experience to evaluate the safety of Coberine™ N707 as a component of food [see Appendix A, entitled “Expert Panel Consensus Statement Regarding the Generally Recognized as Safe (GRAS)

Status of Coberine™ N707 (Enzymatically-Produced Cocoa Butter Equivalent) for Use in Foods"].

F. Availability of Information

The data and information that serve as the basis for this GRAS notification will be maintained at the offices of:

Loders Croklaan, USA, LLC
24708 W. Durkee Road
Channahon, Illinois 60410
U.S.A.

II. INTRODUCTION

A. Objective

The objective of this notification is to show that Coberine™ N707 is generally recognized as safe (GRAS) when used as specified in this document. This conclusion is largely based on the fact this product as produced by IOI Loders Croklaan using traditional manufacturing processing and conditions, is substantially similar in composition to a CBS that is currently on the market which is manufactured by the petitioner of GRASP 8GO348, under identical conditions of intended use; falls under the specifications given in 21 CFR 184.1259 for CBS and meets or approximates the standard for CBS in FCC (2015). An expert panel review of current scientific literature also supports this conclusion.

B. Background Information About the Submission

The purpose of this notification is to show that Coberine™ N707, an enzymatically produced cocoa butter equivalent (CBE) product of IOI Loders Croklaan, USA, LLC ("Loders Croklaan"), is generally recognized as safe (GRAS) when manufactured using a process that differs from the manufacturing process that is approved in the U.S. for producing a cocoa butter substitute (CBS) (21 CFR 184.1259). This notification will also show that: the manufacturing process for Coberine™ N707 employs a combination of processing techniques already in use in the food oil industry (interesterification, fractionation, and refining); Coberine™ N707 has a substantially similar fatty acid and triglyceride composition to cocoa butter (CB) and a CBS that is currently on the market; Coberine™ N707 meets the specifications for CBS as per 21 CFR 184.1259; and Coberine™ N707 meets or closely approximates the Food Chemicals Codex (FCC) 9 (2015) standards for cocoa butter substitute (Food Chemicals Codex, 2015).

Pursuant to (21 CFR170.35), IOI Loders Croklaan hereby claims that Coberine™ N707, an ingredient intended to be added to "Confections and Frosting", as defined in 21 CFR 170.3(n)(9); Coatings of Soft Candy", as defined in 21 CFR170.3(n)(38); and "Sweet Sauces

and Toppings" as defined in 21 CFR170.3(n)(39), at levels not to exceed the current approved levels for use in 21 CFR184.1259, and when produced using current good manufacturing practices for CBS, is exempted from the premarket approval requirements for the Federal Food, Drug, and Cosmetic Act because an independent expert panel of recognized experts (herein referred to as Expert Panel), qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, has determined that this ingredient is generally recognized as safe (GRAS) for such uses.

The following considerations were taken into account for the safety evaluation:

- CB has been consumed for centuries;
- The U.S. Food and Drug Administration (FDA) states that the triglycerides "cocoa butter substitute primarily from palm oil" (1-palmitoyl-2-oleoyl-3-stearin) produced by interesterification or directed esterification and "cocoa butter substitute primarily from high oleic safflower or sunflower oil" (1-3-distearoyl-2-olein) produced by interesterification with ethyl stearate or stearic acid in the presence of a suitable lipase are GRAS as long as they meet the listed specifications (21 CFR 184.1259), and are used at levels not to exceed current good manufacturing practice in "confections and frostings" as defined in 21 CFR 170.3(n)(9), "coatings of soft candy' as defined in 21 CFR 170.3(n)(38), and "sweet sauces and toppings" as defined in 21 CFR 170.3(n)(43), with the exception that it may not be used in standardized food unless permitted by the standard of identity, and are used in food in accordance with 21 CFR 184.1(b)(1);
- The production process for Coberine™ N707 is very similar to the production process described in 21 CFR 184.1259 for CBS;
- Coberine™ N707 is substantially equivalent in chemistry and functionality to the CBS described in 21 CFR 184.1259;
- The triglycerides and fatty acids present in Coberine™ N707 are identical to those found in natural cocoa butter and in CBS approved in the U.S. (21 CFR 184.1259);
- The concentrations of triglycerides, diglycerides, monoglycerides, and free fatty acids in Coberine™ N707 meet the specifications for CBS as described in 21 CFR 184.1259;
- The concentrations of residual solvents in Coberine™ N707 meet the specifications for the CBS described in 21 CFR 184.1259;
- The concentrations of contaminants in Coberine™ N707 fall within the specifications of other edible oils and fats, *e.g.,* for CBS as in 21 CFR 184.1259;

- The lead concentration, acid value, iodine value, residue on ignition (sulfated ash), saponification value, titer (solidification point), unsaponifiable matter content, and water content of stearic acid meet or approximate the standards listed in Food Chemicals Codex (FCC 9) (2015);

- The concentrations of lead, residual catalysts, organic impurities (hexane), free fatty acids (as oleic acid), total glycerides, monoglycerides, diglycerides, and triglycerides in Coberine™ N707, the iodine value, peroxide value, and color of Coberine™ N707 meet or closely approximate the standards listed in Food Chemicals Codex (FCC 9) (2015); and

- A comprehensive search of the scientific literature on the safety and toxicity of enzymatically produced fats indicates that enzymatic modification of oils and fats has been shown to be safe.

The Expert Panel reviewed materials submitted by IOI Loders Croklaan and other information identified in an independent literature search. IOI Loders Croklaan assured the GRAS Expert Panel that is not in possession of any additional unpublished information that is relevant to the GRAS evaluation of Coberine™ N707. Following an independent, critical evaluation of all information, the Expert Panel unanimously determined that Coberine™ N707 is GRAS under the defined conditions of use.

C. Background Information on Cocoa Butter

Cocoa butter is one of the most expensive and widely used raw materials in the chocolate and confectionary industries due to its unique melting characteristics and physical properties. CB is responsible for the snap, gloss, mouthfeel, flavor release, and shelf life of the final product (Windhab et al., 2009). Despite some variations in composition among different countries of origin, the main fatty acids in CB, which account for about 95% of those present, are palmitic (C16:0, P), stearic (C18:0, St), and oleic acid (C18:1, O). Table 1 shows the ranges of fatty acid compositions for the major CB-producing countries.

Table 1. Fatty Acid Composition (Wt %) of Cocoa Butter from Different Countries of Origin

Country of Origin	Palmitic Acid (P) (C16:0)	Stearic Acid (St) (C18:0)	Oleic Acid (O) (C18:1)
Ecuador	25.6	36.1	34.7
Brazil	23.9 – 25.2	33.2 – 33.4	36.6 – 37.8
Ghana	25.1 – 25.4	37.6 – 37.8	32.8 – 33.6
India	25.6	36.6	33.9
Nigeria	25.8	36.3	33.6
Ivory Coast	25.7 – 25.9	35.4 – 37	33 – 34.5
Indonesia	24.2	37.4	34.4
Malaysia	25 – 25.1	37.6	33.6

From Shukla (2005).

CB is composed mainly of triglycerides (TAG), three of which account for greater than 75% of disaturated, monounsaturated TAG (Sat-O-Sat): rac-1-palmitoyl-2-oleoyl-3-stearoyl glycerol (POSt), 1,3-disteroyl-2-oleoyl glycerol (StOSt), and 1,3-dipalmitoyl-2-oleoyl glycerol (POP), as shown in Table 2 (Foubert et al., 2004). These particular TAG are largely responsible for the crystallization and polymorphic behavior of chocolates, providing chocolates with their characteristic textural and sensory properties.

Table 2. Triacylglycerol Composition (Wt %) of Cocoa Butter from Different Geographical Origins

TAGs	Malaysia	Ivory Coast	Nigeria	Ecuador	San Domingo	Brazil
PPP	0.221	0.385	0.514	0.383	0.364	0.256
MOP	0.201	0.253	0.262	0.302	0.233	0.205
PPSt	0.844	0.688	0.836	0.948	0.577	0.583
POP	**17.8**	**18.3**	**18.3**	**18.9**	**19.4**	**17.0**
PLP	1.84	1.79	1.36	1.55	1.91	2.18
PStSt	1.03	0.334	0.464	0.696	0.263	0.317
POSt	**40.7**	**41.7**	**43.0**	**41.0**	**41.4**	**38.7**
POO	2.38	2.40	1.80	2.36	3.08	5.02
PLSt	2.67	2.88	2.51	2.46	3.00	2.97
PLO	0.493	0.364	0.322	0.383	0.435	0.337
StStSt	0.563	0.223	0.282	0.615	0.182	0.235
StOSt	**25.9**	**25.2**	**25.7**	**25.2**	**23.2**	**23.8**
StOO	2.82	2.86	2.09	2.86	3.54	5.96
StLSt+OOO	1.29	1.4	1.27	1.04	1.35	1.38
StOA	1.32	1.21	1.33	1.27	1.13	1.10

From Foubert et al., (2004).

In recent years, the production of CB has been impeded due to the difficulty of cultivating cocoa beans and low productivity because of pest attack. However, the demand for chocolate; chocolate consumption in emerging countries; and world cocoa prices have increased (Afoakwa, 2007). The price of cocoa beans increased from USD 2307/ton to USD 3270/ton between January 2012 and December 2014. Hence, a considerable amount of research is being conducted with the goal of developing cheaper and suitable alternatives to CB (Lipp & Anklam, 1998).

The three main types of fats that are used as alternatives to CB are Cocoa Butter Substitutes (CBS), Cocoa Butter Replacers (CBR) or non-lauric substitutes, and Cocoa Butter Equivalents (CBE) (Smith, 2001). CBE have a similar melting profile, molecular composition, and polymorphism as CB and are completely compatible with CB without presenting any eutectic behavior. CBE is prepared by blending natural fats that are rich in Sat-O-Sat, mainly POP, POSt

and StOSt, to match the TAG composition of CB as closely as possible (Talbot, 2005). Generally, the hard stearin fraction of fats, which has a high StOSt TAG content, can be used alone or in combination with TAG, such as POP, to produce CBE. According to EU Chocolate Directive 2000/36/EC, six vegetable oils that are rich in Sat-O-Sat TAG are currently permitted to be used as CBE in the EU: illipe, kokum, shea butter, mango kernel, sal, and palm mid fraction (Lipp & Anklam, 1998).

In addition to blending natural fats rich in Sat-O-Sat, the production of CBE *via* lipase-catalyzed reactions of commercial oils aiming for similar TAG compositions as CB with full compatibility has been encouraged (Macrae, 1983; Chang et al., 1990; Sridhar et al., 1991; Chong et al., 1992; Osborn and Akoh, 2002; Khumalo et al., 2002; Çiftçi et al., 2009a and b; Mohamed, 2012). Lipase-catalyzed reactions are widely used to modify the structure and composition of oils and fats in order to improve their nutritional and functional properties (Osborn and Akoh, 2002).

In comparison with chemically catalyzed processes, enzyme-catalyzed processes operate under milder reaction conditions of temperature, pH, and pressure, require less energy, and have lower overall capital costs. Enzymatic catalysis can be region-(1, 3, or 2-position) and fatty acid-specific and can yield products with better-defined chemical structure and composition (Macrae, 1983; Marangoni and Rousseau, 1995; and Ramamurthy and McCurdy, 1995).

A number of enzymatic reaction strategies can be found in the literature; however, acidolysis is the most commonly used technique for producing structure lipids (Rajendran et al., 2009, Scrimgeour, 2005, Akoh, 2002, Willis and Marangoni, 2002). During acidolysis, the transfer of an acyl group between an acid and an ester occurs. First, hydrolysis of an ester bond between the native fatty acid and glycerol moiety of the TAG molecule takes place, releasing the fatty acid and producing a diacylglycerol (DAG) containing one hydroxyl group. This step is followed by the formation of a new ester bond between the generated hydroxyl group and a new fatty acid (Reyes and Hill, 1994). The mechanism of acidolysis is quite similar to that of enzymatic interesterification in which the initial hydrolysis of the donor ester is required to produce the free fatty acid. Acidolysis can be easily controlled and several modifications can be imparted to the product. It also produces natural products that are free of *trans* fatty acids.

D. FDA Summary of Regulatory Information Used to Support the GRAS Notification for Coberine™ N707

The regulatory information from FDA used to support this notification is summarized in Table 3, Table 4 and Table 5.

Table 3. Regulatory Information Used to Support This Notification

CFR Sections Referenced (Title 21—Food and Drugs)		
Part	**Section**	**Section Title**
172-Food additives permitted for direct addition to food for human consumption	172.860	Fatty acids
	172.861	Cocoa butter substitute from coconut oil, palm kernel oil, or both oils
173-Secondary direct food additives permitted in food for human consumption	173.140	Esterase-lipase derived from *Mucor miehei*
	184.1090	Stearic acid
	184.1259	Cocoa butter substitute
	184.1420	Lipase enzyme preparation from *Rhizopus niveus*

Table 4. GRAS Notifications for Modified Triglycerides

GRAS Notice Number	Substance	Notifier	Reference
GRN 000131	High 2-Palmitic Vegetable Oil [BETAPOL™ (Structured Triglycerides) for use in term and preterm infant formula]	Loders Croklaan	FDA (2003)
GRN 000217	Tailored triglycerides containing approximately 12 percent medium-chain fatty acids	Nisshin Oillio Group USA, Inc.	FDA (2006c)
GRN 000192	InFat™ High 2-Palmitic Acid Vegetable Oil	Enzymotec Inc.	FDA (2006a)

Table 5. Relevant GRAS Notifications for Lipases

GRAS Notice Number	Substance	Notifier	Reference
GRN 000043	Lipase derived from *Aspergillus oryzae* carrying a gene encoding lipase from *Thermomyces lanuginosus*	Novo Nordisk	FDA (2000)
GRN 000081	Lipase from *Candida rugosa*	Amano Enzyme, Inc.	FDA (2001a)
GRN 000113	Lipase enzyme preparation from *Aspergillus oryzae*	Enzyme Technical Association	FDA (2002)
GRN 000216	Lipase enzyme preparation from *Rhizopus oryzae*	Amano Enzyme, Inc.	FDA (2006b)
GRN 000068	Lipase derived from *Penicillium Camembertii*	Amano Enzyme, Inc.	FDA (2001b)

E. FDA Regulatory Framework

Ingredients for use in conventional foods and beverages must undergo premarket approval by FDA as food additives or, alternatively, the ingredients to be incorporated into such foods and beverages must be determined to be generally recognized as safe (GRAS). The authority to make GRAS determinations is not restricted to the FDA, as GRAS determinations may be provided by experts who are qualified by scientific training and experience to evaluate effectively the safety of foods and beverages and their ingredients, under the proposed conditions of use.

In 1997, the FDA altered how GRAS determinations could be made. FDA has eliminated the formal GRAS petitioning process and now allows a notification procedure to take the place of the petitions. FDA outlines the necessary content required in order to make GRAS determinations, while also encouraging determinations to be provided to the FDA in the form of a notification; however, notifications to the FDA are strictly voluntary.

F. Current / Historical Uses of Cocoa Butter Substitutes in the U.S. and Other Countries

Natural cocoa butter has been used for centuries in the candy industry either as a component of the chocolate liquor or as a separate added ingredient to make coatings for confectionaries without evidence of toxicity. The use of cocoa butter equivalents in some countries is described below.

U.S.

Currently, FDA does not allow a product to be referred to as "chocolate" if the product contains interesterified vegetable oils and fats. Nevertheless, products with cocoa butter substitutes are permitted and often branded or labeled as "chocolatey" or "made with chocolate" (21 CFR 172.861 and 21 CFR 184.1259).

Russia

In Russia, the use of CBR of POP type, produced from unmodified vegetable oils and vegetable oil fractions and (or) modified vegetable oils is allowed in accordance with the Technical Regulation on Fat and Oil Products TR CU 024/2011 (USDA, 2013).

China

In China, the use of cocoa butter substitutes is allowed as per the China's National Food Safety Standard on Chocolate and Its Products SPS/N/CHN/524 (USDA, 2012).

Japan

The Japanese Fair Trade Commission allows the use of any edible oils and fats other than cocoa butter to make "Chocolate Material" or "Quasi Chocolate Material".

III. CHEMISTRY AND MANUFACTURING OF COBERINE™ N707

A. Identity of the Ingredient

Loders Croklaan's Coberine™ N707 is the product of the enzymatic interesterification of palm oil and stearic acid. As is the case for other food-grade vegetable oils, Coberine™ N707 predominantly consists of fat (>99 g fat/100 g product). The fat phase is predominately triglycerides (average 99.7% of the fat phase), with only traces of monoglycerides and diglycerides and a limited amount of unsaponifiable matter, typically found in refined vegetable oils. Table 6 shows the typical nutritional composition of Coberine™ N707

Table 6. Typical Nutritional Composition of Loders Croklaan's Coberine™ N707

NUTRITION FACTS (PER 100G)		
	CALCULATED	MEASURED
Calories	900	
Calories from fat	900	
Calories from carbohydrates	0	
Total fatty acids		
Saturated fatty acids		61 (gram)
Monounsaturated fatty acids		31 (gram)
Polyunsaturated fatty acids		3 (gram)
Trans fatty acids		<1 (gram)
Insoluble fiber	0	
Potassium (mg)	0	
Folic acid (mcg)	0	
Cholesterol (mg)	0	
Sodium (mg)	0	
Carbohydrates (polyols) (gm)	0	
Dietary fiber (gm)	0	
Sugar (gm)	0	
Protein (gm)	0	
Vitamin A (IU)	0	
Vitamin C (mg)	0	
Calcium (mg)	0	
Iron (mg)	0	

B. Chemistry of Coberine™ N707

The European community (EC) number, EC name, Chemical Abstracts Service (CAS) number, and molecular weight range of Coberine N707 are shown in Table 7.

Table 7. Nomenclature of Coberine™ N707

EC number:	293-398-2
EC name:	Oils, palm, interesterified
CAS number (EC inventory):	91079-12-8
Molecular formula:	Not applicable
Molecular weight range:	ca. 833-889 (predominantly)

1. Identities of the Main Components of the Ingredient

The triglycerides 1, 3-dipalmitoyl-2-oleylglycerol (POP), 1-palmitoyl-2-oleyl-3-stearoylglycerol (POSt) and 1, 3-stearoyl-2-oleylglycerol (StOSt) are the predominant components of Coberine™

N707 and account for greater than 75% of the ingredient. They are further described in the following paragraphs.

Chemical name: 1, 3-dipalmitoyl-2-oleylglycerol (POP)

CAS Number: 2190-25-2

Empirical Formula: $C_{53}H_{100}O_6$

Other names: 1,3-Bis(hexadecanoyloxy)propan-2-yl (9Z)-Octadec-9-enoate; 1,3-Bis(palmitoyloxy)-2-propanyl (9Z)-9-octadecenoate; 1,3-Dipalmitoyl-2-oleoylglycerol; 1,3-Bis(palmitoyloxy)propan-2-yl (9Z)-Octadec-9-enoate; 1,3-Dihexadecanoyl-2-(9Z)-octadecenoyl-sn-glycerol; 1,3-Dihexadecanoyl-2-(cis-9-octadecenoyl)glycerol; 1,3-Dipalmitoyl-2-oleoyl-sn-glycerol; 1,3-palmitin-2-olein; 1-Hexadecanoyl-2-(9Z-octadecenoyl)-3-hexadecanoyl-glycerol; Triglyceride POP.

Figure 1 shows the empirical formula and structure of POP.

Figure 1. Structure of 1, 3-dipalmitoyl-2-oleylglycerol (POP)

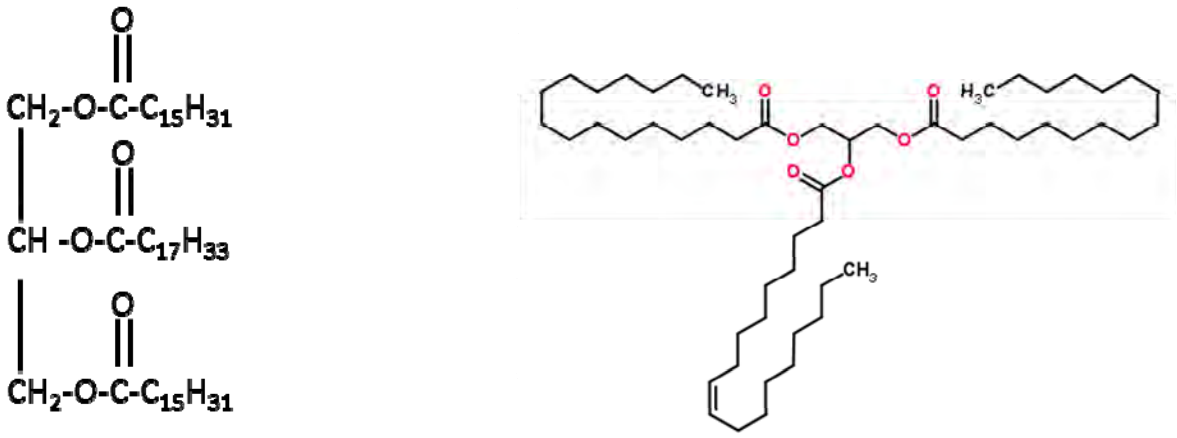


Table 8. Physical Characteristics of 1, 3-Dipalmitoyl-2-Oleylglycerol (POP)

Property	Value
Physical state at 20°C and 101.3 KPa	Solid
Melting/freezing point	37.3°C (β-form)
Color	Pale yellow/white
Density	0.917 gram/cm^3
Boiling point	792.9°C at 760 mmHg

Chemical name: 1-Palmitoyl-2-Oleyl-3-Stearoylglycerol (POSt)

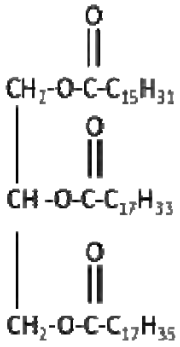
CAS Number: 2190-27-4

Empirical Formula: $C_{55}H_{104}O_6$

Other names: Cocoa butter substitute primarily from palm oil; 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; Olein, 1-palmito-3-stearo-2-; Palmitin, 2-Oleo-3-stearo-1-; Stearin, 2-oleo-3-palmito-1-; 1-(((1-Oxohexadecyl)oxy)methyl)-2-((1-oxooctadecyl)oxy)ethyl oleate; 1-(Hexadecanoyloxy)-3-(octadecanoyloxy)propan-2-yl (9Z)-octadec-9-enoate; Triglyceride POSt.

Figure 2 shows the empirical formula and structure of POSt.

Figure 2. Empirical Formula and Structure of 1-Palmitoyl-2-Oleyl-3-Stearoylglycerol (POSt)



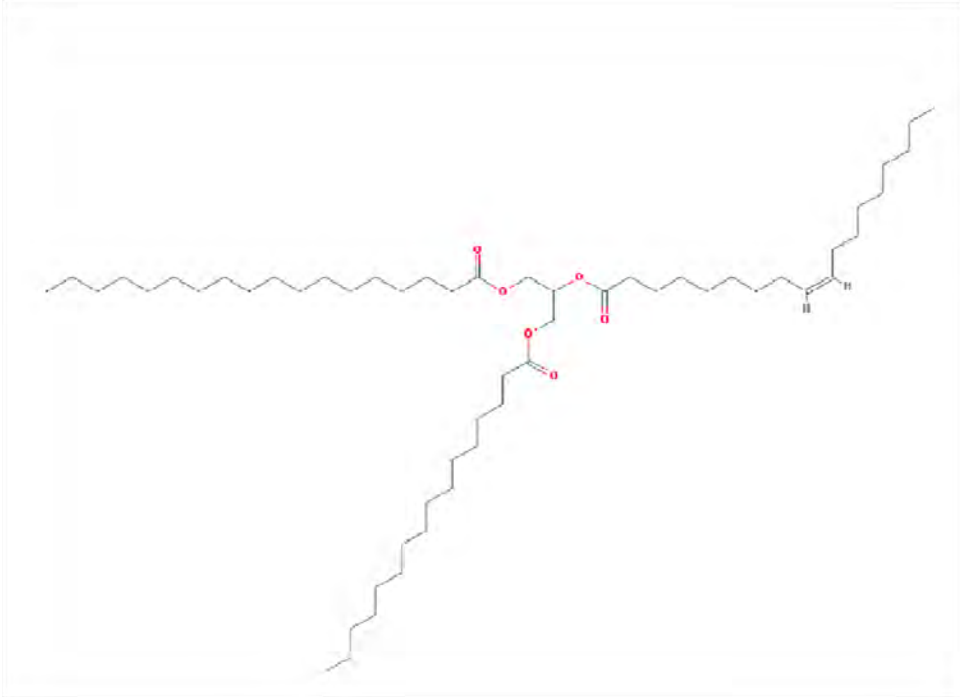


Table 9 shows the physical characteristics of POSt.

Table 9. Physical Characteristics of 1-Palmitoyl-2-Oleyl-3-Stearoylglycerol (POSt)

Property	Value
Physical state at 20°C and 101.3 KPa	Solid
Melting/freezing point	39.0°C (β-form)
Color	Pale yellow/white
Density	0.915 gram/cm^3
Boiling point	800.3°C at 760 mmHg

Chemical name: 1, 3-Distearoyl-2-Oleylglycerol (StOSt)

CAS Number: 2846-04-0

Empirical Formula: $C_{57}H_{108}O_6$

Other names*:* Cocoa butter substitute primarily from sunflower oil or safflower oil; (Z)-9-Octadecenoic Acid 2-[(1-Oxooctadecyl)oxy]-1-[[(1-oxooctadecyl)oxy]methyl]ethyl Ester; 1,3-Di-O-stearoyl-2-O-oleoylglycerol; 1,3-Distearo-2-olein; 1,3-Distearoyl-2-olein; 1,3-Distearoyl-2-oleoylglycerol; 1,3-Distearyl-2-oleylglycerol; 2-Oleo-1,3-distearin; 2-Oleoyl-1,3-distearin; 2-Oleoyl-1,3-distearoylglycerol; Chocoseed; Glyceryl 2-Oleoyl-1,3-distearate; SOS; Triglyceride StOSt.

Figure 3 shows the empirical formula and structure of StOSt.

Figure 3. Empirical Formula and Structure of 1, 3-Distearoyl-2-Oleylglycerol (StOSt)

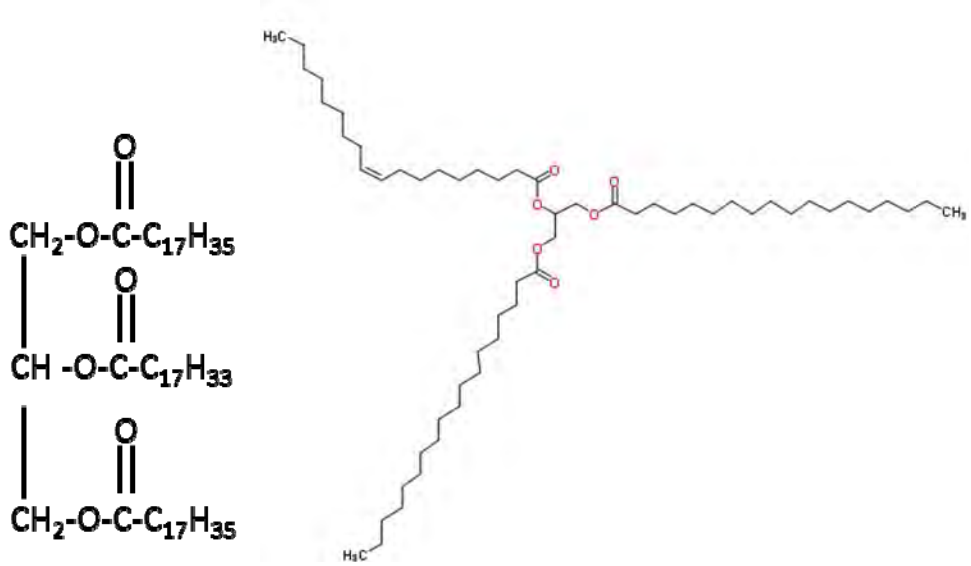


Table 10 shows the physical characteristics of StOSt.

Table 10. Physical Characteristics of 1, 3-Distearoyl-2-Oleylglycerol (StOSt)

Property	Value
Physical state at 20°C and 101.3 KPa	Solid
Melting/freezing point	36.5°C (β'-form)
Color	Pale yellow/white
Density	0.912 gram/cm^3
Boiling point	827°C at 760 mmHg

C. Chemical Characterization

IOI Loders Croklaan's specifications for contaminants, found in Appendix B, apply to all edible oils commercialized by IOI Loders Croklaan globally and are in line with Codex Alimentarius and FEDIOL (The EU Vegetable Oil and Proteinmeal Industry, http://www.fediol.be/). Analyses of three non-consecutive batches of Coberine™ N707 (Appendix C, and Appendix D) show that contaminant levels meet IOI Loders Croklaan's contaminants specifications. The ash content of Coberine™ N707 is given in Appendix E.

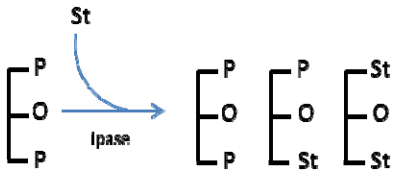
D. IOI Loders Croklaan, USA, LLC Manufacturing Processes for Coberine™ N707

A schematic representation of the manufacturing process for Coberine™ N707 is given in Appendix F. Traditional oil processing steps (*i.e.,* fractionation, interesterification, hydrolysis, and refining) are applied.

The manufacturing of CBS *via* an interesterification process is not new within the food industry or to the FDA. 21 CFR 184.1259 ("Cocoa Butter Substitute") shows that two of the three main cocoa butter components, POSt and StOSt, can be manufactured by lipase interesterification of palm oil with ethyl stearate in the presence of a GRAS lipase and by lipase interesterification of high oleic acid sunflower oil with ethyl stearate or stearic acid (Appendix G). In addition, 21 CFR 172.861 ("Cocoa Butter Substitute from Coconut Oil, Palm Kernel Oil, or Both Oils") discloses that a cocoa butter substitute can be obtained by enzymatic esterification of glycerol with food grade fatty acids derived from edible coconut oil, edible palm kernel oil, or both oils (Appendix H). The manufacturing process for Coberine™ N707 described below is similar to the processes described in 21 CFR 184.1259 and 21 CFR 172.861.

The first step in the manufacturing process of Coberine™ N707 (Figure 4) involves an interesterification reaction (technically best defined as acidolysis) between palm stearin, a palm oil triglyceride fraction rich in palmitate (POP) and the added food grade stearic acid. This is conducted using a food grade 1, 3-specific GRAS lipase such as the lipase derived from *Rhyzopus oryzae* (formerly known as *Rhyzopus delemar* and commercially known as Lipase D from Amano Enzyme, (Table 5), or the lipase from *Rhizomucor mihei* (commercially known as Lipozyme RM IM from Novozymes, (Table 3), or the lipase from *Thermomyces lanuginosus* (Table 5) to produce eiPMF, a mixture of triglycerides enriched in the triglycerides POP, POSt and StOSt. The palmitic acid residues (P) on the triglyceride POP are replaced by stearic acid (St) residues at the positions sn-1 and sn-3.

Figure 4. Selective interesterification of the main triglyceride of palm stearine (POP)



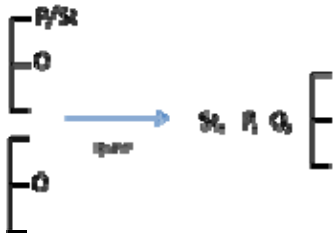
The method for the modification and improvement of edible fats by interesterification is a well-known procedure in the fat industry (Macrae, 1983; Negishi, 2005; de Paula et al., 2010; Bornscheuer, 2013; Ferreira-Dias, 2013). FDA has accepted this technology in approving the GRAS notifications for several modified fats ["High 2-Palmitic Vegetable Oil/Betapol Structured Triglycerides", GRN 000131 (Loders Croklaan, 2003) and GRN 000192 (Enzymotec, Ltd. 2006, updated 2012); "Tailored Triglycerides Containing Approximately 12 Percent Medium-Chain Fatty Acids", GRN 000217 (Nisshin OilliO Group USA, Inc., 2006)] and for using lipases to make modified fats, *e.g.*, 21 CFR 184.1420 "Lipase Enzyme

Preparation from *Rhizopus niveus* Used in the Interesterification of Fats and Oils"; "Lipase from *Candida rugosa*", GRN 000081 (Amano Enzyme Inc., 2001); "Lipase enzyme preparation from *Aspergillus oryzae*", GRN 000113 (Enzyme Technical Association, 2002); and "Lipase enzyme preparation from *Rhizopus oryzae*", GRN 000216 (Amano Enzyme Inc., 2006). The lipase used in this study to generate batch data was lipase enzyme prepared from *Rhizopus oryzae* (Appendix I). Table 5 shows a list of relevant GRAS notifications for lipases.

The second step in the manufacturing process for Coberine™ N707 involves the removal of the excess free fatty acids (primarily P) by distillation and the (solvent or dry) fractionation of the product of interesterification (eiPMF) to obtain an olein fraction of eiPMF [ei(PMF)f], that is further enriched in POP, POSt, and StOSt.

In the third step, a lipase treatment is required to fully hydrolyze possible diglycerides and monoglycerides present in the mixture since small amounts of diglycerides and monoglycerides can heavily affect the crystallization properties of the cocoa butter equivalent (Smith et al., 2011). The controlled hydrolysis, carried out by the lipase from *Penicillium camembertii* (GRN 000068), Amano Enzyme Inc. (2001), is aimed at releasing fatty acids and glycerol from monoglycerides and diglycerides which are removed from the final product during the final step of refining (Figure 5).

Figure 5. Hydrolysis of Diglycerides and Monoglycerides to Release Glycerol (E) and Free Fatty Acids



Refining consists of traditional vegetable oil refining processes including bleaching and deodorization. All processing chemicals used in manufacturing of Coberine™ N707 are appropriate for food use. IOI Loders Croklaan has a certified production process. Certificates of registration for the Food Safety Management System of IOI Edible Oils and Fats at the location where Coberine™ N707 is produced can be found in Appendix J.

Compared with the method of manufacturing used for the production of cocoa butter substitute in 21 CFR 184.1259, the IOI Loders Croklaan method uses stearic acid instead of ethyl stearate to produce the three primary triglycerides of cocoa butter and includes a second enzymatic step to further reduce the monoglyceride and diglyceride concentrations to acceptable levels for optimal crystallization performance.

Compared with the method of manufacturing currently used for the production of cocoa butter substitute from coconut oil, palm kernel oil, or both oils (21 CFR 172.861), the IOI Loders Croklaan method uses triglycerides from palm oil instead of glycerol in the interesterification reaction with stearic acid.

Currently, CBS is commercialized in the U.S. by Fuji Oil Company under the brand “PALMY” using the procedure described in 21 CFR 184.1259. The scheme for the production of PALMY” is shown in Appendix K. The PALMY production method involves an initial interesterification reaction between HOSF and ethyl stearate using a GRAS lipase, followed by the removal of ethanol and solvent fractionation that separates ei(HOSF)f and eiHOSF(s). Next, ei(HOSF)s and palm mid fraction are blended and refined using bleaching and deodorization to produce PALMY.

E. Raw Material Description

The raw materials used for the production of Coberine™ N707 are palm oil derived palm oil mid-fraction (PMF) and food grade stearic acid, complying with 21 CFR 172.860.

1. Palm Mid-Fraction (PMF)

The PMF used for the production of Coberine™ N707 is produced by the multiple fractionation of palm oil. Its main characteristic is a very high content of symmetrical disaturated triglycerides (mainly POP). This fraction is the basis of virtually all true CBE on the market worldwide and is very suitable for use in chocolate-covered centers in place of lauric fats (*e.g.,* coconut). Prior to the enzymatic treatment, the PMF is physically refined (bleached and deodorized) in order to remove impurities that might influence the activity of the enzyme.

2. Stearic Acid

The stearic acid used for the production of Coberine™ N707 is food grade PALMAC 98-18 from IOI Oleochemical Industries Berhad. It contains at least 97.5% of fatty acids of which at least 98% is stearic acid. The specifications for stearic acid can be found in Appendix L. Any food grade stearic acid may be used in the manufacturing process.

PALMAC 98-18 meets the specifications given in 21 CFR 172.860 for “Fatty Acids”, which are:

- Unsaponifiable matter does not exceed 2 percent (Table 11), and
- It is free from chick edema factor (Appendix M).

The unsaponifiable matter analysis of stearic acid PALMAC 98-18 is given in Table 11. Testing was carried out by Dr. A. Verwey B.V., Agrolab Group, Rotterdam (NL). The method used conformed to ISO 3596 (2000)/ NEN EN ISO 3596 (2000).

Table 11. Unsaponifiable Matter Analysis of Stearic Acid PALMAC 98-18

Inspection Lot Number of Stearic Acid PALMAC-18	Unsaponifiable Matter Content (%)
890000520349	0.29
890000521075	0.06
890000521076	0.26

Results of the analyses for check-edema in samples of PALMAC 98-18 are given in Appendix M. The analysis was conducted by DXN Holdings Berhad, Johor, Malaysia.

PALMAC 98-18 meets the standard for stearic acid in FCC 9 (2015). These include:

- Lead: NMT 2 mg/kg, sample 5 gram
- Acid value (Fats and related substances): Between 196 and 211
- Iodine value: NMT 7
- Residue on ignition (Sulfated ash): NMT 0.1%, sample 2 gram
- Saponification value: Between 197 and 212, sample 3 gram
- Titer (Solidification Point): Between 54.5° and 69°
- Unsaponifiable matter: NMT 1.5%
- Water: NMT 0.2%

The results of the analyses for ash and water contents of stearic acid PALMAC 98-18 are found in Appendix N.

3. Specifications for Coberine™ N707

Coberine™ N707 meets the following specifications of 21 CFR 184.1259 for "Cocoa Butter Substitute":

- >90 percent triglycerides; ≤7 percent diglycerides; ≤1 percent monoglycerides; and ≤1 percent free fatty acids;
- Minimum 98 percent total glycerides;
- Clear color;
- Hexane ≤ 5 ppm; and
- Heavy metals as lead (not more than 10 mg/kg).

No fluorine is used in the manufacturing process for Coberine™ N707; therefore, the specification for residual fluorine in 21 CFR 184.1259 is not relevant.

A full copy of the preliminary product datasheet for Coberine™ N707 can be found in Appendix O.

Food Chemicals Codex 9 (2015) also provides specifications for cocoa butter substitute:

- Lead: ≤ 0.1 mg/kg (Coberine™ meets FCC 9 standard of NMT 0.1 mg/kg, Appendix C).
- Residual catalyst as fluoride: ≤ 0.5 mg/kg. Total volume of sodium fluoride TS required for the solution from both Distillate A and Distillate B should not exceed 0.75 ml. Because fluoride is not used in the manufacturing process for Coberine™ N707, this specification is not relevant.
- Hexane: ≤ 5 mg/kg (Table 12)
- Color (fats and related substances): ≤ 2.5 red (Appendix O says 2.5R max color 5 ¼" cell, Lovibond, Appendix P, Table 12)
- Free fatty acids (as oleic acid): ≤ 1.0% (Appendix O, Appendix P, Table 12). Appendix O states that the maximum percentage of free fatty acid is 0.1%)
- Iodine value: 30-33 (Appendix O: Iodine value of Coberine is 33-37). Data using two methods of analysis show a range of 33.6 to 35.2 for one method and 34.4 to 35.65 for the other method (Table 13). In comparison, (the PALMY MM7-LC value ranges from 30 to 38, Appendix W).
- Peroxide value (PV): ≤ 10 mEq/kg (Appendix N says peroxide value=1 max but Appendix V(Storage Trial) says max value is 1.5 mEq/kg fat)
- Total Glycerides: ≥ 98.0% of total (Table 12 and Appendix O)
- Monoglycerides: ≤ 1.0% (Table 12 and Appendix P)

- Diglycerides: ≤ 7% (Table 12 and Appendix P)
- Triglycerides: ≥ 90% (Table 12 and Appendix P)
- Unsaponifiable matter: ≤ 1.0% (Table 14)
- Water: ≤ 0.1% (Table 15)

For the quantitation of triglycerides, diglycerides, monoglycerides, and free fatty acids, high-pressure size exclusion chromatography analyses were carried out internally in accordance with the AOCS Cd 22-91 method for determining the polymerized triglyceride content of oils and fats. The separation is based on the relative retention of solubilized polymer molecules in terms of their molecular size by gel permeation chromatography. The method is also widely used in the oil and fat industry for the determination of triglyceride, diglycerides, monoglycerides, and free fatty acids in view of their different sizes.

21 CFR 184.1259 also states that the color of cocoa butter substitute should be “clear, bright, and free from suspended matter”. The AOCS Cc 13b-45 Wesson Method was carried out for the color determination using a 5.25” cell. Table 12 and Appendix P show that 3 lots of Coberine™ N707 had a clear appearance. In addition, 21 CFR 184.1259 notes, that the product should be free from foreign and rancid odor and taste.

Since IOI Loders Croklaan’s processing method does not make use of ethyl esters, specifications for residual ethanol and residual fatty acid esters are not needed. IOI Loders Croklaan also does not use hexane in this manufacturing process or any of its processing facilities so a specification for residual hexane is not needed. However, since the processing description shows the possibility of carrying out solvent fractionation with acetone, data have been provided that show that acetone meets the FCC specifications (Appendix Q).

In summary, an analysis of one lot of acetone has shown that acetone meets FCC standards shown in Appendix Q.

Analyses for residual acetone were carried out on several fractions of Coberine™ N707 (Table 12).

The average analysis for dry and wet fractionations for Coberine™ N707 showing compliance with the 21 CFR 184.1259 specification is given in Table 12. The analyses were carried out by the Dr. A. Verwey B.V. Laboratory, AgroLab Group, Rotterdam, Netherlands following the certified in-house method QMP_504_VW_607. The Certificate of Analysis numbers are REPORT 61754 – 126511, REPORT 61754 – 126520 and REPORT 61754 – 126521; original analyses are available on request.

Table 12. Average Analysis for Coberine™ N707 Showing Compliance with 21 CFR 184.1259 Specifications

	21 CFR 184.1259	LC Coberine™ N707 dry fractionation (n=8)	LC Coberine™ N707 wet fractionation (n=4)
Triglycerides	>90%	98.7%	99.2%
Diglycerides	<7%	0.5%	0.25%
Monoglycerides	<1%	0.0%	0.0%
Fatty acids	<1%	0.1%	0.0%
Total glycerides	>98%	99.2%	99.5%
Color	clear	clear	clear
(R 5.25")	(Not specified)	1.06	0.8
Solvents			
• **hexane**	<5ppm	Not applicable	Not applicable
• **acetone**	Not applicable	Not measured	<1 mg/kg (n=3)

The results for each analyzed lot of Coberine™ N707 demonstrate compliance with the specifications in 21 CFR 184.1259 and are given in Appendix P**.** Table 13 shows the iodine value analyses for Coberine™ N707 using two different analytical methods. These values are slightly higher than the specification in FCC 9 (30-33) for cocoa butter substitutes, but are lower than the range of the iodine value for PALMY shown in Appendix W.

Table 13. Iodine Value Analysis for Coberine

General info.	FE-121614-37-1	FE-121614-37-2	FE-121614-37-3	FE-121614-37-4	FE-121614-37-5	FE-121614-37-6
Product name	eCBE 8.5.1 16122014	eCBE 8.5.2 16122014	eCBE 8.5.3 16122014	eCBE 8.5.4 16122014	eCBE 8.5.5 16122014	eCBE 8.5.6 16122014
	PR-20141224-002	**PR-20141224-003**	**PR-20141224-004**	**PR-20141224-005**	**PR-20141224-006**	**PR-20141224-007**
IV Wijs	35.2	35	33.7	33.9	33.6	34.9
IV FTnIR	35.24	35.62	34.54	34.43	34.38	35.65

Table 14. Unsaponifiable Matter Content Analysis for Coberine™ N707

Dry fractionation route

Production batch code	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical Code	PR-20141224-006	PR-20141224-007	PR-20141224-003
Type	pilot plant	pilot plant	production
Date	Nov. 18, 2014	Nov. 17, 2014	Nov. 28, 2014
Unsaponifiable Matter	0.14	0.07	0.27

Wet fractionation route

Production Batch Code	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	FE-121614-37-1 ex PG
Analytical Code	PR-20141224-004	PR-20141224-005	PR-20141224-002
Type	pilot plant	pilot plant	production
Date	Nov. 18, 2014	Nov. 17, 2014	Nov. 28, 2014
Unsaponifiable Matter	0.11	0.13	0.16

Moisture analysis was carried out internally following the ISO 8534:2008, “Animal and vegetable fats and oils -- Determination of water content -- Karl Fischer method (pyridine free)”. The results of this analysis are shown in Table 15.

Table 15. Moisture Analysis for Coberine™ N707

Dry fractionation route

Production Batch Code	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20141224-6	PR-20141224-7	PR-20141224-3
Type	pilot plant	pilot plant	production
Date	Nov 18, 2014	Nov. 17, 2014	June 24, 2014
Moisture (%)	0.01	0.01	0.02

Wet fractionation route

Production Batch Code	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	FE-121614-37-1 ex PG
Analytical code	PR-20141224-004	PR-20141224-005	PR-20141224-002
Type	pilot plant	pilot plant	production
Date	Nov. 28, 2014	Dec. 3, 2014	Dec. 2, 2014
Moisture (%)	0.01	0.02	0.02

F. Compositional Analyses of Coberine™ N707

The following analyses were carried out to characterize Coberine™ N707: fatty acid analysis (FAME), triglycerides analysis, solid fat content (SFC) analysis using nuclear magnetic resonance (NMR), and cooling curve analysis (Jensen). Analysis of the competitive product PALMY manufactured by Fuji Oil Co., Ltd, the company that submitted GRASP 8G0348, for use of safflower and sunflower oil in the manufacturing of CBS was also done. A statement describing the chain of custody of the samples of the PALMY analyzed and compared with Loders Croklaan's can be found in Appendix R.

1. Fatty Acid Analysis (FAME)

For the FAME analysis, which was carried out internally, the following procedure was followed. The AOCS Ce 2-66 method was used for sample preparation. This method provides a means for preparing methyl esters of long-chain fatty acids for further analysis by Gas-Liquid Chromatography (GLC). For the fatty acid analysis, the ISO 15304:2002 method was used. This International Standard specifies a gas chromatographic method using capillary columns for the determination of the content of *trans* fatty acid isomers of vegetable oils and fats. The method is specially designed to evaluate, by a single capillary gas chromatographic (GC) procedure, the amount of *trans* isomers formed during (high temperature) refining, or during hydrogenation of

vegetable oils or fats. The method may also be used to report all other fatty acids (*e.g.,* to determine the full fatty acid composition and total amounts of saturated fatty acids, mono-unsaturated fatty acids and poly-unsaturated fatty acids) from the same sample and in the same analysis.

The average fatty acid compositions of Coberine™ N707, cocoa butter, and Fuji Cocoa Butter Substitute (PALMY) are given in Table 16**.** Original data for cocoa butter can be found in Padley et al., (1986). Raw data for Coberine™ N707 and PALMY can be found in Appendix S.

Table 16. Average Fatty Acid Compositions for Coberine™ N707, Cocoa Butter, and Fuji Cocoa Butter Substitute (PALMY)

Fatty Acid(s)	LC Coberine™ N707 Dry Fractionation (n=8)	LC Coberine™ N707 Wet Fractionation (n=4)	Cocoa Butter Typical[1]	Fuji Cocoa Butter Substitute (PALMY)[3] (n=2)
C12:0	0.1	0.1	E[2]	E
C14:0	0.4	0.5	0.02-0.16	E
C16:0	25.6	24.5	23.6-30.5	34.9
C18:0	37.6	39.0	30.2-36.5	26.6
C18:1	32.2	32.1	33.2-38.6	34.0
C18:2	3.2	3.0	2.2-4.8	2.5
C18:3	0	0	0.1-0.2	E
C20:0	0.5	0.5	0.7-1.4	E
C22:0	0.1	0.1	0.2	E
Total Trans Fatty Acids	0.3	0.3	E	E
Total SAFA calculated	63.1	63.8	55-69*	61.5
Total MUFA calculated	31.9	32.1	33.2-38.6*	34
Total PUFA calculated	3.2	3.0	2-5*	2.5

[1]Padley et al., (1986).
[2]E: minor constituents which are believed to be roughly equivalent to Coberine™ N707
*not defined in Padley et al., (1986) but estimated from individual fatty acid values
[3]See Appendix R for chain of custody statement for PALMY.

2. Fatty Acid Profile Comparison Between Food Chemicals Codex (FCC 9) Specifications for Fatty Acids in Cocoa Butter Substitute, IOI Loders Croklaan's Coberine™ N707, and Fuji Cocoa Butter Substitute

The fatty acid profiles of two lots of IOI Loders Croklaan's Coberine™ N707 were compared with the fatty acid specifications in FCC 9 for CBS (FCC, 2015), and the fatty acid profiles of two

samples of Fuji CBS, which is the subject of 21 CFR 184.1259 (Table 17). The weight % values for 14:0 fatty acids in Coberine™ N707 (0.4% for both lots) exceeded the value in the FCC specification for CBS (0%) as did the value for Fuji CBS (0.5% for both lots). This was also the case for C16:0 fatty acids, for which the lots of Coberine™ N707 had values of 24.5% and 26.4%. Values for Coberine™ N707 more closely approximated the FCC range of 21-24%, than the Fuji CBS values of 35.1% and 34.7%. For C18:0 fatty acids, the weight % values for two lots of Coberine™ N707 were 39.1% and 37.0%, which were slightly below the FCC range of 40-44% for CBS but were greater than the values for Fuji CBS (26.5 and 26.8%).

For the C18:1 group; a detailed sub-analysis was conducted. The C18:1 group (18:1T and 18:1cis (C) gave weights (%) of 0.1% and 32.5% (total =32.6%) and 0.1 and 31.8 (total = 31.9%) for Coberine™ N707 which fell within the range of 31-35% for 18:1 in FCC 9 specification for CBS. Corresponding values were 0.2 and 33.8% (total = 34%) and 0.2 and 34.1% (total = 34.3%) for the two lots of Fuji CBS, respectively, which also were in the range for the C18:1 fatty acids FCC 9 specification for CBS. For fatty acids in the ≥20C group, values for C20:0 and C22:0 totaled 0.6 for both lots of Coberine™ N707, which fell within the FCC 9 specifications range of 0.3-0.7 for CBS. One Fuji CBS sample gave values of 0.5% and 0.4% for C20:0 and C22:0, respectively (total = 0.9%); however, only the value for C22:0 was reported for the other sample (0.4%). No data were available for weight (%) values for C≤12 and C16:1, for which the FCC 9 specification was 0.0.

In summary, some values for Coberine™ N707 meet or fall within the range for the FCC specifications or were within the acceptable range of those values per cGMP standards and product specifications. All fatty acid percent weight values for Coberine™ N707 fall within the FCC specification range for CBS or between the FCC specification range for CBS and the value(s) for Fuji CBS, which has GRAS status.

Table 17. Fatty Acid Composition Comparison of the Food Chemicals Codex 9 Fatty Acid Specifications for Cocoa Butter Substitute, and the Fatty Acid Profiles of Two Lots of Loders Croklaan's Coberine™ N707, and Fuji Cocoa Butter Substitute

Fatty Acid	FCC 9 Specification for Cocoa Butter Substitute Weight % (Range)	Loders Croklaan's Coberine™ N707 LC Asia CBE Dec 13 (2) Weight % (Range)	Loders Croklaan's Coberine™ N707 (Date Not Specified) Weight % (Range)	Fuji Coca Butter Extract (Sample from Hershey) LC Wormerveer Weight % (Range)	Fuji Coca Butter Substitute (Sample from Hershey) LCUS Lab Weight % (Range)
≤12	0.0	NA	NA	NA	NA
12:0	0.0	NA	NA	0.1	0.1
14:0	0.0	0.4	0.4	0.5	0.5
16:0	21—24	24.5	26.4	35.1	34.7
16:1	0.0	NA	NA	NA	NA
16:1C[1]	Not specified	NA	NA	0	0.0
16:1T[2]	Not specified	NA	NA	0	NA
18:0	40—44	39.1	37.0	26.5	26.8
18:1	31—35	NA	NA	34	34.3
18:1T[2]	Not specified	0.1	0.1	0.2	0.2
18:1C[1]	Not specified	32.5	31.8	33.8	34.1
18:2	0.5—1.5	NA	NA	2.6	NA
18:2T[2]	Not specified	0.1	0.1	0.1	0.0
18:2C[1]	Not specified	2.7	3.3	2.5	2.5
≥20C[1]	0.3—0.7	NA	NA	NA	NA
20:0	Not specified	0.5	0.5	NA	0.5
22:0	Not specified	0.1	0.1	0.4	0.4

*Not an exact specification category for Cocoa Butter Substitute in FCC (2015) 9th edition.
NA: Not Available
[1]: C= cis
[2]: T= trans
[3]: See Appendix R for chain of custody statement for PALMY.

2. Triglyceride Analyses

The triglyceride analyses of Coberine™ N707 were carried out by high-resolution capillary gas chromatography following an internal procedure based on the ISO 23275-2:2006 method entitled "Animal and Vegetable Fats and Oils Cocoa Butter Equivalents in Cocoa Butter and Plain Chocolate - Part 2: Quantification of Cocoa Butter Equivalents". Table 18 shows a comparison of the mean triglyceride compositions of the wet and dry fractionations of Coberine™ N707, cocoa butter, (data from Foubert et al., 2004), and PALMY. The results show a closer similarity of Coberine™ N707 to cocoa butter than of PALMY to cocoa butter. The raw

data for the triglyceride fractionations of Coberine™ N707 and for two samples of PALMY (PALMY 1 and PALMY 2) can be found in Appendix T.

Table 18. Triglyceride Composition Comparison for Coberine™ N707, Cocoa Butter, and Fuji Cocoa Butter Substitute (PALMY)

	LC Coberine™ N707 Dry fractionation (n=8)	LC Coberine™ N707 Wet fractionation (n=4)	Cocoa Butter[1] Typical (n=20)	PALMY (n=2)
PPP	0.8	1	0.2-0.5	1.2
MOP	0.6	0.5	0.2-0.3	E[2]
MLP	0.1	0.1	E	E
PPSt	1.0	1.0	0.6-0.9	E
POP	14.8	13.9	17.0-19.4	43.2
PLP	1.6	0.8	1.4-1.9	E
PStSt	0.5	0.9	0.3-1.0	0.3
POSt	38.1	39	38.7-41.7	10.8
POO	2.7	2.7	1.8-5.0	E
PLSt	3.5	3.5	2.5-3.0	E
PLO	0.6	0.6	0.3-0.5	E
PLL	0.1	0.1	E	E
StStSt	0.1	0.1	0.2-0.6	0.7
StOSt	28.6	28.7	25.2-25.9	28.1
StOO	2.8	2.9	2.1-6.0	E
StLSt	2.4	2.6	E	E
OOO	0.3	0.2	E	1.3
StLO	0.5	0.5	E	E
AOSt	0.6	0.3	1.1-1.3	E
Total SOS	81.5	81.6	84.0	82.0

1 Summary of data from Foubert et al., (2004). Represents triacylglycerol compositions of cocoa butter from various countries (West Africa, Ivory Coast, Nigeria, Indonesia, Malaysia, San Domingo, Ecuador, Brazil).
2E: minor constituents which are believed to be roughly equivalent to Coberine™ N707
3See Appendix R for chain of custody statement for PALMY.

3. Measurement of Solid Fat Content

Measurement of the Solid Fat Content (SFC) in edible oils and fats is essential for the bakery, confectionery, and margarine industries since it measures the texture of fat as melting occurs. For a number of years, Nuclear Magnetic Resonance (NMR) has been the method of choice for the determination of SFC. The method used for the analysis of the samples was ISO 8292-1:2008, entitled “Animal and Vegetable Fats and Oils - Determination of Solid Fat Content by Pulsed NMR - Part 1: Direct Method”. The average SFC values for dry and wet fractionations of Coberine™ N707 are given in Table 19. The data demonstrate Coberine™ N707 crystallizing in a similar way as cocoa butter and PALMY.

Cocoa butter data were obtained internally from cocoa butter samples from Ivory Coast and are representative of the most popular types of cocoa butters. The raw data for Coberine™ N707 and PALMY can be found in Appendix U entitled “SFC Analysis of Coberine™ N707 and PALMY”.

Table 19. A Comparison of the Solid Fat Content of Coberine™ N707, Cocoa Butter (Internal Data) and Fuji Cocoa Butter Substitute (PALMY), Commercialized in USA

	LC Coberine™ N707 Dry fractionation (n=3)	LC Coberine™ N707 Wet fractionation (n=2)	Cocoa butter typical (n=4)	PALMY[1] (n=2)
S26N20 NMR	74	77.5	74.4	73.9
S26N25 NMR	64	64.5	68.3	60.5
S26N30 NMR	41	37	43.9	46.3
S26N35 NMR	3	4	1.4	1.3
S26N40 NMR	0	0	0	0

[1]: See Appendix R for chain of custody statement for PALMY.

4. Cooling Curve Data (Jensen)

Traditionally, the crystallization properties of CBE have been measured and monitored for quality control purposes by means of the Jensen cooling curve. This is a very specific method involving the measurement of temperature of the fat as it cools in a controlled way. Jensen cooling curves were obtained according to the method of Standard British Institution, BS 684-1.13:1976 entitled “Methods of Analysis of Fats and Fatty Oils. Physical Methods. Determination of Cooling Curve”. From the curves T_{min}, T_{max} and time $(t)_{max}$ were obtained. T_{min} is the minimum temperature of the Jensen curve, T_{max} is the maximum temperature of the Jensen curve and t_{max} is the time taken to reach that temperature. These parameters are important in distinguishing the factory performance of different cocoa butters and CBEs in the making of chocolate-based products.

The average Jensen parameters of Coberine™ N707 and cocoa butter samples are given in Table 20. Cocoa butter data were obtained internally from cocoa butter samples from Ivory Coast, representative of the most popular types of cocoa butters. Raw data for Jensen Cooling Parameters of Coberine™ N707, Cocoa Butter and PALMY can be found in Appendix V. The results show that the Jensen cooling characteristics of Coberine™ N707 are close to those of cocoa butter and PALMY. It is consequently expected that Coberine™ N707, cocoa butter, and PALMY will perform in a similar way during chocolate based product production.

Table 20. Jensen Cooling Parameters for Coberine™ N707, Cocoa Butter (Internal Data) and Fuji Cocoa Butter Substitute (PALMY)

	LC Coberine™ N707 Dry fractionation (n=3)	LC Coberine™ N707 Wet fractionation (n=3)	Cocoa butter Typical[1] (n=4)
T(max) Jensen	29.9	29.8	29.4
T(min) Jensen	24.7	24.7	23.7
time (max) Jensen	60.3	59.8	66.5

[1]Cocoa butter data were obtained internally from cocoa butter samples from Ivory Coast, representative of the most popular types of cocoa butters.

5. Nutritional Considerations

Nutrional data for Coberine™ N707, cocoa butter, and PALMY is shown in Table 21. The SAFA, PUFA, MUFA and trans fatty acid contents of cocoa butter, PALMY and Coberine™ N707 are essentially equal. Substitution of cocoa butter or PALMY with Coberine™ N707 would presumably have no effect on the nutritional characteristics of the food.

Table 21. Nutritional Data Comparison Among Coberine™ N707, Cocoa Butter, and Fuji Cocoa Butter Substitute (PALMY), Commercialized in the U.S.

	LC Coberine™ N707 Dry fractionation (n=3)	LC Coberine™ N707 Wet fractionation (n=3)	Cocoa butter typical[a]	PALMY[b]
Calories	900	900	884	
Calories from fat	900	900	884	
Calories from carbohydrates	0	0	0	
Total fatty acids				
Saturated fatty acids (gram)	59	59	59.7	61
Monounsaturated fatty acids (gram)	29.9	29.7	32.9	35
Polyunsaturated fatty acids (gram)	3.3	3.2	3	4
Trans fatty acids(gram)	0.3	0.3	<1	<1
Insoluble fiber	0	0	0	
Potassium (mg)	0	0	0	
Folic acid (mcg)	0	0	0	
Cholesterol (mg)	0	0	0	
Sodium (mg)	0	0	0	
Carbohydrates (polyols) (gram)	0	0	0	
Dietary fiber (gram)	0	0	0	

	LC Coberine™ N707 Dry fractionation (n=3)	LC Coberine™ N707 Wet fractionation (n=3)	Cocoa butter typical[a]	PALMY[b]
Sugar (gram)	0	0	0	
Protein (gram)	0	0	0	
Vitamin A (IU)	0	0	0	
Vitamin C (mg)	0	0	0	
Calcium (mg)	0	0	0	
Iron (mg)	0	0	0	

[a]Nutritional data taken from http://www.nutritionvalue.org/Oil,_cocoa_butter_nutritional_value.html
[b]See Appendix R for chain of custody statement for PALMY.

7. Stability Documentation

c. Stability Data on Coberine™ N707

Edible fats and oils are not highly perishable because of their low water activity. Microorganisms require water to grow. Nevertheless, fats and oils have variable shelf lives during which minor changes in their sensory characteristics occur due to rancidity. Two types of rancidity are known: hydrolytic rancidity and oxidative rancidity.

Hydrolytic rancidity results in the formation of free fatty acids and soaps (salts of free fatty acids) and is caused by either the reaction of lipid and water in the presence of heavy metals or by the action of lipase enzymes. Low levels of free fatty acids are not necessarily objectionable, particularly if they are sixteen or eighteen carbon fatty acids as commonly found in cocoa butter substitutes, since these fatty acids have limited taste impact. The analysis of free fatty acids (FFA) in fat is used to check the progress of hydrolytic rancidity during storage. For the FFA analysis, the ISO 669:2009 method entitled “Animal and Vegetable Fats and Oils - Determination of Acid Value and Acidity” was used. In the ISO 669:2009 method, the number of milligrams of potassium hydroxide required to neutralize the free fatty acids present in 1 gram of fat is measured by titration.

Oxidative rancidity occurs in fats and oils that contain unsaturated fatty acids, mostly because unsaturated fats are less stable than saturated fats. Oxidation produces an accumulation of aldehydes and ketones, which are compounds that are also responsible for the unfavorable flavors and odors. One of the most widely used tests for oxidative rancidity is the measure of the peroxide value. Peroxide value (PV) is a measure of the concentration of peroxides and hydroperoxides formed in the initial stages of lipid oxidation. Milliequivalents of peroxide per kg of fat are measured by titration with iodide ion. The ISO 3960:2007 method entitled “Animal and Vegetable Fats and Oils - Determination of Peroxide Value - Iodometric (Visual) Endpoint Determination” was used for the PV analysis.

Color changes were also monitored during storage using the AOCS Cc 13b-45 Wesson Method. Storage trial data can be found in Appendix X entitled “Storage Trial for Coberine™ N707”. Storage data show that no oxidative changes are seen in Coberine™ N707 after storage at ambient temperature for 6 months.

IV. INTENDED FOOD USES AND ESTIMATED DIETARY INTAKE

A. Estimated Dietary Consumption of Cocoa Butter Equivalent (Coberine™ N707) in the U.S. Population Based on Authorized Food Uses

The estimated daily intake of Coberine™ N707 when used as intended in “Confections and Frostings”, “Soft Candy”, and in “Sweet Sauces and Toppings” was assessed. The individual food-uses and use levels (including estimated coating inclusion rate for soft candy) that were employed in the current intake analysis are summarized in Table 22. Food codes representative of each authorized food-use were selected from the NHANES 2011-2012 dataset (CDC, 2014; USDA, 2014). See Appendix Y for the full list of food codes included and for the consumption data for each food category. Food codes were grouped into food-use categories in accordance with 21CFR 170.3 (2014c).

Table 22. Summary of the Individual Authorized Food-Uses and Intended Use-Levels for Cocoa Butter Equivalent (Coberine™ N707) in the U.S. (2011-2012 NHANES Data)

Food Category	Authorized Food-Uses[a]	Typical Estimated Coating Inclusion Rate (%)[b]	Typical Use-Levels[b] (%)
Confections and Frostings	Confections and frostings	NA	10 to 30
Soft Candy	Coatings of soft candy (including chocolate-based candies)	10 to 40	25 to 40
Sweet Sauces, Toppings, and Syrups	Sweet sauces and toppings	NA	5 to 30

NA: Not Applicable
[a]In accordance with the United States Code of Federal Regulations, 21 CFR 184.1259 (CFR, 2014a).
[b]For the purposes of the intake assessment, the maximum coating inclusion rate and maximum use level for each food use were used.

1. Statistical Methods

For the intake assessment, consumption data from individual dietary records detailing food items ingested by each survey participant were collated by computer and used to generate estimates for the intake of cocoa butter substitute by the U.S. population[2]. Estimates for the

[2] Statistical analysis and data management were conducted in DaDiet Software (Dazult Ltd., 2014). DaDiet Software is a web-based software tool that allows accurate estimate of exposure to nutrients and to substances added to foods, including

daily intake of cocoa butter substitute represent projected 2-day averages for each individual from Day 1 and Day 2 of NHANES 2011-2012 data; these average amounts comprised the distribution from which mean and percentile intake estimates were generated. Mean and percentile estimates were generated incorporating survey weights in order to provide representative intakes for the entire U.S. population. All-person intake refers to the estimated intake of cocoa butter substitute averaged over all individuals surveyed, regardless of whether they potentially consumed food products containing cocoa butter substitute, and therefore includes individuals with "zero" intakes (*i.e*. those who reported no intake of food products containing cocoa butter substitute during the 2 survey days). All-user intake refers to the estimated intake of cocoa butter substitute by those individuals who reported consuming food products containing cocoa butter substitute, hence the "all-user" designation. Individuals were considered 'users' if they consumed 1 or more food products containing cocoa butter substitute on either Day 1 or Day 2 of the survey.

Mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (LSRO, 1995). As such, the reliability of estimates for the intake of cocoa butter substitute based on the consumption of certain foods (such as uses in sweet sauces in toppings) may be questionable for certain individual population groups. These values were not considered when assessing the relative contribution of specific food uses to total cocoa butter substitute consumption and are marked with an asterisk in Table 23 and Table 24 and in Appendix Y.

a. Estimated Daily Intake of Coberine™ N707 from Currently Authorized Food Uses in the U.S.

Table 23 summarizes the estimated total intake of cocoa butter equivalent (gram/person/day) in the U.S. population, by age group considering all authorized food-uses. Table 24 presents this data on a per kilogram body weight basis (mg/kg body weight/day). The percentage of users ranged from 10.2 to 43.0%. Children were the greatest percentage of users at 43.0%, whereas only 10.1% of infants were identified as users of food categories in which cocoa butter substitute is authorized for use. The intake estimates of consumers (*i.e.*, "all-user" intakes) are considered the worst-case estimate of intakes of a substance; therefore, results among users only are discussed below in detail.

Among the total population, the mean and 90th percentile all-user intakes of cocoa butter substitute were determined to be 5.0 and 11.2 grams/person/day, respectively. Of the individual population groups, male teenagers and male adults had similar intakes, and were determined to have the greatest exposure to cocoa butter substitutes at the mean (5.5 to 6.0 grams/person/day) and 90th percentile (12.6 to 12.7 grams/person/day). Young children had the

contaminants, food additives, and novel ingredients. The main input components are concentration (use level) data and food consumption data. Data sets are combined in the software to provide accurate and efficient exposure assessments.

lowest intakes on an absolute basis at the mean and 90th percentile 2.9 and 7.3 grams/person/day) (Table 23).

Table 23. Summary of the Estimated Daily Intake of Cocoa Butter Equivalent (Coberine™ N707) from Authorized Food-Uses in the U.S. by Population Group (2011-2012 NHANES Data)

Population Group	Age Group (Years)	All-Person Consumption (gram/day)		All-Users Consumption (gram/day)			
		Mean	90th Percentile	% Users	n	Mean	90th Percentile
Infants	Up to 1	<0.1*	NA	1.2	7	1.8*	3.7*
Young Children	1 to 3	0.9	2.7	30.2	150	2.9	7.3
Children	4 to 11	1.7	5.7	43.0	509	4.0	8.5
Female Teenagers	12 to 19	1.7	5.0	33.9	169	5.0	12.1
Male Teenagers	12 to 19	1.6	5.7	26.3	140	6.0	12.6
Female Adults	20 and up	1.8	5.8	36.8	743	4.9	9.7
Male Adults	20 and up	1.9	6.2	35.2	651	5.5	12.7
Total Population	All Ages	1.8	5.8	35.4	2,369	5.0	11.2

NA: Not available

*: Value was not considered when assessing the relative contribution of specific food uses to total cocoa butter substitute consumption because mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (LSRO 1995)

Total population intakes were 84 and 185 mg/kg body weight/day at the mean and 90th percentile, respectively when expressed on a body weight basis (Table 24). Young children had the highest reliable mean and 90th percentile intakes at 210 and 552 mg/kg body weight/day. Male adults had the lowest mean and 90th percentile all-user intakes of 64 and 138 mg/kg body weight/day, respectively.

Table 24. Summary of the Estimated Daily Per Kilogram Body Weight Intake of Cocoa Butter Equivalent (Coberine™ N707) from Authorized Food-Uses in the U.S. by Population Group (2011-2012 NHANES Data)

Population Group	Age Group (Years)	All-Person Consumption (mg/kg bw/day)		All-Users Consumption (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Infants	Up to 1	2*	NA	1.2	7	185*	421*
Young Children	1 to 3	63	200	30.2	149	210	552
Children	4 to 11	62	201	43.0	509	144	325
Female Teenagers	12 to 19	28	94	34.0	165	82	155
Male Teenagers	12 to 19	25	85	26.4	139	93	200
Female Adults	20 and up	26	87	36.6	736	70	147
Male Adults	20 and up	22	71	35.0	645	64	138
Total Population	All Ages	30	92	35.3	2,350	84	185

Bw: body weight; NA: not available

*: Value was not considered when assessing the relative contribution of specific food uses to total cocoa butter substitute consumption because mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size (LSRO 1995).

Food consumption data have been combined with information on the authorized food-uses of cocoa butter substitute as a direct substance in foods to estimate all-person and all-user intakes of this material among the U.S. population. The intake methodology employed is generally considered to be 'worst case' as a result of several conservative assumptions made in the consumption estimates. For example, it is assumed that all food products within a food category contain the ingredient at the maximum specified level of use. In addition, it is well established that the length of a dietary survey affects the estimated consumption of individual users. Short-term surveys, such as the typical 2- or 3-day dietary surveys, may overestimate the consumption of food products that are consumed relatively infrequently (Anderson, 1988). Furthermore, focusing on the intakes of users only means that only the intakes by consumers of foods containing the ingredient are assessed, without dilution of intakes by considering non-users.

In summary, on an all-user basis, male teenagers and male adults were estimated to have the highest absolute mean and 90th percentile intakes of cocoa butter substitute at 5.5 to 6.0 gram/person/day and 12.6 to 12.7 gram/person/day, respectively. When expressed on a body weight basis, intakes were highest among young children, at 210 and 552 mg/kg body weight/day at the mean and 90th percentile. Overall, the percentage of users was relatively low for these food categories among all age groups, but particularly among infants, under 1 year. In terms of

contribution to total mean intake of cocoa butter substitute, the confectionary and frostings food category was the main contributor across population groups (52.4 to 65.4%), followed by sweet candy coatings (19.6 to 37.4%) and sweet sauces and toppings (4.9 to 18.8%).

V. COMPREHENSIVE DISCUSSION OF THE BASIS FOR THE DETERMINATION OF GRAS STATUS

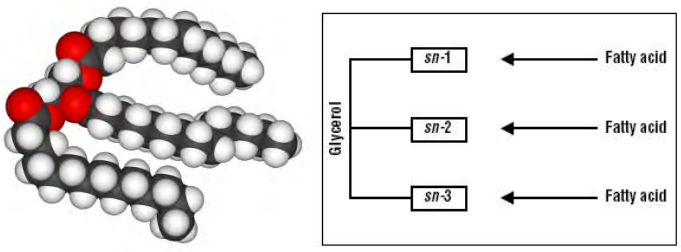
A. Absorption, Distribution, Metabolism and Excretion

Coberine™ N707 is composed mainly of triglycerides, which are organic molecules that are derived from both plants and animals. Triglycerides, also known as fats or oils, are made up principally of carbon and hydrogen and are nonpolar and thus, insoluble in water. Dietary triglycerides, and more importantly, their metabolites, free fatty acids, serve several important biological functions.

Triglycerides are a major energy source for the body as one gram of fat supplies 9 kcals (37.8 kJ), which is more than twice the energy supplied by an equivalent amount of carbohydrates or proteins. Fat is stored in the body as triglycerides called triacylglycerol depots. These subcutaneous depots serve as insulation against cold in most terrestrial animals. This is especially true for marine mammals, as the depots are less dense than water, which aids buoyancy, with the result that less energy is expended during swimming. Triglycerides play major roles in the absorption of nutrients, appetite, cognitive function, immune function, and cellular signaling pathways and are important dietary constituents for optimal growth and development of infants (Carta et al., 2015; Hansen and Artmann 2008, Happe and Gambelli, 2015; Legrand and Rioux, 2010; Onge et al., 2014).

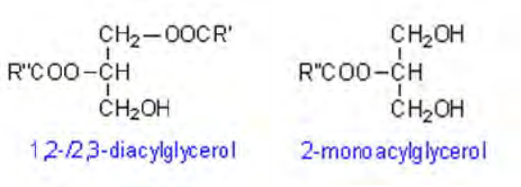
Triglycerides consist of a glycerol backbone bound to three fatty acids, as shown in Figure 6. A numbering system has been recommended to describe these forms. The prefix "sn" is placed before the stem name of the compound, when the stereochemistry is defined (sn=stereospecific numbering).

Figure 6. Typical Triglyceride Structure.



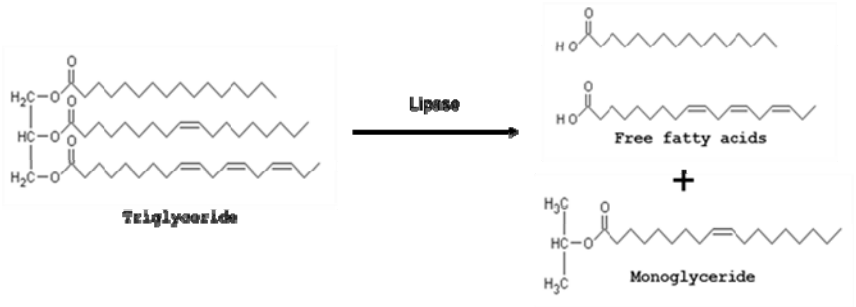
Diglycerides and monoglycerides contain two and one bound fatty acids per glycerol, respectively, and exist in various isomeric forms, *i.e,* the fatty acid can exist in various positions on the glycerol (Figure 7). Although monoglycerides and diglycerides exist in trace amounts in animals and plants, both are key intermediates in the biosynthesis of triglycerides and other lipids.

Figure 7. Typical Structure of Diglycerides and Monoglycerides



When triglycerides are digested, they are metabolized into free fatty acids and a monoglyceride by pancreatic lipases. Lipases also exist in saliva. Lipases typically act on the sn-1 and sn-3 positions and yield a sn-2 monoglyceride, as described in Figure 8**.**

Figure 8. Specific Gut Lipase Hydrolysis



Some fatty acids are more readily absorbed as a monoglyceride than as a free fatty acid. The chain length of the free fatty acid governs its subsequent uptake, which occurs either *via* the portal or the lymphatic system. Small and medium chain fatty acids can be directly absorbed into the blood stream through the portal vein (portal system). Dietary fatty acids of short and medium chain-length are not usually esterified, but they are oxidized rapidly in tissues as a source of fuel to support biological functions. However, long chain fatty acids are absorbed into the intestinal wall, reassembled into triglycerides, and secreted into the blood stream as chylomicrons. Because of the fatty acid composition of Loders Croklaan's Coberine™ N707, its absorption follows the latter route, which is represented in Figure 9**.**

Figure 9. Digestion and Absorption of Lipids in Humans[3]

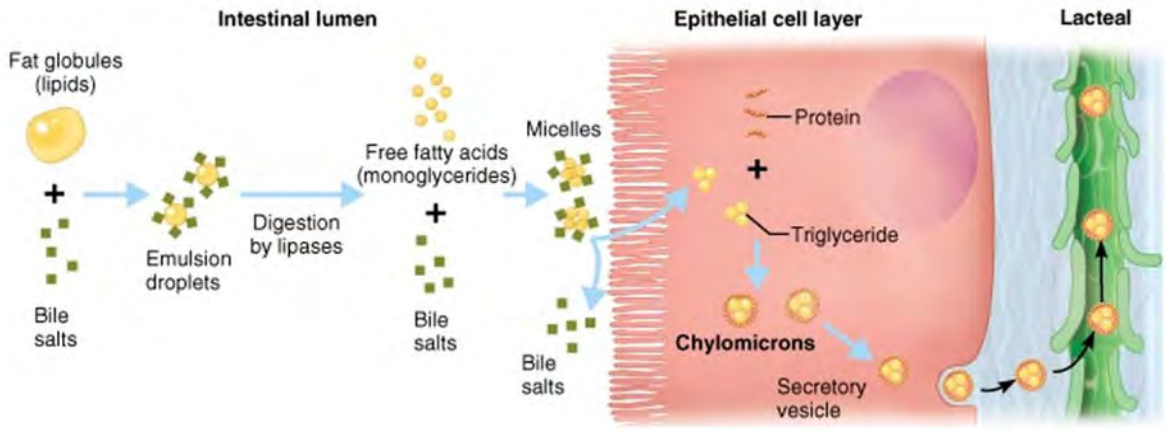
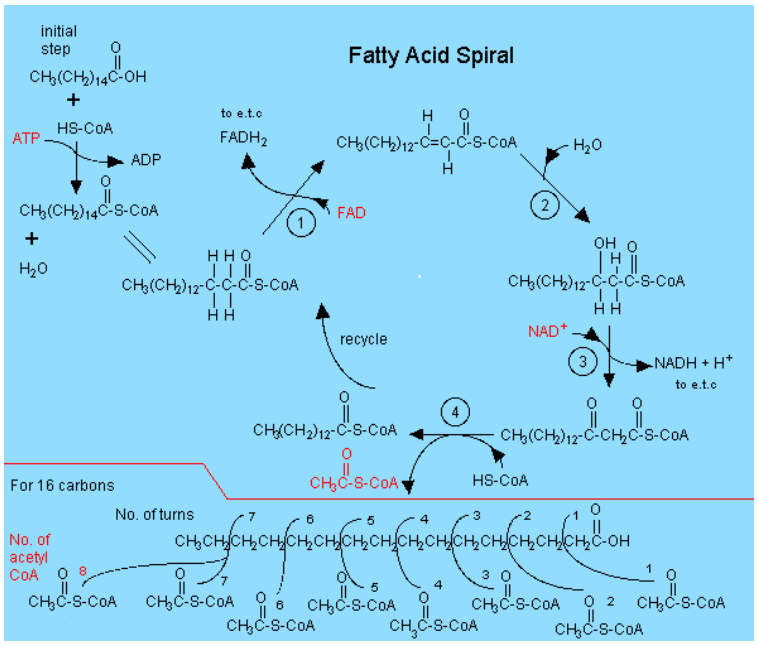


Figure 10. Beta-Oxidation of a Fatty Acid (*e.g.*, Palmitic Acid)[4]



[3] Available from: http://bioserv.fiu.edu/~walterm/fund_sp2004/digestion/present.htm

[4] Available from: http://chemistry.elmhurst.edu/vchembook/621fattyacidrx.html

Free acids can be mobilized quickly when required for transport in an appropriate form to the heart, liver and other tissues where they can be oxidized. Whereas the brain typically relies on carbohydrates for fuel, the heart and skeletal muscle prefer fatty acids as a source of energy. Fatty acids can then be burned as fuel (beta-oxidation) or used for other biological processes throughout the body.

Beta-oxidation occurs in the mitochondria and/or in peroxisomes to generate acetyl-CoA. The process is the reverse of fatty acid synthesis: two-carbon fragments are removed from the carboxyl end of the acid, as shown in Figure 10. This occurs after dehydrogenation, hydration, and oxidation to form a beta-keto acid. The acetyl-CoA then converts to ATP, CO_2, and H_2O using the citric acid cycle and releases energy of 106 ATP. Unsaturated fatty acids require additional enzymatic steps for degradation.

B. Review of Studies to Support Safety of Coberine™ N707

The safety information of Coberine™ N707 relies mainly on data developed to establish the safety of Coberine™ N707 components, and on the substantial similarity between Coberine™ N707 and CB and Coberine™ N707 and PALMY.

Natural cocoa butter has been used for centuries in the candy industry either as a component of the chocolate liquor or as a separate added ingredient to make a coating for confectionaries without evidence of toxicity. In addition, PALMY, a triglyceride mixture produced by interesterification of palm oil is currently used in the U.S. to replace natural cocoa butter. During digestion, PALMY releases mainly palmitic acid, stearic acid, oleic acid, and 2-monoglycerides. Similar triglycerides have been introduced and accepted as a substitute for cocoa butter.

IOI Loders Croklaan intends to replace either cocoa butter or a cocoa butter substitute with Coberine™ N707 in applications where these ingredients are already used. The components of Coberine™ N707 are palmitic, stearic, and oleic fatty acids and sn-2 monoglycerides, as is also the case for cocoa butter and PALMY. These components are found naturally as part of glycerides, lipids, lipoproteins, and membranes of both plants and animals. Moreover, they are the same fatty acids, monoglycerides, and glycerol components that are found in a broad range of edible fats, oils, and emulsifiers that are GRAS. They are consequently already a part of the everyday normal child and adult diet. The synthesis and metabolism of these substances are well understood (Cosmetic Ingredient Review Expert Panel, 1987) and are documented in biochemistry textbooks (Nelson and Cox, 2008). They are released in the gut when digested as is described in Section I.A.

Supportive evidence for the safety of Coberine™ N707 comes from previously published studies developed to establish the safety of cocoa butter substitutes that are enzymatically produced from palm and from high oleic sunflower oil and on the safety of other fats made from enzymatic interesterification using palm and fatty acids as starting components, as occurs in the processing of Coberine™ N707. Examples are a transesterified palm oil with palmitoleic acid,

used as cooking oil, and Betapol™, the subject of GRN 131, which is an interesterified fat mimicking human breast milk fat and used in infant formulas. As a component (esterified) of fats, stearic acid occurs in many animal and vegetable fats and oils, but it is more abundant in animal fat (up to 30% in beef tallow) than vegetable fat (typically <5%). The important exceptions are cocoa butter and shea butter, for which the stearic acid content is 28–45% of the total fatty acids. The average intake of stearic acid is 5.7 grams/day (8.1% of total fat) for women and 8.2 grams/day (8.4% of total fat) for men, according to data from NHANES (USDA, 2012b). For females and males, aged 20 years and over, dietary stearic acid intake accounts for 25.7% of SAFA (saturated fatty acid) intake (2.3% of total calories) and 17.9% of SAFA (2.8% of total calories), respectively.

Oleic acid is found in many vegetable oils and animal fats, frequently constituting greater than 50% of the total fatty acid concentration. Oils rich in oleic acid include olive oil and pecan oil (80%). The average intake of oleic acid is 23.7 grams/day (34.1% of total fat) for women and 33.4 grams/day (34.0% of total fat) for men, according to data from NHANES (USDA, 2012b).

Palmitic acid is also widely distributed and is present in practically all vegetable oils and fats at concentrations of at least 5%. Palmitic acid accounts for 54.2% of SAFAs (5.8% of total calories) for females and 54.5% of SAFAs (6.0% of total calories) for males (USDA, 2012b).

Monoglycerides are fatty acid monoesters of glycerol. They can be found in small percentages in vegetable oils and fats. Lipases that are naturally present in plants hydrolyze triglycerides prior to denaturation during the refining process. Most monoglycerides are removed during refining. Only crude oils, such as extra virgin and virgin olive oil still have monoglycerides, but usually at percentages below 0.25%. Because of emulsification properties linked to their polarity, monoglycerides of lauric, linoleic, myristic, oleic, palmitic, and stearic acids are the most common emulsifiers in the food industry and account for approximately 70% of emulsifier usage (O'Brien, 2009). They are known in Europe under the E-471 and are generally recognized as safe (GRAS) by the FDA under 21 CFR 182.1505.

1. Safety Studies on an Enzymatically Esterified Substitute Oil (ESO) from Safflower Oil and Stearic Ethyl Ester

An *in vitro* study, an acute toxicity study, and a subchronic oral toxicity in rats were conducted on the CBS derived from high oleic safflower oil and triglycerides derived from palm oil, prepared by enzymatic interesterification using a 1, 3-position specific lipase (ESO) (Shimoda et al., 1994 a, b, c). These studies were submitted to FDA in support of GRASP 8G0348 which requested that 21 CFR 184.1259 be amended to affirm that the use of safflower or sunflower oil in the manufacturing process for cocoa butter substitute is GRAS.

Cocoa butter substitute made from high-oleic safflower or sunflower oil used for these studies was prepared by interesterification of partially saturated triglycerides derived from palm oil and

ethyl stearate in the presence of a lipase enzyme preparation. The analytical data of the ESO on the sample in the Shimoda studies are given in Table 25. Studies conducted on this ESO are described below.

Table 25. Analytical data for ESO

Lipid Composition (Wt %)		Fatty acid composition (Wt %)		General physiochemical measurements	
Triglycerides	92.5	C14:0	0.1	Acid value	0.09
Diglycerides	4.5	C16:0	5.1	Saponification value	180.3
Monoglycerides	0	C16:1	0	Iodine value	43.6
Free fatty acids	0	C18:0	48.7	Color	Vis spectrum
Free sterols	0.5	C18:1	36.3	Peroxide value	0.48
Sterol esters	0.4	C18:2	9.1	Heavy metal	n.d.
		C18:3	0.6	Arsenic	n.d.

n.d.-Not detected

a. *In Vitro* Studies on ESO

1. Bacterial Reverse Mutation Assay on an Enzymatically Esterified Substitute Oil (ESO) from Safflower Oil and Stearic Ethyl Ester

Shimoda et al., (1994b) studied the mutagenicity of an enzymatically esterified substitute oil (ESO) made from safflower oil and stearic ethyl ester in the bacterial reversion assay in the absence and presence of metabolic activation (S9 mix). *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, and TA 1537 and *Escherichia coli* strain WP2 uvrA were used in the study. ESO was dissolved in acetone because it is only slightly soluble in water and dimethyl sulfoxide, which are the typical solvents for the mutagenicity assay. A preliminary study in *S. typhimurium* strain TA 98 (which exhibits similarities to TA 1537) and TA 100 (which exhibits similarities to TA 1534) showed that acetone does not have toxic effects on *S. typhimurium* or the S9 mix. Acetone was used as the solvent at a dose of 100 µL/plate in the dose range finding study and the main study. A dose range finding study conducted with 8, 40, 200, 1,000, or 5,000 µg/plate showed no effect of ESO in the presence of metabolic activation. In the absence of metabolic activation, ESO had no effect on bacterial lawn growth of TA 98, but it was associated with a slight inhibition of growth of TA 100 at the 5,000 µg/plate dose, which the authors interpreted as insignificant. As a result, the maximum concentration used in the main study was 5,000 µg/mL. In the main study, 5,000 µg/plate of ESO inhibited bacterial growth in the absence of metabolic activation. In the presence of metabolic activation, growth inhibition occurred in the WP2 uvrA strain but did not occur in any of the *S. typhimurium* strains. The positive control elicited

increases in the number of revertants. Based on these results, the authors concluded that ESO is not mutagenic to bacteria (Shimoda et al., 1994b).

b. Acute Toxicity Study on an Enzymatically Esterified Cocoa Butter Substitute Oil (ESO) from Safflower Oil and Stearic Ethyl Ester

Shimoda et al., (1994c) conducted an acute oral toxicity study of ESO in 5-week-old male and female rats. The rats were randomly assigned based on stratification by body weight to either a control group (distilled water, 50 mL/kg) or a 50 mL/kg ESO group, approximately 45 g/kg, (n=10 animals/sex/dose group). The rats were fasted for approximately 16 hours prior administration of a single dose of ESO or distilled water *via* oral gavage in a volume of 5 mL per 100 grams of body weight. They were assessed for general signs of toxicity immediately following administration of ESO or water and at 30 min, 1, 2, 4, 6, and 8 hours following administration, after which they were assessed each morning through day 14 when they were killed. No deaths occurred during the study; therefore, the exact lethal dose LD_{50} could not be determined. As a result, the LD_{50} was designated as >50 mL/kg for both sexes. Male and female rats experienced reversible physiological effects that occurred due to the large amount of fat administered. Necropsy revealed no abnormal results for the ESO treatment group. One female rat in the control group exhibited mild hypertrophy of the right kidney to compensate for the absence of a left kidney. Histopathological analyses of organs were not performed because no macroscopic abnormalities were observed. The authors concluded that ESO is not acutely orally toxic at the administered dose.

c. Subchronic Toxicity Study on an Enzymatically Esterified Substitute Oil (ESO) from Safflower Oil and Stearic Ethyl Ester

Shimoda et al., (1994a) conducted a 90-day oral, subchronic, toxicity test with an additional 35-day recovery period on ESO and reference oil (palm oil) in 5-week-old male and female rats. ESO or palm oil (10/sex/dose group) was administered by oral gavage over 90 days at a dose of 1, 3, or 10 mL/kg bw/day, after which a subset of animals was further observed for 35 days. A control group of animals was administered 1 mL/kg bw of distilled water. In the recovery study, 5 male rats and 5 female rats were included in the control group and the 10 mL/kg ESO and palm oil treatment groups. No animals in any treatment group died during the treatment or during recovery periods. The feces of rats of both sexes that were treated with 10 mL/kg ESO were grayish white and had the appearance of the test substance starting in week 11 of treatment; however, this was no longer apparent once the recovery period began. No other clinical signs were observed. There was no significant difference between test groups for cumulative body weight gain, although male rats that were administered 10 ml/kg ESO experienced statistically significant reductions in body weight gain from week 7 of treatment and female rats also showed reduced weight gain on days 47, 52, and 82 compared with controls. There was no complete recovery of weight gain for males during the recovery period, in contrast with female rats. Both male and female rats in the 10 mL/kg bw ESO and palm oil dose groups showed significant

reductions in food consumption on the majority of days and increased cumulative food efficiency during the treatment phase but not during the recovery phase of the study. Water consumption was comparable to the control group after the treatment period ended.

Urinalysis, hematological, serum biochemical, and ophthalmologic results revealed either no effects or effects that fell in the normal physiological range or no changes that the authors considered to be related to the test article at the end of the recovery period other than a significant reduction in the potassium concentration for males in the palm oil group. Significant changes in rats that were administered ESO were not considered to be toxic. Histopathological changes did not exhibit a dose-dependent severity or incidence and were, therefore, described by the authors as spontaneous or physiological changes that are often seen in rats. Treatment with palm oil (reference oil) led to diffuse vacuolization and the presence of fat droplets in the liver, but these effects were not observed at the end of the recovery period in animals given 10 mL/kg. A decrease in body weight gain observed in the animals of both sexes in the 10 mL/kg ESO group and palm oil groups was the only finding to be taken into account from the toxicological point of view. Therefore, the maximum no-effect dose in the present study was estimated to be 3 mL/kg for the two substances (Shimoda et al., 1994a). The authors concluded that ESO is a safe ingredient in the human diet.

2. Toxicity Studies on Heated, Transesterified Palm Oil

a. Bacterial Mutagenicity Test on Heated, Transesterified Palm Oil

The mutagenicity of heated (210°C) liquid oil produced by acidolysis of palm oil and palmitoleic acid (transesterified palm oil) was compared with the mutagenicity of heated and unheated peanut oil (Cohen et al., 1983). No mutagenic potential was reported for any of the oils.

b. Chronic Toxicity on Heated, Transesterified Palm Oil

Cohen et al., (1983) conducted a one-year toxicity test in which rats were fed diets containing 15% heated, liquid transesterified palm oil (Koor Foods Ltd., Israel), heated peanut oil, or unheated peanut oil. Growth rate inhibition was observed over the first 8 weeks of the study for female rats and throughout the 13-week growth period for male rats who were fed either heated palm oil or heated peanut oil, but not for rats that were fed unheated peanut oil. There was a significantly higher serum concentration of cholesterol for female rats fed heated peanut oil than for female rats fed heated palm oil or unheated peanut oil for one year ($P<0.05$), but no difference in total protein, albumin, globulins, total fat, glucose, uric acid, and inorganic phosphorus. The activities of serum glutamic-oxaloacetic transaminase, alkaline phosphatase, and acetylcholinesterase were also measured in rats that were fed the diet for one year. No difference was reported between rats fed either heated palm oil or heated peanut oil, but rats of both sexes in these groups had a significantly higher alkaline phosphatase activity than rats in the unheated peanut oil group ($P<0.01$). Liver hypertrophy was observed in association with elevated alkaline phosphatase activity, which the authors described as possibly indicative of

liver metabolic hypertrophy. The authors reported that general appearance, behavior, survival, and reproductive performance were comparable across groups.

3. Comparison of the General, Reproductive, and Postnatal Developmental Toxicity of a Human Milk Fat Substitute Derived from Oleic Acid and Triglycerides Derived from Palm Oil (Betapol™) with Palm Oil

The general, reproductive, and post-natal developmental toxicity of a human milk fat equivalent (Betapol™) produced by enzymatic acidolysis of palm oil stearin and oleic acid (transesterified palm stearin) was compared with that of food grade reference oil (palm oleine) in Crl: CD (SD) BR VAF/Plus rats (Spurgeon et al., 2003). The primary constituents of Betapol™ are 1, 3-dioleoyl 2-palmitoyl triglyceride and 1, 2-dipalmitoyl 3-oleoyl triglyceride. Animals (160 animals/sex) were assigned using a stratified randomization process to one of five treatment groups. The negative control group was fed a commercially available rodent breeding diet (LAD 2) containing 2.3 to 4.7% fat (Group 1). Groups 2, 3, 4, and 5 consumed a standard purified diet containing no Betapol™ and 15% reference oil, 1.5% Betapol™ and 13.5% reference oil, 7.5% Betapol™ and 7.5% reference oil, and 15% Betapol™, and 0% reference oil, respectively. There were 32 mating pairs in the F_0 generation and 28 mating pairs in F_1 generation for each experimental group. The parental (F_0 generation) was given the allocated treatment in the diet starting at 6 weeks of age until weaning, which resulted in at least 10 weeks of exposure before mating and a total exposure of at least 5 months. Animals in the F_1 and F_2 generations were indirectly exposed to the substances until they weaned. Initiation of consumption of solid food generally began around age 14 days, and food intake was measured from age 4 weeks and lasted for approximately 6 months for F_1 animals with at least 10 weeks of exposure before cohabitation. Some females in the F_2 generation were treated until they were killed after sexual maturation.

There were no significant differences between groups in mortality, and the authors did not consider any deaths of animals to be attributable to treatment. An association with blood sampling and bleeding that typically occurred after mating of litters was observed. The authors reported some instances of statistically significant differences from the comparative control group and the palm oil group---such as food and water consumption and pale feces (possibly because of the high fat content of the diets)—but noted that effects tended toward the results of the negative control group (LAD diet). There was a dose-dependent elevation in ovary weight for rats in the F_1 and F_2 generations. This occurred in the absence of both microscopic changes the ovary and any adverse effects in fertility and reproductive performance for the F_0 and F_1 rats and sexual maturation in F_2 rats. As a result, the findings were considered by the authors as unlikely to be of toxicological significance. F_1 males that were given Betapol™ in the diet had elevated triglyceride levels after weaning, but had no other significant changes in clinical chemistry, organ weight, histopathological results, or reproductive effects. Liver pathological changes, minimal increases in hepatocyte vacuolation and periportal fat deposition were observed in some animals, in particular, females in the F0 generation given Betapol™ but the

clinical changes were thought to be due to increased fat absorption. The authors concluded that the results of the study did not indicate the presence of an unexpected toxicant and that Betapol™ was substantially equivalent to palm oil (Spurgeon et al., 2003). Betapol™ is currently commercialized in Europe, China, USA, Korea, Australia, and New Zealand.

C. Allergenicity

Lipids, the components of lipids, and the raw materials used (palm oil and stearic acid) are not allergenic. In the GRNs for these three enzyme preparations, the safety of these and other enzyme preparations was noted.

VI. GRAS CRITERIA AND EXPERT PANEL EVALUATION OF THE GRAS STATUS OF COBERINE™ N707

A. GRAS Criteria

FDA defines “safe” or “safety” as it applies to food ingredients as:

> “… reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.”[5]

Amplification is provided in that the determination of safety is to include probable consumption of the substance in question, the cumulative effect of the substance and appropriate safety factors. It is FDA’s operational definition of safety that serves as the framework against which this evaluation is provided.

Furthermore, in discussing GRAS criteria, FDA notes that:

> “…General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.”

> “General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information.”[6]

[5] See 21 CFR 170.3(i).
[6] See 21 CFR 170.30(a).

FDA discusses in more detail what is meant by the requirement of general knowledge and acceptance of pertinent information within the scientific community, i.e., the so-called "common knowledge element," in terms of the two following component elements:[7]

- Data and information relied upon to establish safety must be generally available, and this is most commonly established by utilizing published, peer-reviewed scientific journals; and

- There must be a basis to conclude that there is consensus (but not unanimity) among qualified scientists about the safety of the substance for its intended use, and this is established by relying upon secondary scientific literature such as published review articles, textbooks, or compendia, or by obtaining opinions of expert panels or opinions from authoritative bodies, such as JECFA and the National Academy of Sciences.

The apparent imprecision of the terms "appreciable," "at the time," and "reasonable certainty" demonstrates that the FDA recognizes the impossibility of providing absolute safety in this or any other area (Lu, 1988; Renwick, 1990; Rulis and Levitt, 2009).

As noted below, this safety assessment to ascertain GRAS status of Coberine™ N707 for the specified food uses meets FDA criteria for reasonable certainty of no harm under the intended conditions of use by considering both the technical and common knowledge elements.

B. Expert Panel Discussion of the Safety of Coberine™ N707 (Cocoa Butter Equivalent)

The Expert Panel reviewed published and unpublished information that was provided by IOI Loders Croklaan, USA, or identified through an independent search of the published literature in order to determine if IOI Loders Croklaan's Cocoa Butter Equivalent, Coberine™ N707, when produced using current Good Manufacturing Practices for cocoa butter substitutes at levels not to exceed the amounts specified in Table 22 in confections and frosting (10 to 30%), soft candy (25 to 40%), and sweet sauces and toppings (5 to 30%), can be designated as GRAS on the basis of scientific procedures. IOI Loders Croklaan intends to use the product as an ingredient in the above food categories as a replacement for cocoa butter or cocoa butter substitute in accordance with the United States Code of Federal Regulations, 21 CFR 184.1259 (CFR 2014a). The ingredient will not be used in standardized foods unless it meets the standard of identity.

The Expert Panel notes that there is a history of safe consumption of cocoa butter and cocoa butter substitutes and cocoa butter equivalents across the world. The Expert Panel reviewed the manufacturing process, specifications, and chemical composition of the cocoa butter equivalent Coberine™ N707. Coberine™ N707 is manufactured using a certified production process that is

[7]See Footnote 1.

similar to the manufacturing processes for cocoa butter substitute described in 21 CFR 184.1259 and 21 CFR 172.861. The manufacturing process for Coberine™ N707 includes the removal of free fatty acids and uses a food grade GRAS lipase to completely hydrolyze diglycerides and monoglycerides. Other GRAS notifications using techniques similar to that described for Coberine™ N707 include GRN 000131, GRN 000192, and GRN 000217. For use of lipases for producing modified fats, safety documentation can be found in GRN 000081, GRN 000113, GRN 000216, and GRN 000068.

In an amendment to the manufacturing practice described in 21 CFR 184.1259, stearic acid was listed as an alternative starting material for manufacturing cocoa butter substitute from high oleic acid safflower or sunflower oil. FDA's specifications for stearic acid in 21CFR 184.1090 state that stearic acid should be a white to yellowish color solid, meet the specifications of the FCC, and be used in food in accordance with current good manufacturing practices. FCC 9 (2015) lists specifications for stearic acid that include values for lead, acid, iodine, and saponification, residue on ignition, (sulfated ash), titer (solidification point), and unsaponifiable matter and water content of stearic acid. Stearic acid should also meet the specifications of fatty acids as in 21 CFR 172.860 which include unsaponifiable matter not exceeding 2 percent and the absence of chick edema factor. The stearic acid used in the manufacturing process for Coberine™ N707 is GRAS and meets these specifications. The acetone used in the manufacturing process for Coberine™ N707 meets the specifications of FCC 9 (2015) and the residues in the product have been measured to be less than 1 mg/kg.

The manufacturing process for Coberine™ N707 complies with current Good Manufacturing Practices and Food Safety Systems, and all ingredients used in the production of Coberine™ N707 have GRAS status or are regulated as food additives. The food grade specifications for Coberine™ N707 are adequate. The final product adheres to predetermined product specifications and acceptable specific contaminant levels. The Panel notes that Coberine™ N707 is substantially similar in composition to cocoa butter and Fuji's cocoa butter substitute, PALMY, as shown in the comparative analyses of fatty acids, triglycerides, solid fat content and cooling curve data (Jensen). The individual fatty acid compositions of the wet and dry fractions of Coberine™ N707 meet or closely approximate the fatty acid compositions of cocoa butter and Fuji's cocoa butter substitute. The fatty acid and percent weight values for Coberine™ N707 are within the FCC specification range for cocoa butter substitute or between the FCC specification range for cocoa butter substitute and the value for Fuji's cocoa butter substitute. The nutrient composition of Coberine™ N707 is similar to that of cocoa butter. In addition, the amounts of total SAFA, MUFA, and PUFA in Coberine™ N707 also closely approximate the estimated amounts of these substances in cocoa butter and in Fuji's cocoa butter substitute and meet or approximate the FCC 9 (2015) specifications for cocoa butter substitute. The slight deviations from the specifications listed in FCC 9 (2015) for fatty acid composition of cocoa butter substitute are not considered to be a safety issue. Levels of fatty acids in the *trans* isomeric form

in Coberine™ N707 are low and fall within the range of those found in other products on the market.

Contaminant levels in Coberine™ N707 meet the specifications for IOI Loders Croklaan's contaminants and those in 21 CFR 184.1259, and the specifications adhere to Codex Alimentarius and the EU Vegetable Oil and Proteinmeal Industry. Coberine™ N707 also meets or closely approximates the standards for cocoa butter substitute described in FCC 9 (2015). The value for iodine in Coberine™ N707 is 33 to 37 in the Coberine™ N707 specification. The iodine value for Coberine™ N707 ranged from 33.6 to 35.7 using two analytical methods, which closely approximates the FCC specifications and partially overlaps, but also exceeds that of the FCC specification range of 30 to 33. In comparison, the PALMY MMC specification range for iodine is 30 to 38. Storage data show that Coberine™ N707 is stable and that no oxidative changes were observed after storage at ambient temperature for 3 months.

Based on the similarity of the manufacturing processes for Coberine™ N707 and Fuji cocoa butter substitute, the GRAS statuses of the enzymes used to manufacture Coberine™ N707 (described in Section I.D), the product specifications for Coberine™ N707 falling within the ranges of those specified in 21 CFR 184.1259 and the FCC (2015) for CBS and a cocoa butter substitute (Fuji's Cocoa Butter Extract), and the similarity of the chemical and nutritional composition of Coberine™ N707 to the above substances, the Expert Panel considers Coberine™ N707 to be substantially equivalent to Fuji's Cocoa Butter Extract.

The Expert Panel also considered the estimated exposure to Coberine™ N707 from proposed uses and use levels in its assessment of the safety of Coberine™ N707. An analysis of the estimated exposure to consumers when Coberine™ N707 is used as intended showed that an individual at the mean consumption level would consume 5 grams/person/day and an individual in the 90th percentile for consumption would consume 11.2 grams/person/day of Coberine™ N707. On a mg/kg bw/day basis, an individual at the mean consumption level would consume 84 mg/kg bw/day and a user in the 90th percentile would consume 185 mg/kg bw/day of Coberine™ N707.

The Expert Panel compared the estimated intake of Coberine™ N707 from the proposed uses and use levels to those of other fatty acids that have achieved GRAS status. GRN 217 estimated the mean and 90th percentile intakes of tailored triglycerides, were 11 and 31 grams/person/day, respectively. GRN 192 for InFat™ (High 2-Palmitic Acid Vegetable Oil) estimated that for consumers only the estimated intake of high 2-palmitic acid vegetable oil by individuals of all ages (99.3% eaters) from all proposed food uses was 35 grams/person/day and 66 grams/person/day for individuals at the mean and 90th percentiles of intake, respectively. In addition, GRN 131, estimated the daily exposure to the substance of interest for individuals at the 90th percentile of energy intake to be approximately 5.5 grams/kg bw in preterm and term infants. GRN 131 also noted that the highest reported fat intake recommendation published by ESPGAN was 9 grams/kg bw. The Expert Panel for the subject of GRN 131 concluded that the

maximum exposure to the substance was within the recommendation and within general safe exposures to fats. The Expert Panel for the GRAS evaluation of Coberine™ N707 notes that the estimated intake of Coberine™ N707 at the mean and 90th percentiles were lower than or equal to the intakes of the three fatty acids with GRAS status described in GRNs 217, 192, and 131.

No *in vitro* toxicity*,* animal toxicity, or clinical studies have been conducted on Coberine™ N707; however, consideration of the safety of Coberine™ N707 rests on published studies that investigated the safety of (1) enzymatically esterified substitute oil from safflower oil and stearic acids which was submitted in support of GRASP 8GO348 (Shimoda et al. 1994a, b, and c), (2) heated, transesterified palm oil (Cohen et al. 1983), and (3) a triglyceride mixture comprising fatty acids present in edible oils and fats, the subject of GRN 131 (Spurgeon et al., 2003). This information is generally available and is summarized below:

Two bacterial mutagenicity assays reported that transesterified fats and oils are not mutagenic:

- A bacterial mutagenicity assay on an enzymatically esterified substitute oil (ESO) made from safflower oil and stearic acid ester showed that concentrations of ESO up to 5,000 µg/mL/plate were not mutagenic in the presence or absence of metabolic activation in *Salmonella typhimurium* strains or an *Escherichia coli* strain (Shimoda et al., 1994b) and

- A bacterial mutagenicity study on heated, transesterified palm oil revealed no mutagenic potential of the palm oil (Cohen et al., 1983).

An acute oral toxicity study on the transesterified fat, ESO, in rats (Shimoda et al., 1994c) reported an LD_{50} of > 50 mL/kg bw.

The Expert Panel weighted most heavily the results of subchronic and chronic toxicity studies on a transesterified fat, a transesterified oil, and a modified triglyceride fat:

- A subchronic oral toxicity study on ESO determined a maximum no effect level of 3 mL/kg bw (Shimoda et al., 1994a);

- A chronic toxicity test showed no adverse effects for animals fed heated, transesterified palm oil for one year at 15% of the diet (Cohen et al., 1983); and

- A general reproductive and postnatal developmental toxicity study on, a modified triglyceride fat, the subject of GRN 131, at 15% of the diet (equivalent to 10 gram/kg bw/day) showed changes that were not considered to be of toxicological significance and the authors reported that there was no evidence of an unexpected toxicant (Spurgeon et al., 2003).

IOI Loders Croklaan intends to use Coberine™ N707 as a replacement for cocoa butter or other cocoa butter substitutes, as per 21 CFR 184.1259. The chemical similarity of Coberine™ N707

to cocoa butter and Fuji's PALMY provide a strong scientific basis for this substitution. The food categories in which Loders Croklaan intends to use Coberine™ N707 are the same as those listed in 21 CFR 184.1259. As a result, no expanded use of the ingredient in food is expected.

Every species has an optimal level of fat in the diet. Estimates of fat intake in the diet and recommended intake levels vary. The Expert Panel considered the relationship between intake of Coberine™ N707 when used as proposed and the normal intake of fat per day. Gurr (1984) estimated that the normal human diet includes 120 grams of fat per person per day, which is equivalent to 2 grams/kg bw of fat per day for a 60 kg individual. The Institute of Medicine (IOM) recommended a total fat intake of 30-40% of daily calories for children ages 1 to 3 years, 25-35% of daily calories for children and adolescents ages 4 to 18 years, and 20-35% of daily calories for adults ages 19 years and older. Based on a 2,000 calorie/day diet, this would be an estimated 400 to 700 calories from fat/day or 44 to 78 grams of total fat per person per day and 0.73 to 1.3 gram/kg bw/day for a 60 kg adult. The Scientific Report of the Dietary Guidelines for Americans (2015) recommends an intake of less than 10% of calories per day from saturated fat. This would amount to an estimated 22 grams of saturated fat per day.

If Coberine™ N707 were to be consumed by an individual at the mean as a replacement for currently used cocoa butter substitute, it would account for approximately 4.2% of fat intake in the diet if the normal dietary intake is 120 gram/person/day. Correspondingly, if Coberine™ N707 replaced fat in an individual at the 90th percentile, it would account for 9.33% of fat intake in the diet. At the maximum intake level, the EDI of Coberine™ N707 would represent approximately 10% of the normal fat intake. Using more conservative estimates for ranges of 44 to 78 g of total fat/day, at the mean dietary intake levels would be 25.4% and 11.3% for 44 g total fat/day and 78 g/day, respectively, and 25% and 14.4% for an individual at the 90th percentile of consumption. The studies reviewed on other fats and oils speak to no known toxicity of fats. Based on the results of the studies above, the Expert Panel considers that that Coberine™ N707 is likely to be safe at the proposed levels of use and as safe as any other fats or oils in the diet.

C. Panel Findings on the Safety of Coberine™ N707

GRAS Associates has determined that Coberine™ N707, as described herein, is GRAS for use in food products as described in Table 22 of the dossier on the basis of scientific procedures. The Expert Panel recognizes the history of safe consumption of cocoa butter and cocoa butter substitutes across the world. The manufacturing process for Coberine™ N707 is similar to that described in other GRAS notifications and adheres to current Good Manufacturing Practices processes. Coberine™ N707 adheres to product specifications, is stable, has acceptable contaminant levels, and its fatty acid and triglyceride compositions, solid fat content, and cooling curve data are similar to those of cocoa butter and a cocoa butter substitute that is currently on the market and is produced by the petitioner for GRASP 8G0348. In addition, Coberine™ N707 meets or closely approximates the FCC specifications for cocoa butter substitute and meets the

relevant CFR standard. Based on this information, the Expert Panel considers Coberine™ N707 to be substantially chemically equivalent to cocoa butter and another cocoa butter substitute that is currently on the market.

Coberine™ N707 is intended to be used as a replacement for cocoa butter and cocoa butter substitutes that are currently on the market in the same food categories: “Confection and Frostings”, “Coatings of Soft Candy (Including Chocolate Based Candies)”, and “Sweet Sauces and Toppings” at levels of 10-3%, 25 to 40%, and 5 to 30%, respectively. No expanded use of the substance is anticipated. The exposure to an individual at the 90th percentile would be expected to be 11.2 gram/person/day or 185 mg/kg bw/day, which is below or equal to the level for some fats and oils that are GRAS. Toxicological studies on other fats and oils described in the GRAS dossier for Coberine™ N707 indicated that they are not mutagenic and that there is little acute oral toxicity associated with them. Subchronic and chronic oral toxicity studies on fats and oils, and a development and reproductive toxicity study on a modified triglyceride fat support the safety of Coberine™ N707 at the proposed use levels. Effects seen at high levels of fats and oils are likely to be nutritional risk factors and are not considered to be toxicological risk factors. Based on the information reviewed above, the Expert Panel considers IOI Loders Croklaan’s enzymatically produced cocoa butter equivalent, Coberine™ N707, to be GRAS.

This GRAS determination is based on data generally available within the public domain pertaining to the safety of Cocoa Butter Substitute or Equivalent, and on consensus among a panel of experts (the Expert Panel) who are qualified by scientific training and experience to evaluate the safety of this substance as a component of food. The Expert Panel consisted of the following qualified scientific experts: Richard Kraska, Ph.D., DABT (Co-Founder, Chief Scientific Officer and Executive Vice President, GRAS Associates), Robert McQuate, Ph.D. (Co-Founder, Chief Regulatory Officer and Senior Vice President Business Development, GRAS Associates), and Kara Lewis, Ph.D. (Independent Consultant, GRAS Associates). Additional information about Drs. Kraska and McQuate can be found on the GRAS Associates website.

D. Common Knowledge Elements for GRAS Determinations

The first common knowledge element for a GRAS determination requires the data and information relied upon to establish safety to be generally available; this is most commonly established by utilizing studies published in peer-reviewed scientific journals. The second common knowledge element for a GRAS determination requires that consensus exists within the broader scientific community about the safety of the substance.

1. Generally Available Information

Loders Croklaan’s enzymatically-produced cocoa butter equivalent, Coberine™ N707, the subject of this GRAS notification, meets the publicly available specifications given in 21 CFR 184.1259 for cocoa butter substitute and meets or approximates the standard for cocoa butter substitute published in FCC (2015). The enzymatically-produced cocoa butter equivalent is

generated using traditional manufacturing processes and conditions via a process that is similar to those described in 21 CFR 184.1259 and 21 CFR 172.861. Although no safety studies have been conducted on the specific product, the published scientific literature reviewed in the GRAS dossier that address the safety of fats and oils lends support to the safety of Coberine™ N707. The information cited in this safety assessment was obtained primarily from publicly available sources including scientific articles published in peer-reviewed scientific journals as well as the GRAS notifications for the fats and oils are publicly available on the FDA website. Some of the articles reviewed in the dossier have been included in previous GRAS notifications. As a result, the common knowledge element regarding general availability of primary scientific information that supports the safety of Loders Croklaan's enzymatically produced cocoa butter equivalent has been fulfilled.

2. Scientific Consensus

The second common knowledge element for a GRAS determination requires that there is a basis to conclude that consensus exists among qualified scientists about the safety of the substance for its intended use. The safety and human uses of triglycerides, fats and oils have been discussed and published and a cocoa butter substitute to which Loders Croklaan's enzymatically-produced cocoa butter equivalent is substantially chemically similar is currently on the market. It is likely that a cocoa butter equivalent that meets or closely approximates FCC specifications and the relevant CFR standards would be considered to be GRAS. The available scientific evidence supports the conclusion that scientific consensus exists for the subject GRAS determination.

VII. CONCLUSIONS[8]

GRAS Associates has concluded that the intended food uses of Cocoa Butter Equivalent, Coberine™ N707, as described in Table 22 are GRAS based on scientific procedures, as long as production occurs in accordance with GMP requirements and at consumption levels not to exceed 11.2 gram/person/day or 185 mg/kg bw/day. Food uses of IOI Loders Croklaan's Coberine™ N707 as described herein may therefore be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21, Section 170.3 of the Code of Federal Regulations.

This declaration has been made in accordance with FDA's standard for food ingredient safety, *i.e.*, reasonable certainty of no harm under the intended conditions of use.

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[8] The detailed educational and professional credentials for two of the individuals serving on the Expert Panel can be found on the GRAS Associates website at: www.gras-associates.com. Drs. Kraska and McQuate worked on GRAS and food additive safety issues within FDA's GRAS Review Branch earlier in their careers and subsequently continued working within this area in the private sector. All three panelists have extensive technical backgrounds in the evaluation of food ingredient safety. Dr. Lewis served as Chair of the Panel.

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Appendix A Expert Panel Consensus Statement Regarding the Generally Recognized as Safe (GRAS) Status of Coberine™ N707 (Enzymatically Produced Cocoa Butter Equivalent) for Use in Foods

We, the members of the Expert Panel, who are qualified by scientific experience and training to evaluate the safety of ingredients added to food, following an independent and collective review of the information presented herein, unanimously conclude that the intended food uses of IOI Loders Croklaan's Cocoa Butter Equivalent, Coberine™ N707, as described in Table 22 are GRAS based on scientific procedures. IOI Loders Croklaan's Coberine™ N707 as described herein may therefore be marketed and sold for its intended purpose as described in the U.S. without the promulgation of a food additive regulation under Title 21, Section 170.3 of the Code of Federal Regulations.

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Kara Lewis, Ph.D.

(b) (6)

Robert McQuate, Ph.D.

Appendix B Standard Contaminant Specifications, IOI Loders Croklaan

It is IOI Loders Croklaan policy to ensure that all steps in the procurement and manufacturing process of products are carried out in a way which ensures that products are safe for use in foods and conform to accepted microbiological standards and relevant EU food legislation.

Monitoring

Good Manufacturing Practice (GMP), which includes HACCP risk analysis as well as a hygiene and transport standards, is applied throughout the manufacturing process. As a consequence, control takes place on a monitoring basis. Sampling schemes and analysis schedules are applied to raw materials and end-products as well as products in all stages of processing.

Microbiology

Total plate count	max.	1000	/g	ISO 4833
Salmonella		absent	in 25 g	ISO 6579
Yeast	max.	10	/g	ISO 7954
Moulds	max.	10	/g	ISO 7954
Enterobacteriaceae	max.	10	/g	ISO 21528-2
E. coli	max.	10	in 1 g	ISO 16649-2

Refined oils are sterile and have a too low moisture content for bacteria to affect the quality of the oil.

Trace metals and contaminants

Trace Metals

Iron (Fe)	max.	0.50	mg/kg	
Copper (Cu)	max.	0.05	mg/kg	
Nickel (Ni)	max.	0.10	mg/kg	
Cadmium (Cd)	max.	0.02	mg/kg	
Mercury (Hg)	max.	0.10	mg/kg	
Arsenic (As)	max.	0.10	mg/kg	
Lead (Pb)	max.	0.10	mg/kg	

Radio Activity

CS 134 & 137	max.	600	Bq/kg	

Mycotoxins

Aflatoxin B1 *	max.	2	µg/kg	
Aflatoxin B1+B2+G1+G2 *	max.	4	µg/kg	

* Not relevant for Palm and Palm kernel products.

PCB (IUPAC No.)

Sum of PCB 28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES-6)	max	40	µg/kg	

Dioxins, furans and dioxin like PCB's

Dioxin	max.	0.75	pg/g	WHO-PCDD/F-TEQ
Sum of dioxin, furans and dioxin like PCB's	max.	1.25	pg/g	WHO-PCDD/F-PCB-TEQ

PAH

4 PAH's (Sum of benzo(a)pyrene, benzo(a)anthracene, chrysene and benzo(b)fluoranthene)	max.	10	µg/kg	
Benzo(a)pyrene	max.	2.0	µg/kg	

Pesticides

Chlorine pesticides

Captafol	max.	0.02	mg/kg	
Chlordane	max.	0.02	mg/kg	
Campheclor (Toxaphene)	max.	0.1	mg/kg	
DDT (sum of ppDDT, opDDT, ppDDE and ppDDD)	max.	0.05	mg/kg	
Dichlorbenil	max.	0.05	mg/kg	
Dieldrin (sum of Aldrin and Dieldrin)	max.	0.02	mg/kg	
Endosulfan (total Alpha & Beta isomers and sulphate)	max.	0.10	mg/kg	
Endrin	max.	0.01	mg/kg	
Heptachlor (sum of heptachlor and heptachlor epoxide)	max.	0.01	mg/kg	
Heptachlorociclohexane (HCH)	max.	0.01	mg/kg	
Hexachlorobenzene (HCB)	max.	0.01	mg/kg	
Lindane (gamma HCH isomer)	max.	0.01	mg/kg	
Methoxychlor	max.	0.01	mg/kg	
Nitrofen	max.	0.02	mg/kg	

Nitrogen Pesticides

Amitraz	max	0.05	mg/kg	
Diclofop – methyl	max.	0.05	mg/kg	
Captan	max.	0.02	mg/kg	
Carbaryl	max.	0.05	mg/kg	
Procymidone	max.	0.05	mg/kg	
Propoxur	max.	0.05	mg/kg	
Vinclozolin	max.	0.05	mg/kg	

Pyrethorides

Cypermethrin	max.	0.05	mg/kg	
Deltamethrin	max.	0.05	mg/kg	
Fenvalerate	max.	0.05	mg/kg	
Permethrin	max.	0.10	mg/kg	

Phosphor Pesticides

Azinphos – methyl	max.	0.05	mg/kg	
Acephate	max.	0.05	mg/kg	
Bromophos - ethyl	max.	0.05	mg/kg	
Chlorpyrifos	max.	0.05	mg/kg	
Chlorpyrifos – ethyl	max.	0.05	mg/kg	
Chlorpyrifos – methyl	max.	0.05	mg/kg	
Diazinon	max.	0.02	mg/kg	
Dichlorvos	max.	0.01	mg/kg	
Dimethoate	max	0.05	mg/kg	
Disulfoton	max.	0.02	mg/kg	
Ethion	max.	0.02	mg/kg	
Fenitrothion	max.	0.01	mg/kg	
Fenthion	max	0.02	mg/kg	
Malathion	max	0.02	mg/kg	
Methamidophos	max.	0.01	mg/kg	
Methidathion	max.	0.05	mg/kg	
Mevinphos	max.	0.01	mg/kg	
Parathion - methyl	max	0.05	mg/kg	
Phosphamidon	max.	0.01	mg/kg	
Pirimiphos – methyl	max	0.05	mg/kg	
Trichlorphon	max.	0.10	mg/kg	

Fatty Acids

Erucic acid**	max.	50	g/kg	Of total fatty acids

** Erucic acid is not strictly considered a contaminant because it is a fatty acid naturally occurring in some oils and fats. However, Regulation (EC) nr. 1881/2006 states there is a maximum on the amount of Erucic acid.

Appendix C Contaminants Analyses of Three Non-Consecutive Batches of Coberine™ N707

Production Batch Code	Specifications	FE-121614-37-4 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code		PR-20141224-005	PR-20141224-007	PR-20141224-003
Date		Nov. 18, 2014	Nov 17, 2014	June 24, 2014
Type		pilot plant (wet)	pilot plant (dry)	production (dry)
Trace metals and contaminants				
Iron (Fe)	max. 0.50 mg/kg	< 0.1 mg/kg	< 0.1 mg/kg	< 0.1 mg/kg
Copper (Cu)	max. 0.05 mg/kg	< 0.05 mg/kg	< 0.05 mg/kg	< 0.05 mg/kg
Nickel (Ni)	max. 0.10 mg/kg	< 0.06 mg/kg	< 0.06 mg/kg	< 0.06 mg/kg
Cadmium (Cd)	max. 0.02 mg/kg	< 0.02 mg/kg	< 0.02 mg/kg	< 0.02 mg/kg
Mercury (Hg)	max. 0.10 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
Arsenic (As)	max. 0.10 mg/kg	< 0.02 mg/kg	< 0.02 mg/kg	< 0.02 mg/kg
Lead (Pb)	max. 0.10 mg/kg	< 0.05 mg/kg	< 0.05 mg/kg	< 0.05 mg/kg
Mycotoxins				
B1	max. 2 µg/kg	< 0.1 µg/kg	< 0.1 µg/kg	< 0.1 µg/kg
B1+B2+G1+G2	max. 4 µg/kg	< 0.1 µg/kg	< 0.1 µg/kg	< 0.1 µg/kg
PCB (IUPAC No.)				
PCB28+52+101+153+180 (ICES-6)	max. 40 µg/kg	< 6 µg/kg	< 6 µg/kg	< 6 µg/kg
Dioxins, furans and dioxin like PCB's				
Dioxin	max. 0.75 pg/g	0.158 pg/g	0.158 pg/g	0.158 pg/g
Dioxin+furans+dioxin like PCB's	max. 1.25 pg/g	0.271 pg/g	0.271 pg/g	0.271 pg/g
PAH				
BaP+BaA+Chr+Bbf	max. 10 µg/kg	2.8 µg/kg	2.8 µg/kg	1.7 µg/kg
Benzo(a)pyrene	max. 2 µg/kg	1.3 µg/kg	1.3 µg/kg	0.3 µg/kg
Chlorine pesticides				
• Captafol	max. 0.02	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg

Production Batch Code	Specifications	FE-121614-37-4 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
	mg/kg			
• Chlordane	max. 0.02 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Campheclor	max. 0.1 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg
• DDT	max. 0.05 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Dichlorbenil	max. 0.05 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Dieldrin	max. 0.02 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Endosulfan	max. 0.10 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Endrin	max. 0.01 mg/kg	< 0.010 mg/kg	< 0.010 mg/kg	< 0.010 mg/kg
• Heptachlor	max. 0.01 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Heptachlorociclohexane	max. 0.01 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg
• Hexachlorobenzene	max. 0.01 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg
• Lindane	max. 0.01 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg	< 0.001 mg/kg
• Methoxychlor	max. 0.01 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Nitrofen	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg

Production Batch Code	Specifications	FE-121614-37-4 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code		PR-20141224-005	PR-20141224-007	PR-20141224-003
Type		pilot plant	pilot plant	production
Date		Dec. 3, 2014	Nov. 17, 2014	June 24, 2014
Pesticides				
Nitrogen pesticides				
• Amitraz	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Diclofop-methyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Captan	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg

Production Batch Code	Specifications	FE-121614-37-4 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
• Carbaryl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Procymidone	max. 0.05 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Propoxur	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Vinclozolin	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
Pyrethorides				
• Cypemethrin	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Deltamethrin	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Fenvalerate	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Permethrin	max. 0.10 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
Phosphor pesticides				
• Aziphos-methyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Acephate	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Bromphos-ethyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Chlorphyrifos-ethyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Chlorphyrifos-methyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Diazinon	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Dichlorvos	max. 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Dimethoate	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Disulfoton	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Ethion	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Fenitrothion	max. 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Fenthion	max. 0.02 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Malathion	max. 0.02	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg

Production Batch Code	Specifications	FE-121614-37-4 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
	mg/kg			
• Methamidophos	max. 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Methidathion	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Mevinphos	max. 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Parathion-methyl	max. 0.05 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Phosphamidon	max. 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg
• Pirimiphos-methyl	max. 0.05 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg	< 0.005 mg/kg
• Trichlorphon	max. 0.10 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg	< 0.01 mg/kg

Appendix D Microbiological Contaminants Analyses for Coberine™ N707

Dry fractionation route

Analytical Code PG	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code WV	PR-20141224-006	PR-20141224-007	PR-20141224-003
Type	pilot plant	pilot plant	production
Date	Nov. 18, 2014	Nov. 17, 2014	June 24, 2014
Aerobic Plate Count (conform ISO 4833 at 30°C)	less than 10 cfu/g	Micro-organism present but less than 40 cfu/g	less than 10 cfu/g
Salmonella (Vidas easy SLM eq. ISO 6579)	not detected / 25 g	not detected / 25 g	not detected / 25 g
Yeasts (equal to NEN-ISO 21527 2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Moulds (equal to NEN-ISO 21527 2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Moulds & Yeast (conform NEN ISO 21527-2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
E.Coli (conform ISO 16649-02)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Enterobacteriaceae (conform ISO 21528-2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g

Wet fractionation route

Analytical Code PG	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	FE-121614-37-1 ex PG
Analytical code WV	PR-20141224-004	PR-20141224-005	PR-20141224-002
Type	pilot plant	pilot plant	production
Date	Nov. 28, 2014	Dec. 3, 2014	Dec. 2, 2014
Aerobic Plate Count (conform ISO 4833 at 30°C)	less than 10 cfu/g	Micro-organism present but less than 40 cfu/g	Micro-organism present but less than 40 cfu/g
Salmonella (Vidas easy SLM eq. ISO 6579)	not detected / 25 g	not detected / 25 g	not detected / 25 g
Yeasts (equal to NEN-ISO 21527 2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Moulds (equal to NEN-ISO 21527 2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Moulds & Yeast (conform NEN ISO 21527-2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
E.Coli (conform ISO 16649-02)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g
Enterobacteriaceae (conform ISO 21528-2)	less than 10 cfu/g	less than 10 cfu/g	less than 10 cfu/g

Appendix E Ash Content of Coberine™ N707

Ash analysis was carried out by the Dr. A. VERWEY B.V. Laboratory, AgroLab Group, Rotterdam, Netherlands following the method ISO 6884 (2008)/n) conform NEN 6327 (1977). Certificate of analysis numbers are REPORT 118306 – 156549, REPORT 118306 – 156551, REPORT 118306 – 156552, REPORT 118306 – 156553, REPORT 118306 – 156554, and REPORT 118306 – 156555; original analysis is available under request. Results on ash are shown in the following table:

Dry fractionation route

Production batch Code	**FE-121614-37-5 ex PG**	**FE-121614-37-6 ex PG**	**FE-121614-37-2 ex PG**
Analytical code	PR-20141224-6	PR-20141224-7	PR-20141224-3
Type	pilot plant	pilot plant	production
Date	Nov. 18, 2014	Nov. 17, 2014	June 24, 2014
Ash %	<0.01	<0.01	<0.01

Wet fractionation route

Production batch Code	**FE-121614-37-3 ex PG**	**FE-121614-37-4 ex PG**	**FE-121614-37-1 ex PG**
Analytical code	PR-20141224-004	PR-20141224-005	PR-20141224-002
Type	pilot plant	pilot plant	production
Date	Nov. 28, 2014	Dec. 3, 2014	Dec. 2, 2014
Ash %	<0.01	<0.01	<0.01

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1521 AZ Wormerveer

Date 03.09.2015
Customer no. 100436

REPORT 118306 - 156549

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156549**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-002**
Description of the sample	**eCBE 8.5.1 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method
Physical - chemical analysis						
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977) n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

(b) (6)

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REPORT 118306 - 156551

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156551**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-003**
Description of the sample	**eCBE 8.5.2 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method
Physical - chemical analysis						
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977) n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

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REPORT 118306 - 156552

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156552**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-004**
Description of the sample	**eCBE 8.5.3 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method	
Physical - chemical analysis							
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977)	n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

(b) (6)

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IOI Loders Croklaan B.V.
Hogeweg 1
1521 AZ Wormerveer

Date 03.09.2015
Customer no. 100436

REPORT 118306 - 156553

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156553**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-005**
Description of the sample	**eCBE 8.5.4 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method
Physical - chemical analysis						
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977) n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

(b) (6)

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 01.09.2015
End of testing: 03.09.2015

Dr. A. VERWEY B.V.
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Date 03.09.2015
Customer no. 100436

REPORT 118306 - 156554

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156554**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-006**
Description of the sample	**eCBE 8.5.5 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method	
Physical - chemical analysis							
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977)	n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

[redacted]

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 01.09.2015
End of testing: 03.09.2015

The analytical results are only valid for the delivered sample material. A plausibility check is hardly possible for samples of unknown origin. Duplication of this document or of parts of it requires the authorization from laboratory.

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Hogeweg 1
1521 AZ Wormerveer

Date 03.09.2015
Customer no. 100436

REPORT 118306 - 156555

Order	**118306 PR-20141224-002 / PR-20141224-003 / PR-20141224-004 / PR-20141224-005 / PR-20141224-006 / PR-20141224-007**
Sample no.	**156555**
Sample acceptance	**01.09.2015**
Date of sampling	**01.09.2015**
Sample code	**PR-20141224-007**
Description of the sample	**eCBE 8.5.6 16122014**
Packaging	**Glass (Abt. 100 ml)**

	Unit	Result				Method
Physical - chemical analysis						
ash content	%	**<0,01**				conform ISO 6884 (2008) / conform NEN 6327 (1977) n)

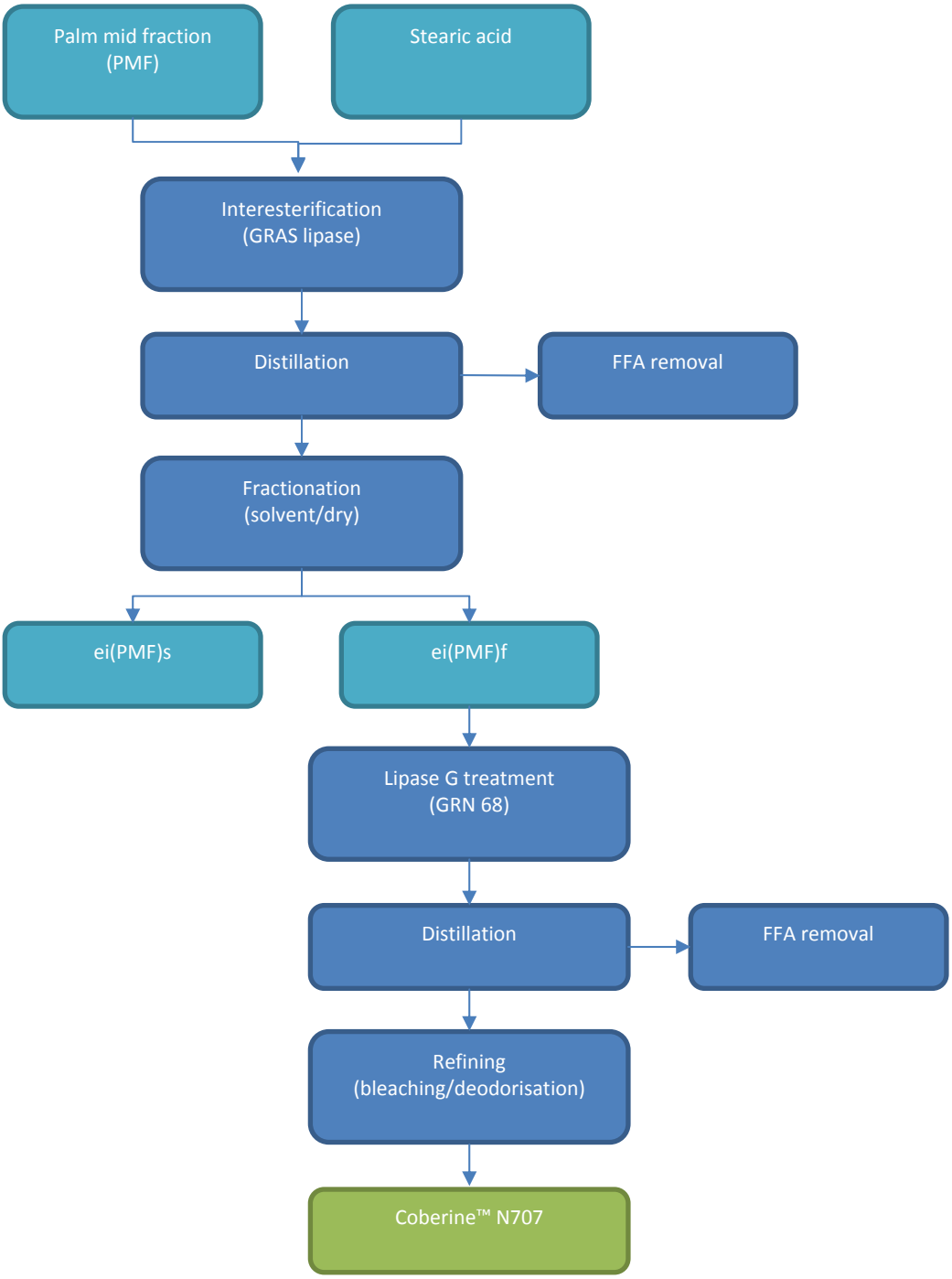
Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

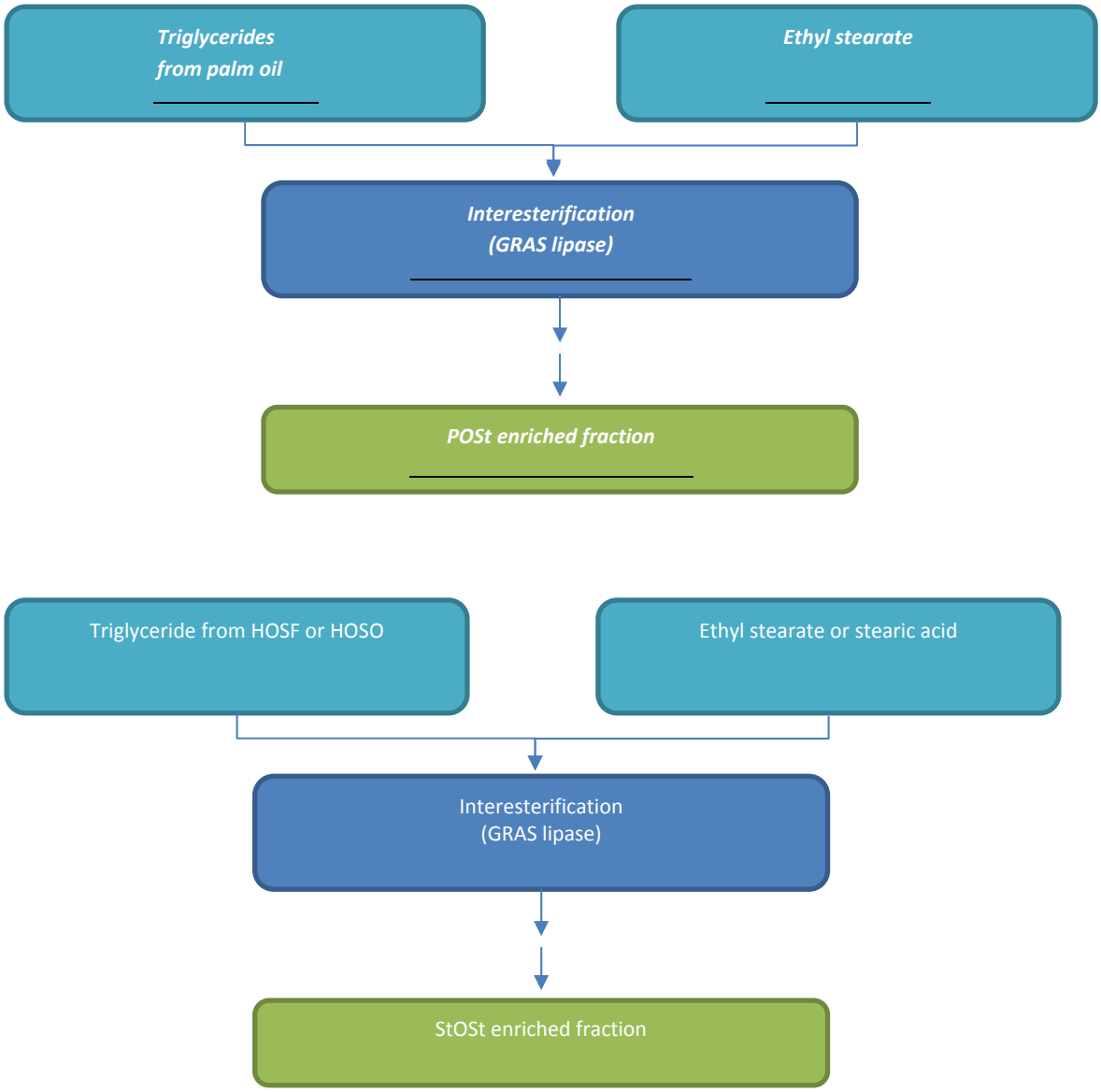
(b) (6)

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 01.09.2015
End of testing: 03.09.2015

Appendix F Loders Croklaan Coberine™ N707 Processing

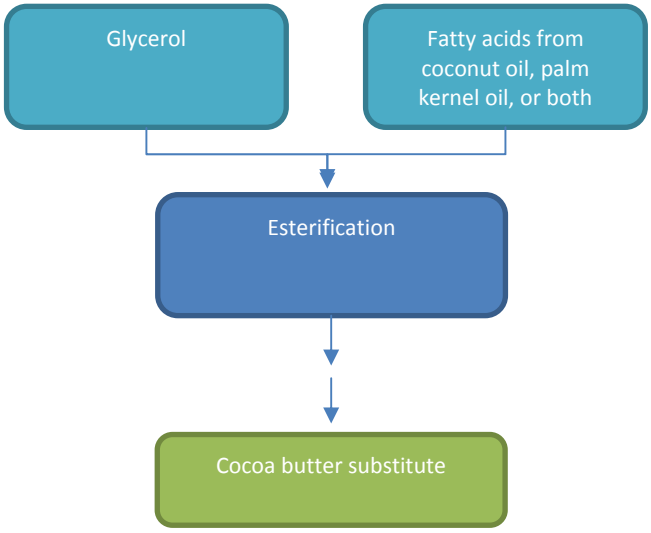


Appendix G 21 CFR 184.1259, "Cocoa Butter Substitute" Processing



HOSF: High oleic acid sunflower oil
HOSO: high oleic acid safflower oil
POSt: *rac* 1-palmitoyl-2-oleoyl-3-stearoyl glycerol
StOSt: 1,3-distearoyl-2-oleoyl-sn-glycerol

Appendix H 21 CFR 172.861, "Cocoa Butter Substitute from Coconut Oil, Palm Kernel Oil, or Both Oils" Processing



Appendix I Product Sheet for Lipase Enzyme Used to Generate Batch Data on Coberine™ N707

Product Data Sheet BIOCATALYST L (5B06310)

KERRY

Kerry Ingredients & Flavours
Kilnagleary, Carrigaline,
Co. Cork, Ireland
Tel: 00 353 21 437 6400
Fax: 00 353 21 437 6480

Product Data Sheet Feb'10 Update

Product Name:	BIOCATALYST L
Product Code:	5B06310
Date Printed	June 08, 2010

General Description
Biocatalyst L is a triacylglycerol lipase derived from the fungus *Rhizopus oryzae*. Lipase enzymes catalyse the hydrolysis of fats and oils to give free fatty acid, partial glycerides and glycerol. The reaction is reversible and the enzymes can be shown to catalyse the formation of glycerides from glycerol and fatty acid or interesterification between fats and oils under certain conditions. Lipases may be specific or non specific. **Biocatalyst L** is a 1,3 lipase i.e. it hydrolyses the release of fatty acids from the 1 and 3 positions of the glycerides.

Application
Biocatalyst L may used in the food industry for hydrolysis of oils and fats and also for flavour modification.

Specification
Lipase activity: min 1.0 OLu/mg

Legal Status
Biocatalyst L meets requirements for food grade enzymes as designated by JECFA/FCC.
Local food regulations should always be consulted with respect to specific applications and necessary declarations. Legislation may vary from country to country.

Handling Precautions
Biocatalyst L is available 30kg boxes when stored dry at 18ºC or below, will maintain at least 95% activity for a minimum of 12 months. After this time period, reassay is advisable.

Handling Precautions
Enzymes may cause skin or eye irritation and inhalation of aerosol can result in sensitisation of susceptible individuals. Standard handling procedures should be followed to prevent direct contact with the product or inhalation of aerosol.
A seperate Material Safety Data Sheet (MSDS) is available on request.

Reason for update
Feb'10: Amending packaging details from 1m^3 Matcon containers to 30kg boxes.
Oct'07: Amending packaging details and removal of activity profiles.

Appendix J Loders Croklaan Quality Certificates

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Food Safety System Certification 22000

TÜV SÜD Management Service

CERTIFICATE OF REGISTRATION

The Food Safety Management System of

IOI EDIBLE OILS

IOI LODERS CROKLAAN OILS SDN BHD

at

PLO 8 & 9, Jalan Timah, Pasir Gudang Industrial Estate,
81700 Pasir Gudang, Johor, Malaysia

has been assessed and complies with
the requirements of

FSSC 22000:2011

Certification scheme for food safety systems
including
ISO 22000:2005, ISO/TS 22002-1: 2009
and additional FSSC 22000 requirements.

This certificate is applicable for:

Manufacture of Edible Oils and Fats via Refining, Fractionation, Hydrogenation, Interesterification, Flaking, Texturising and Packing Processes

This certificate is provided on the base of the FSSC 22000 certification scheme.
The certification system consists of an annual audit of the
food safety management systems and an annual verification of the
PRP-elements and additional requirements as included in the scheme
and the ISO/TS 22002-1: 2009.

Certificate of registration No: 12 520 45098 TMS
Report No.: 70796863

Initial certification date: 2013-02-20
Expiry date: 2016-02-19

(b) (6)

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-02-01

Munich, 2013-02-20

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Food Safety System Certification 22000

TÜV SÜD Management Service

CERTIFICATE OF REGISTRATION

The Food Safety Management System of

IOI EDIBLE OILS

IOI LIPID ENZYMTEC SDN BHD

at

**PLO 8 & 9, Jalan Timah, Pasir Gudang Industrial Estate,
81700 Pasir Gudang, Johor, Malaysia**

has been assessed and complies with
the requirements of

FSSC 22000:2011

Certification scheme for food safety systems
including
ISO 22000:2005, ISO/TS 22002-1: 2009
and additional FSSC 22000 requirements.

This certificate is applicable for:

**Manufacture of Edible Oils and Fats via
Enzymatic Process, Hydrogenation, Solvent Fractionation,
Thermal Fractionation, Distillation and Refining Processes**

This certificate is provided on the base of the FSSC 22000 certification scheme.
The certification system consists of an annual audit of the
food safety management systems and an annual verification of the
PRP elements and additional requirements as included in the scheme
and the ISO/TS 22002-1: 2009.

Certificate of registration No: 12 520 45099 TMS
Report No.: 70796862

Initial certification date: 2013-02-20
Expiry date: 2016-02-19

(b) (6)

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-02-01

Munich, 2013-02-20

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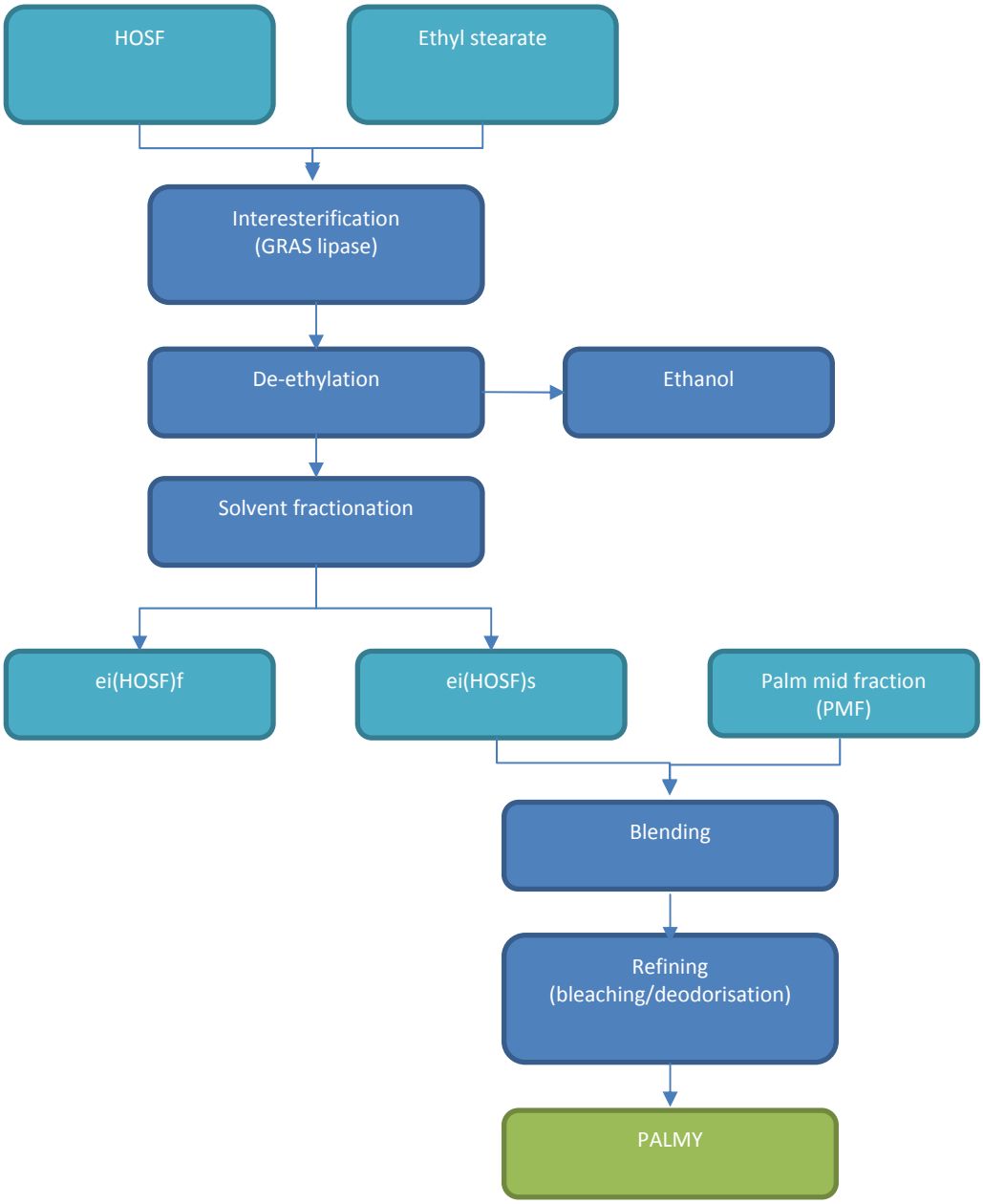
Appendix K Fuji Cocoa Butter Substitute (PALMY) Processing



Appendix L Specifications for Stearic Acid PALMAC 98-18

IOI OLEOCHEMICALS

Acidchem International Sdn Bhd (111715-H)

SPECIFICATION SHEET

Product Name : P98-18 F 25KG PR PB 16+6X36" FLAKES
Speccode : IOI9818

Parameter	Spec	Unit	Method
Titer	67.0 - 69.0	°C	AOCS Tr 1a-64
Acid Value	194.00 - 198.00	mg KOH/g	In-house Method based on AOCS Te 1a-64
Saponification Value	195.00 - 199.00	mg KOH/g	AOCS Tl 1a-64
Iodine Value	1.00 Max	g I2/100g	In-house Method based on AOCS Tg 1a-64
Colour	60 Max	APHA	In-house Method based on ASTM D1209-93
Colour (5¼" Lovibond)_Y	2.0 Max	Yellow	AOCS Cc 13b-45
Colour (5¼" Lovibond)_R	0.2 Max	Red	AOCS Cc 13b-45
Fatty Acid Composition			
C16	2.00 Max	%	In-house method based on AOCS Ce 2-66 & Ce 1e-91
C18	98.00 Min	%	In-house method based on AOCS Ce 2-66 & Ce 1e-91
C18:1	1.00 Max	%	In-house method based on AOCS Ce 2-66 & Ce 1e-91
Others	1.50 Max	%	In-house method based on AOCS Ce 2-66 & Ce 1e-91

CERTIFIED BY:

MAK KING SENG
B.SC. (HONS) AMIC
QUALITY CONTROL MANAGER

Printed by: 0929
Printed date/ time: 07.12.2011 17:30:50

Page 1 of 1

2411, Lorong Perusahaan Satu, Prai Industrial Complex, 13600 Prai, Penang, Malaysia, P.O.Box 237, 12720 Butterworth, Penang, Malaysia
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A Member of the IOI Oleochemicals Group

Appendix M Chick-Edema Factor Analysis of Stearic Acid PALMAC 98-18

DXN HOLDINGS BERHAD (363120-V) **Laboratory Department**

Northern Office :
Lot 1109, Mk. Malau,
Daerah Kubang Pasu,
06000 Jitra, Kedah.
Tel: 04-916 1288 Fax: 04-917 3610

Central Office:
2A G&1, The Strand Damansara, Jln PJU 5/20C,
Dataran Sunway, Kota Damansara,
47810 Petaling Jaya, Selangor.
Tel: 03-6150 5895 Fax: 03-6151 5895

Southern Office:
No. 33, Jalan Molek 1/8,
Taman Molek,
81100 Johor Bahru, Johor.
Tel: 07-351 0631 Fax: 07-351 0635

Website: www.lab.dxn2u.com Email: lab@dxn2u.com, labjb@dxn2u.com, labkl@dxn2u.com, labpng@dxn2u.com

NO. OF PAGES	:	1 OF 1
LAB REF. NO.	:	NCL/14080361
REPORT DATE	:	05 SEPTEMBER 2014
TO	:	IOI LIPID ENZYMTEC SDN. BHD. PLO 8&9, JALAN TIMAH, PASIR GUDANG INDUSTRIAL ESTATE, 81700 PASIR GUDANG, JOHOR, MALAYSIA.

CERTIFICATE OF ANALYSIS

RECEIVED DATE	:	28 AUGUST 2014
TEST PERFORMANCE DATE	:	28 AUGUST 2014
SAMPLE DESCRIPTION	:	SAMPLE PM
CODE/REFERENCE NO.	:	EAC-082614-181-PM

CHEMICAL / PHYSICAL TEST

TEST PARAMETER	UNIT	METHOD USED	RESULT
Chick Edema Factors (hexa-, hepta-, and octachlorodibenzo-p-dioxins)	-	AOAC 968.23	Absent

Remark:
The detection limit of chick edema Factors (hexa-, hepta-, and octachlorodibenzo-p-dioxins) will be ND(<1) pg/g respectively.

KHOO HWA CHUAN, *Chemist*
BSc AMIC (A/2212/4433/03/052)

ORIGINAL

ND denotes not detected NG denotes No Growth (Numeric number) denotes detection limit*

Appendix N Analysis of Water and Ash for Stearic Acid PALMAC 98-18

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IOI Loders Croklaan B.V.
Hogeweg 1
1521 AZ Wormerveer

Date 16.10.2015
Customer no. 100436

REPORT 135269 - 161820

Order	**135269 QC-20151012-001 / QC-20151012-002 / QC-20151012-003**
Sample no.	**161820**
Sample acceptance	**13.10.2015**
Date of sampling	**13.10.2015**
Sample code	**QC-20151012-001**
Description of the sample	**Stearic Acid**
Packaging	**Glass (2x)**

	Unit	Result			Method	
Physical - chemical analysis						
Residue on ignition (Sulfated Ash)	%	**<0,100**			conform FCC 9 Appendix II	n)
Water content (Karl Fischer)	%	**0,02**			conform FCC 9 Appendix II	n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

[redacted]

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 13.10.2015
End of testing: 16.10.2015

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Hogeweg 1
1521 AZ Wormerveer

Date 16.10.2015
Customer no. 100436

REPORT 135269 - 161823

Order	**135269 QC-20151012-001 / QC-20151012-002 / QC-20151012-003**
Sample no.	**161823**
Sample acceptance	**13.10.2015**
Date of sampling	**13.10.2015**
Sample code	**QC-20151012-002**
Description of the sample	**Stearic Acid**
Packaging	**Glass (2x)**

	Unit	Result			Method	
Physical - chemical analysis						
Residue on ignition (Sulfated Ash)	%	**<0,100**			conform FCC 9 Appendix II	n)
Water content Karl Fischer	%	**0,01**			conform ISO 8534 (2008) / conform NEN EN ISO 8534 (2008)	n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

[redacted]

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 13.10.2015
End of testing: 16.10.2015

The analytical results are only valid for the delivered sample material. A plausibility check is hardly possible for samples of unknown origin.

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Hogeweg 1
1521 AZ Wormerveer

Date 16.10.2015
Customer no. 100436

REPORT 135269 - 161824

Order	**135269 QC-20151012-001 / QC-20151012-002 / QC-20151012-003**
Sample no.	**161824**
Sample acceptance	**13.10.2015**
Date of sampling	**13.10.2015**
Sample code	**QC-20151012-003**
Description of the sample	**Stearic Acid**
Packaging	**Glass (2x)**

	Unit	Result				Method	
Physical - chemical analysis							
Residue on ignition (Sulfated Ash)	%	**<0,100**				conform FCC 9 Appendix II	n)
Water content Karl Fischer	%	**0,02**				conform ISO 8534 (2008) / conform NEN EN ISO 8534 (2008)	n)

Explanation: "<" or "n.q." represent the fact that the concentration of the analyte is below the limit of quantification (LOQ).

n) Not accredited

[redacted]

Verwey Jacqueline Lubeek / Brigitte Dorchain, Tel. +31/108080451
Customer Service
Start of testing: 13.10.2015
End of testing: 16.10.2015

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page 3 of 3

Appendix O Datasheet for Coberine™ N707

Coberine™ N707

Preliminary Product Data Sheet

Product Description:
Coberine N707 is a bland non-hydrogenated vegetable fat produced by enzymatic interesterication.

Typical data suggests, that in its physical and chemical characteristics, Coberine N707 is equivalent to cocoa butter and may replace this fat in all ratios. This means Coberine N707 may be used for total replacement of the added cocoa butter in the formula. The user is advised to fully evaluate the functionality and shelf life of the Cocoa Butter Equivalent in their intended finished product at their own facilities, as performance may be affected by varying formulations and process conditions..

Ingredient Statement:
Vegetable Oil (palm,soybean). Kosher. (US)
Modified Vegetable Oil (palm,soybean). Kosher. (Canada)

Typical Data:

Free Fatty Acid (% as oleic)	0.1% max
Color (5 1/4" cell) Lovibond	2.5 R max
Peroxide Value	1 max
Iodine Value	33-37
Triglyceride SOS (%)	26-30%
NMRs Stabilized at 26ºC	
SFC at 20ºC	65 min
SFC at 25ºC	53 min
SFC at 30ºC	32 min
SFC at 35ºC	5 max

The typical data provided here is valid at the point of shipment from our manufacturing facility.

Packaging:
Coberine N707 is available in bulk.

Storage and Handling:
Coberine N707 needs no refrigeration. However, like all fats, it will absorb odors and should be stored in a dry place away from odor-producing substances. Based on the typical data a shelf-life of 14 days is suggested for bulk product stored at 104-122ºF.*

Service:
A sales representative will be pleased to assist you in the use of this product. For additional information, technical support or service, please call Loders Croklaan at 800-621-4710.

*Actual shelf-life may vary and is dependent upon several factors including the type of application, interaction between the shortening and components of the finished product, process conditions used in the preparation of the finished product and conditions of subsequent storage and shipping of the finished product. The user is advised to carry out a full evaluation of the shortening to determine its suitability in their finished product.

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Revised Date 9/14

Let's create together

IOI Loders Croklaan
800-621-4710 (US) • 866-558-5556 (Canada) • www.croklaan.com

IOI GROUP

Appendix P Analytical Specifications for Coberine™ N707

Dry Fractionation Route

Production batch code	21 CFR 184.1259	FE-061814-36-1 ex PG	FE-060414-35-1 ex PG	PR-20110714-002 ex WV	PR-20130226-009 ex PG
Analytical code		PR-20140624-001	PR-20140624-003	PR-20140513-001	PR-20140513-002
Type		lab scale	lab scale	pilot plant	lab scale
TAG	>90%	99.7%	99.7%	97.8%	96.5%
DAG	<7%	0.0%	0.0%	0.4%	1.5%
MAG	<1%	0.0%	0.0%	0.0%	0.0%
FFA	<1%	0.0%	0.0%	0.1%	0.2%
Total glycerides	>98%	99.7%	99.7%	98.2%	98.0%
Color	clear	clear	clear	clear	clear
R 5.25"	Not specified	0.4	0.4	Not carried out	Not carried out

Production batch code	PR-20140311-001 ex WV	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20140513-003	PR-20141224-006	PR-20141224-007	PR-2014224-003
Type	pilot plant	pilot plant	pilot plant	production
TAG	99.2%	99.3%	99.0%	98.5%
DAG	0.2%	0.3%	0.4%	1%
MAG	0.0%	0.0%	0.0%	0.1%
FFA	0.1%	0.0%	0.0%	0.1%
Total glycerides	99.4%	99.6%	99.4%	99.6%
Color	clear	clear	clear	clear
R 5.25"	Not carried out	1.2	1.7	1.6

Solvent Fractionation Route

Production batch code	21 CFR 184.1259	FE-061814-36-2 ex PG	FE-060414-35-2 ex PG	FE-121614-37-3 Ex PG	FE-121614-37-4 ex PG
Analytical code		PR-20140624-002	PR-20140624-004	PR-20141224-004	PR-20141224-005
Type		lab scale	lab scale	pilot plant	pilot plant
TAG	>90%	99.3%	99.1%	99.0%	99.4%
DAG	<7%	0.0%	0.0%	0.7%	0.3%
MAG	<1%	0.0%	0.0%	0.0%	0.0%
FFA	<1%	0.0%	0.0%	0.0%	0.0%
Total glycerides	>98%	99.3%	99.1%	99.7%	99.7%
Color	clear	clear	clear	clear	clear
R 5.25"	Not specified	0.4	0.4	1.2	1.2

Appendix Q Analytical Data Showing that Acetone Meets the FCC (2015) Specifications

Date: 3 Mar 2016

Food Chemical Codex (FCC), 9th Edition Compliance Summary for Acetone from Sasol Chemical, South Africa.

No	FCC parameter & Limit	Sasol Committed Specification	Acetone sample (Date of sample: 7 Jan 16)	
			CoA from Sasol (by 3rd party lab)	Ex lab test result (IOI sent)
a	Identification: A yellow precipitate of iodoform forms	No commitment	Not tested	Pass
b	Assay: 99.5% - 100.5% C_3H_6O, by weight	Min 99.90%	99.99%	Not tested
c	Lead: Max 1 mg/kg	No commitment	Not tested	ND (<1.0 mg/kg)
d	Aldehydes (as formaldehyde): Max 0.002%	No commitment	Not tested	ND (<0.0001 mg/kg)
e	Methanol: Max 0.05%	Methanol & Ethanol – Max 200 mg/kg	Methanol & Ethanol – 27 mg/kg	Not tested
f	Phenols: No color appears	No commitment	Not tested	Pass
g	Acidity (as acetic acid): Max 0.002%	Max 20 mg/kg	9 mg/kg	Not tested
h	Alkalinity (as ammonia): Max 10 mg/kg	No commitment	Not tested	ND (<1.0 mg/kg)
i	Distillation range: Within a range of 1°, including 56.1°	55.8 – 56.6°C	56.0 – 56.5°C	Not tested
j	Nonvolatile residue: Max 10 mg/kg	No commitment	Not tested	ND (<1.0 mg/kg)
k	Refractive index: Between 1.358 and 1.360 at 20°	No commitment	Not tested	1.359
l	Solubility in water: The solution remains clear for at least 30 min.	No opalescence	No opalescence	Not tested
m	Specific gravity: Max 0.7880 at 25°/25° (equivalent to 0.7930 at 20°/20°)	0.789 – 0.792@ 20°C	0.7906 @ 20°C	Not tested
n	Substances reducing permanganate: The pink color does not completely disappear.	No commitment	Not tested	Pass
o	Water: Max 0.5%	Max 0.30%	0.171%	Not tested

Conclusion: The Acetone from Sasol Chemical, South Africa is complies with Food Chemical Codex (FCC), 9th Edition

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c/o m... 526

Intertek

ORIGINAL

NO. : SG130-0024797

CERTIFICATE OF ANALYSIS

S/NO.: L16-1/T174/3-3

8TH JANUARY 2016

REPRESENTING	:	MESSRS SASOL CHEMICALS PACIFIC LTD
PRODUCT	:	ACETONE
SOURCE	:	SHORE TANK NO. 8406
TYPE OF SAMPLE	:	AVERAGE
PORT	:	SINGAPORE
LOCATION	:	OILTANKING ODFJELL TERMINAL SINGAPORE PTE LTD
DATE OF SAMPLE	:	7TH JANUARY 2016

The above sample was tested on 7th January 2016 in accordance with the test methods stipulated as per Sasol Sales Specification 'Revision 1: November 2012 (Asia Pacific)'.

	Test	Method	Limits	Result
1)	Appearance	ASTM E2680	Clear & Bright	Clear & Bright
2)	Colour (Pt-Co Scale)	ASTM D1209	5 max	5
3)	Water (wt.%)	ASTM E1064	0.30 max	0.171
4)	Acetone (wt.%)	G.C.	99.90 min	99.99
5)	Benzene (mg/kg)	G.C.	0.8 max	<0.5
6)	Acidity as Acetic Acid(mg/kg)	ASTM D1613	20 max	9
7)	Permanganate Time @ 25°C (mins)	ASTM D1363	90 min	>90
			*Typical Values	
8)	Density @ 20°C (kg/L)	ASTM D4052	0.789-0.792	0.7906
9)	Distillation Range (°C)	ASTM D1078		
	IBP		55.8	56.0
	DP		56.6	56.5
10)	Methanol & Ethanol (mg/kg)	G.C.	200	27
11)	Di-Acetone Alcohol (mg/kg)	G.C.	120	40
12)	Methyl Ethyl Ketone (mg/kg)	G.C.	20	<10
13)	Residue on Evaporation (mg/100ml)	ASTM D1353	1	0.1
14)	Miscibility with water	ASTM D1722	No Opalescence	No Opalescence

Note: *Typical values are not guaranteed parameters.

[redacted]

AN TAIR TEK
APPROVED SIGNATORY

Verified By
[redacted]
Name: ... Technical Dept. CLH Industries Sdn. Bhd.

This report (including any enclosures and attachments) is prepared for the exclusive use of the Customer named in the report and solely for the purpose [illegible] ... purpose from which it is intended, nor do Intertek owe any duty of care to any third party in respect of this report.

PCD/AS

Page 1 of 1

Intertek Testing Services (Singapore) Pte Ltd
UEN No.: 197403138D
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Laboratory: Intertek Universal Laboratory

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DXN HOLDINGS BHD. (363120-V) **Laboratory Division**

Kedah Lab : Lot 1109, Mk. Malau, Daerah Kubang Pasu, 06000 Jitra, Kedah. Tel: 04-916 1288 Fax: 04-917 3610
Penang Lab : No.24, Jalan Kelisa Emas, Taman Kelisa Emas, 13700 Seberang Jaya, Penang. Tel: 04-384 1539 Fax: 04-384 1537
PJ Lab : 43, Jalan SS 22/23, Damansara Jaya, 47400 Petaling Jaya, Selangor. Tel: 03-7732 5454 Fax: 03-7732 5757
JB Lab : No. 33, Jalan Molek 1/8, Taman Molek, 81100 Johor Bahru, Johor. Tel: 07-351 8455 Fax: 07-351 0635

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NO. OF PAGES	:	1 OF 1
LAB REF. NO.	:	nCL/16020337
REPORT DATE	:	03 MARCH 2016
TO	:	IOI LIPID ENZYMTEC SDN. BHD. PLO 8&9, JALAN TIMAH, PASIR GUDANG INDUSTRIAL ESTATE, 81700 PASIR GUDANG, JOHOR, MALAYSIA.

CERTIFICATE OF ANALYSIS

RECEIVED DATE	:	27 FEBRUARY 2016
TEST PERFORMANCE DATE	:	27 FEBRUARY 2016
SAMPLE DESCRIPTION	:	ACETONE (CLP)
LOT NO	:	CL2704 (REF:16/014)

CHEMICAL / PHYSICAL TEST

TEST PARAMETER	UNIT	METHOD USED	RESULT
Identification test	-	USP 36	Pass
Lead	mg/kg	USP 36	ND(<1.0)
Aldehydes (as formaldehyde)	%	USP 36	ND(<0.0001)
Phenols	-	USP 36	Pass
Alkalinity (as ammonia)	mg/kg	USP 36	ND(<0.1)
Nonvolatile residue	mg/kg	USP 36	ND(<0.1)
Refractive index	°	USP 36	1.359
Substances reducing permanganate	-	USP 36	Pass

Remark:

(b) (6)

KHOO HWA CHUAN, *Chemist*
BSc. AMIC (A/2212/4433/03/05)

ORIGINAL

ND denotes not detected *NG denotes No Growth* *(< Numeric number) denotes detection limits* *Symbol * denotes parameter which is not accredited*

sasol
reaching new frontiers

Sasol Solvents
Sales specification

Acetone

Product code 2110
Description Acetone of 99.90 % mass purity.

Specifications

Properties	Units	Limits	Test Methods
Appearance		Clear and free from suspended matter	Visual; ASTM D4176
Colour	Pt-Co	5 max	ASTM D1209; ISO 6271
Acidity as CH_3COOH	mg/kg	20 max	ASTM D1613; ISO 2887
Water	mass %	0.30 max	ASTM D1364; ISO 760
Acetone (dry basis)	mass %	99.90 min	GC
Methanol and ethanol	mg/kg	200 max	GC
Di-acetone alcohol	mg/kg	120 max	GC
Benzene	mg/kg	0.8 max	GC
Methyl ethyl ketone	mg/kg	20 max	GC

Further Properties	Units	Typical values	Test Methods
Miscibility with water		No opalescence	ASTM D1722; ISO 1388-6
Density at 20 °C	g/ml	0.789 – 0.792	ASTM D4052; ISO 12185
Distillation at 101.3 kPa:			ASTM D1078; ISO 918
Initial boiling point	°C	55.8	
Dry point	°C	56.6	
Permanganate test at 25 °C	minutes	120	ASTM D1363; ISO 1388-12
Residue on evaporation	mg/100ml	0.8	ASTM D1353; ISO 759

(Revision 6: February 2010)

The Sales Specification values are continuously checked, documented and stored within the scope of quality assurance. Further properties are of an informational nature only and are not checked regularly. If the Sales Specifications are complied with, it can generally be assumed that all further properties and typical data conform to the values given.

Disclaimers
Because of the nature of our manufacturing processes, our products do not contain any plant and animal products.
It is the responsibility of our customers to determine that their use of our product(s) is safe, lawful and technically suitable in their intended applications.

Head Office
Durban Office
Cape Town Office
Basel Germany GmbH
Basel Chemicals Pacific Ltd.
Basel Japan
Basel Chemicals Pacific Ltd
Basel Middle East FZCo
Basel Chemicals North America
Basel Chemicals (Shanghai) Co. Ltd

Appendix R Chain of Custody of PALMY

IOI GROUP

IOI Loders Croklaan
24708 W Durkee Rd
Channahon, IL, USA, 60410

P: 815-730-5200
F: 815-730-5202
W: www.croklaan.com

W: www.ioiloders.com

January 7th , 2016.

Chain of Custody Information.

The samples of the Fuji Oil Co., Ltd., cocoa butter eqyuivalent (Palmy) were obtained from Hershey Co. in Hershey, PA during November 2012 and sent to IOI Loders Croklaan at 24708 W Durkee Road, Channahon IL 60410.

The samples were analyzed during November 2012 at the analytical laboratory of IOI Loders Crokalaan at 24708 W Durkee Road, Channahon IL 60410 and again during December 2012 at the analytical laboratory of IOI Loders Croklaan, Hogeweg 1, Wormerveer, The Netherlands.

The reference numbers for the samples are 541459 for the Channahon laboratory and CS12-14 for the Wormerveer laboratory.

Mark Weyland
Product Manager
IOI Loders Croklaan

Appendix S FAME Analysis of Coberine™ N707 and PALMY

Dry Fractionation Route

Production batch code	FE-061814-36-1 ex PG	FE-060414-35-1 ex PG	PR-20110714-002 ex WV	PR-20130226-009 ex PG
Analytical code	PR-20140624-001	PR-20140624-003	PR-20140624-001	PR-20140624-002
Type	lab scale	lab scale	pilot plant	pilot plant
C12:0	0.0	0.0	0.1	0.1
C14:0	0.4	0.4	0.4	0.5
C16:0	24.5	24.4	29.2	27.4
C18:0	39.3	39.4	34	35.2
C18:1	32.1	32.1	32.4	32.3
C18:2	2.8	2.6	3	3.7
C18:3	0.0	0.0	0.0	0.0
C20:0	0.5	0.5	0.5	0.5
C22:0	0.1	0.1	0.1	0.1
Total Trans	0.2	0.2	0.3	0.3
SAFA calculated	64.8	64.8	61.2	60.7
MUFA calculated	32.1	32.1	30.8	30.7
PUFA calculated	2.8	2.6	3	3.7

Production batch code	PR-20140311-001 ex PG	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20140624-003	PR-20141224-6	PR-20141224-7	PR-20141224-3
Type	pilot plant	pilot plant	pilot plant	production
C12:0	0.1	0.0	0.1	0.1
C14:0	0.4	0.4	0.5	0.5
C16:0	27.3	22.4	22.7	26.9
C18:0	35.6	41.2	40.6	35.6
C18:1	32.4	32.0	32.1	32.5
C18:2	3.2	3.1	3.3	3.6
C18:3	0.0	0.0	0.0	0.0
C20:0	0.5	0.5	0.5	0.5
C22:0	0.1	0.0	0.1	0.1
Total Trans	0.2	0.3	0.3	0.3
SAFA	61	64.5	64.5	63.7

Production batch code	PR-20140311-001 ex PG	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
calculated				
MUFA calculated	32.4	32.0	32.1	32.5
PUFA calculated	3.2	3.1	3.3	3.7

Wet Fractionation Route

Production batch code	FE-061814-36-2 ex PG	FE-060414-35-2 ex PG	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	PALMY 1	PALMY 2
Analytical code	PR-20140624-002	PR-20140624-004	PR-20141224-004	PR-20141224-005	NA	NA
Type	lab scale	lab scale	pilot plant	pilot plant	commercial	commercial
C12:0	0.1	0.1	0.1	0.1	E	E
C14:0	0.5	0.5	0.5	0.5	E	E
C16:0	25.6	25.6	23.4	23.5	35.1	34.7
C18:0	38.0	38.2	39.9	39.7	26.5	26.8
C18:1	32.2	32.2	32.0	32.1	33.8	34.1
C18:2	2.6	2.5	3.3	3.4	2.5	2.5
C18:3	0.0	0.0	0.1	0.0	E	E
C20:0	0.5	0.5	0.5	0.5	E	E
C22:0	0.1	0.1	0.0	0.0	E	E
Total Trans	0.2	0.2	0.3	0.3	E	E
SAFA calculated	64.8	61.8	64.4	64.3	61.6	61.5
MUFA calculated	32.2	32.2	32.0	32.1	33.8	34.1
PUFA calculated	2.6	2.5	3.4	3.4	2.5	2.5

NA: Not available
E: minor constituents which are believed to be roughly equivalent to Coberine™ N707

Appendix T Triglycerides Analyses of Coberine™ N707 and PALMY

Dry Fractionation Route

Production batch code	FE-061814-36-1 ex PG	FE-060414-35-1 ex PG	PR-20110714-002 ex WV	PR-20130226-009 ex PG
Analytical code	PR-20140624-001	PR-20140624-003	PR-20140513-001	PR-20140513-002
Type	lab scale	lab scale	pilot plant	pilot plant
PPP	0.7	0.6	0.9	1.1
MOP	0.6	0.5	0.5	0.7
MLP	0.1	0.1	0.1	0.1
PPSt	1.1	1	1.1	1.8
POP	13.4	13.5	17.7	16.6
PLP	1.4	1.3	1.4	2.1
PStSt	0.6	0.6	0.3	1
POSt	39.8	40.5	42.7	34.7
POO	1.8	1.7	2.4	3.6
PLSt	3.6	3.6	3.6	3.3
PLO	0.3	0.3	0.3	0.8
PLL	0	0	0	0.1
StStSt	0.1	0.1	0.1	0.2
StOSt	30.3	30.3	23.4	26.8
StOO	2.4	2.3	2.4	3.2
StLSt	2.4	2.3	1.8	2.4
OOO	0	0	0.1	0.3
StLO	0.4	0.4	0.4	0.6
AOSt	0.6	0.4	0.5	0.4
SUMSOS	83.5	84.3	83.8	78.1

Production batch code	PR-20140311-001 ex PG	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20140624-003	PR-20141224-6	PR-20141224-7	PR-20141224-3
Type	pilot plant	pilot plant	pilot plant	production
PPP	0.9	0.6	0.7	1.0
MOP	0.6	0.6	0.6	0.7
MLP	0.1	0.1	0.1	0.1
PPSt	1.2	0.5	0.4	1.1

Production batch code	PR-20140311-001 ex PG	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
POP	16.5	12.2	12.3	15.8
PLP	1.7	1.2	1.6	2.1
PStSt	0.5	0.2	0.2	0.5
POSt	39.2	38.0	36.7	33.4
POO	2.5	1.8	3.0	4.5
PLSt	3.9	3.7	3.2	3.2
PLO	0.4	0.4	1.0	1.3
PLL	0	0.2	0.3	0.3
StStSt	0.1	0.0	0.0	0.1
StOSt	25.8	32.5	31.7	28.0
StOO	2.9	3.2	2.9	3.1
StLSt	2.1	2.6	2.7	2.5
OOO	0.1	0.6	0.5	0.4
StLO	0.5	0.6	0.5	0.5
AOSt	0.5	0.7	0.7	0.6
SUMSOS	81.5	82.7	81.2	77.1

Wet Fractionation Route

Production batch code	FE-061814-36-2 ex PG	FE-060414-35-2 ex PG	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	PALMY 1	PALMY 2
Analytical code	PR-20140624-002	PR-20140624-004	PR-20141224-004	PR-20141224-005	NA	NA
Type	lab scale	lab scale	pilot plant	pilot plant	commercial	commercial
PPP	0.7	0.6	1.28	1.38	1.1	1.2
MOP	0.6	0.5	0.5	0.5	E	E
MLP	0	0.2	0.1	0.1	E	E
PPSt	0.9	0.8	1.1	1.1	E	E
POP	14.6	14.6	12.2	14.1	41.8	44.5
PLP	1.5	1.3	0.1	0.1	E	E
PStSt	0.4	0.3	1.2	1.5	0.3	0.2
POSt	40.9	41.4	38.7	35.0	10.6	10.9
POO	1.9	1.8	1.9	5.0	E	E
PLSt	3.6	3.4	3.7	3.4	E	E
PLO	0.3	0.3	0.4	1.3	E	E
PLL	0	0.1	0.2	0.2	E	E
StStSt	0.1	0.1	0.1	0.0	0.6	0.7
StOSt	28.4	28.4	30.3	27.6	28.7	27.5

StOO	2.4	2.3	3.4	3.3	E	E
StLSt	2.3	2.2	2.9	2.9	E	E
OOO	0.1	0	0.1	0.6	E	E
StLO	0.4	0.3	0.5	0.6	1.8	0.7
AOSt	0.6	0.4	0.0	0.0	E	E
SUMSOS	83.9	84.4	81.2	76.7	81.1	82.9

NA: not available
E: minor constituents which are believed to be roughly equivalent to Coberine™ N707

Appendix U Solid Fat Content (SFC) Analysis of Coberine™ N707 and PALMY

Dry Fractionation Route

Production batch code	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20141224-006	PR-20141224-007	PR-20141224-003
Type	pilot plant	pilot plant	production
S26N20 NMR	79	73	71
S26N25 NMR	67	64	61
S26N30 NMR	39	43	41
S26N35 NMR	5	3	2
S26N40 NMR	0	0	0

Wet Fractionation Route

Production batch code	FE-060414-35-2 ex PG	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	PALMY 1	PALMY 2
Analytical code	PR-20140624-004	PR-20141224-004	PR-20141224-005	NA	NA
Type	lab scale	pilot plant	pilot plant	commercial	commercial
S26N20 NMR	70	77	78	74	73.7
S26N25 NMR	41	63	66	60	60.9
S26N30 NMR	6	34	40	45	47.6
S26N35 NMR	0	4	4	1.9	0.6
S26N40 NMR	0	0	0	0	0

NA: Not available

Appendix V Jensen Cooling Parameters of Coberine™ N707 and PALMY

Dry Fractionation Route

Production batch code	FE-121614-37-5 ex PG	FE-121614-37-6 ex PG	FE-121614-37-2 ex PG
Analytical code	PR-20141224-006	PR-20141224-007	PR-20141224-003
Type	pilot plant	pilot plant	production
T(max) JENSEN	30.2	30.1	29.4
T(min) JENSEN	25.1	24.2	24.7
time (max) JENSEN	52	64	65

Wet Fractionation Route

Production batch code	FE-060414-35-2 ex PG	FE-121614-37-3 ex PG	FE-121614-37-4 ex PG	PALMY 1
Analytical code	PR-20140624-004	PR-20141224-004	PR-20141224-005	NA
Type	lab scale	pilot plant	pilot plant	commercial
T(max) JENSEN	29.4	29.6	30.4	28.6
T(min) JENSEN	24.7	24.5	24.5	24.7
time (max) JENSEN	65	63	51.3	69.0

NA: Not available

Appendix W PALMY Specifications

TECHNICAL SPECIFICATION

FUJI

PALMY MM7-LC

Introduction

Description Palmy MM7-LC is a cocoa butter equivalent made from sunflower/safflower oil and palm oil through a sophisticated interesterification and fractionation process. Palmy MM7-LC is designed to mimic West African cocoa butter's physical characteristics. Like cocoa butter, Palmy MM7-LC must be tempered. It is fully compatible with cocoa butter and when used at levels higher than 5% in chocolate it improves bloom resistance. Additionally, Palmy MM7-LC will give superior snap, gloss and sharp melting behavior to coating formulations.

Product Code 107-02

Physical & chemical characteristics

Iodine Value	30.0 - 38.0	
Moisture	0.1	% Max
Free Fatty Acid (% Oleic)	0.1	% Max
Color (5.25" Lovibond)	2.5	Max R
	25.0	Max Y
Peroxide Value (meq/kg)	1.0	Max
Softening Point (°C) (24hr Stabilization)	32 - 36	
Solid Fat Content (%)	(NMR 40hr Stabilization)	
Temperature (°C)	Min	Max
20	68 - 75.0	
25	60 - 65.0	
30	48 - 53.0	
35	7 - 12.0	
Jensen Cooling Curve (°C)	Tmax	29.3 min
	Tmin	24.3 min

All test methods used by Fuji Vegetable Oil conform to AOCS Official Methods.

Nutritional Data (typical, per 100g)

Moisture	<0.1 g
Ashes	<0.1 g
Total Fat	>99.9 g
Saturates	61.0 g
Mono-unsaturates	35.0 g
Poly-unsaturates	4.0 g
Trans	<1 g

Microbiological Information

Due to the low moisture content of the product and the nature of vegetable refining microbiological contamination is unlikely to occur.

GMO

The palm, sunflower & safflower oils in this product are from non-GMO sources. This product however contains SOY LECITHIN from GMO sources.

Allergen Information

This product contain **SOY LECITHIN.**

Packaging and shelf life

Totes, drums and Cartons: Stored under dry condition (RH <60%) and temperature between 20° and 25°C, the product has a shelf life of 1 year.

Bulk Liquid: Stored in stainless steel tanks, with a temperature of 120-130°F with a nitrogen blanket the product has a shelf life of 30 days.

Ingredients Sunflower/Safflower Oil, Palm Oil, Soy Lecithin

Regulatory Kosher Approved; Conforms to applicable Food and Drug regulations.

Exempt from MSDS requirements

The information in this bulletin, to the best of our knowledge, is true and accurate. Any recommendations or suggestions are made without warranty or guarantee since the conditions of use are beyond our control.

Fuji Vegetable Oil, Inc. Sales and Marketing: 1 Barker Ave., White Plains, NY 10601 USA TEL: (914)761-7900 FAX: (914)761-7919
Plant and R&D: 120 Brampton Road, Savannah, GA 31408 TEL: (912)966-5900 FAX: (912)966-6913

SPECIFICATION # 107-02 Revision # 1 (Page 1 of 1) UNCONTROLLED COPY
CONFIDENTIAL Revision Date: 26-MAY-2009 Issued by: Lorna Smith

Appendix X Storage Trial for Coberine™ N707

Dry fractionation route

Production batch code	FE-121614-37-5 ex PG			FE-121614-37-6 ex PG			FE-121614-37-2 ex PG		
Analytical code	PR-20141224-006			PR-20141224-007			PR-20141224-003		
Type	pilot plant			pilot plant			production		
	t = 0	t = 3 mon	t = 6 mon	t = 0	t = 3 mon	t = 6 mon	t = 0	t = 3 mon	t = 6 mon
FFA oil	0.02	0.02	0.02	0.01	0.02	0.02	0.11	0.14	0.14
PV	0.6	0.5	0.7	0.9	0.6	1.6	1.3	0.7	0.4
Y5¼"	11	11	11	15	16	13	14	14	13
R5¼"	1.3	1.2	1.3	1.9	1.8	1.6	1.7	1.7	1.6

Wet fractionation route

Production batch code	FE-121614-37-3 ex PG			FE-121614-37-4 ex PG			FE-121614-37-1 ex PG		
Analytical code	PR-20141224-004			PR-20141224-005			PR-20141224-002		
Type	pilot plant			pilot plant			production		
	t = 0	t = 3 mon	t = 6 mon	t = 0	t = 3 mon	t = 6 mon	t = 0	t = 3 mon	t = 6 mon
FFA oil	0.03	0.03	0.04	0.04	0.04	0.04	0.09	0.09	0.1
PV	0.6	0.3	0.7	0.8	0.9	0.7	1.1	1.1	1.9
Y5¼"	10	10	10	11	10	10	26	26	23
R5¼"	1.4	1.2	1.3	1.4	1.3	1.3	2.6	2.5	2.4

Appendix Y Estimated Daily Intake of Cocoa Butter Substitute by the U.S. Population Based on Authorized Food-Uses

Table Y-1 Estimated Daily Per Kilogram Body Weight Intake of Cocoa Butter Substitute from Individual Authorized Food-Uses by the Total U.S. Population (2011-2012 NHANES Data)

Food-Use Category	% Contribution to Total Mean Intake	All-Person Consumption (mg/kg bw/day)		All-Users Consumption (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
All	***100***	***30***	***92***	***35.3***	***2,350***	***84***	***185***
Confections and Frostings	57.2	17	57	21.2	1,411	80	177
Soft Candy Coating	25.7	8	21	13.8	851	56	102
Sweet Sauces and Toppings	16.9	5	na	6.2	394	81	177

bw = body weight; NA = not available

Appendix Y-2

Representative NHANES Food Codes for Authorized Food-Uses of Cocoa Butter Substitute in the U.S. (2011-2012 NHANES Data)

Representative NHANES Food Codes for Authorized Food-Uses of Cocoa Butter Substitute in the U.S.

Confectionary and Frostings

[Cocoa Butter Substitute] = 30%

91305010	Icing, chocolate
91305020	Icing, white
91707010	Fondant, chocolate covered
91707000	Fondant
91723000	Marshmallow

Adjusted for a frosting content of 35 to 68%
[Cocoa Butter Substitute] = 10.5 to 20.4%

53116510	Cake, pumpkin, with icing
53208000	Cookie, marshmallow, chocolate-covered
53208200	Cookie, marshmallow pie, chocolate covered
53209010	Cookie, sugar wafer, chocolate-covered
91731000	Peanuts, chocolate covered
91727010	Nuts, chocolate covered, not almonds or peanuts
54102020	Crackers, graham, chocolate covered
53244020	Cookie, butter or sugar, with icing or filling other than chocolate
91739010	Raisins, chocolate covered
91734000	Peanut butter, chocolate covered

Adjusted for a frosting content of 15.7 to 34.8%
[Cocoa Butter Substitute] = 4.7 to 10.5%

53101200	Cake, angel food, with icing or filling
53101250	Cake, angel food, with fruit and icing or filling
53102200	Cake or cupcake, applesauce, with icing or filling
53102700	Cake or cupcake, banana, with icing or filling
53104260	Cake or cupcake, carrot, with icing or filling
53104400	Cake or cupcake, coconut, with icing or filling
53105270	Cake or cupcake, chocolate, devil's food or fudge, with icing or filling
53105500	Cake, chocolate, with icing, diet
53105600	Cake, chocolate, devil's food, or fudge, pudding-type mix, made by "Lite" recipe (eggs and water added to dry mix, no oil added to dry mix), with icing, coating, or filling
53105750	Cake, chocolate, devil's food, or fudge, pudding type mix, made by "cholesterol free" recipe (water, oil and egg whites added to dry mix), with "light" icing, coating or filling
53117200	Cake or cupcake, spice, with icing or filling
53120270	Cake or cupcake, white, with icing or filling
53121270	Cake or cupcake, yellow, with icing or filling
53120350	Cake, white, pudding-type mix (oil, egg whites, and water added to dry mix), with icing
53121330	Cake, yellow, pudding-type mix (oil, eggs, and water added to dry mix), with icing
53106050	Cake, chocolate, devil's food, or fudge, pudding-type mix (oil, eggs, and water added to dry mix), with icing, coating, or filling
53118200	Cake, sponge, with icing

53105300 Cake, German chocolate, with icing and filling
53108200 Cake, cupcake, chocolate, with icing or filling
54102200 Crackers, graham, sandwich-type, with filling
91701010 Almonds, chocolate covered
91723010 Marshmallow, chocolate covered
91708150 Yogurt covered fruit snacks candy, with added vitamin C
91708160 Yogurt covered fruit snacks candy rolls, with high vitamin C
91709000 Gumdrops, chocolate covered
91716110 Halvah, chocolate covered
53520160 Doughnut, chocolate, cake type, with chocolate icing
53521100 Doughnut, chocolate, raised or yeast, with chocolate icing
53521230 Doughnut, custard-filled, with icing
91703040 Caramel candy, chocolate covered
91706000 Coconut candy, chocolate covered
91718050 Honey-combed hard candy with peanut butter, chocolate covered
91770030 Dietetic or low calorie candy, chocolate covered
51161020 Roll, sweet, with fruit, frosted
51161150 Roll, sweet, with fruit and nuts, frosted
51161280 Roll, sweet, with raisins and icing, Mexican (Pan Dulce)
53116020 Cake, pound, with icing
53204100 Cookie, brownie, with icing or filling
53209005 Cookie, chocolate, with icing or coating
53239050 Cookie, shortbread, with icing or filling
53240010 Cookie, animal, with frosting or icing
53244010 Cookie, butter or sugar, with chocolate icing or filling
51160110 Roll, sweet, cinnamon bun, frosted
53108220 Snack cake, chocolate, with icing or filling, reduced fat and calories
53109200 Snack cake, not chocolate, with icing or filling
53109220 Snack cake, not chocolate, with icing or filling, reduced fat and calories
53109300 Cake, Dobos Torte (non-chocolate layer cake with chocolate filling and icing)
53112150 Cake, frozen yogurt and cake layer, not chocolate, with icing
53112160 Cake, frozen yogurt and cake layer, chocolate, with icing
53114100 Cake or cupcake, lemon, with icing or filling
53114250 Cake, lemon, lowfat, with icing
53115200 Cake or cupcake, marble, with icing or filling
53115320 Cake or cupcake, nut, with icing or filling

Soft Candy Coatings

Adjusted for a maximum coating inclusion rate of 40%
[Cocoa Butter Substitute] = 16%

91700010 Candy, NFS
91700500 M&M's Almond Chocolate Candies
91703010 Caramel, chocolate-flavored roll
91703020 Caramel, flavor other than chocolate
91703040 Caramel candy, chocolate covered
91703050 Caramel with nuts and cereal, chocolate covered
91703060 Caramel with nuts, chocolate covered
91703070 Rolo
91703200 TWIX Caramel Cookie Bars (formerly TWIX Cookie Bars)
91703250 TWIX Chocolate Fudge Cookie Bars
91703300 TWIX Peanut Butter Cookie Bars
91703400 Whatchamacallit
91705030 Kit Kat
91705090 Chocolate candy with fondant and caramel
91705430 Kit Kat White
91706000 Coconut candy, chocolate covered

91706400	Coconut candy, Puerto Rican style
91708150	Yogurt covered fruit snacks candy, with added vitamin C
91708160	Yogurt covered fruit snacks candy rolls, with high vitamin C
91709000	Gumdrops, chocolate covered
91713010	Fudge, chocolate, chocolate-coated
91713020	Fudge, chocolate, chocolate-coated, with nuts
91715000	Fudge, caramel and nut, chocolate-coated candy
91715100	SNICKERS Bar
91715200	Baby Ruth
91715300	100 GRAND Bar
91716110	Halvah, chocolate covered
91718100	Butterfinger
91718110	Butterfinger Crisp
91718200	Chocolate-flavored sprinkles
91723010	Marshmallow, chocolate covered
91723020	Marshmallow, candy-coated
91723050	Marshmallow, coconut-coated
91726110	Nougat, with caramel, chocolate covered
91726130	MILKY WAY Bar
91726140	MILKY WAY MIDNIGHT Bar (formerly MILKY WAY DARK Bar)
91726150	MARS Almond Bar (formerly MARS bar)
91726410	Nougat, chocolate covered
91726420	3 MUSKETEERS Bar
91726425	3 Musketeers Truffle Crisp Bar
91728000	Nut roll, fudge or nougat, caramel and nuts
91731010	M&M's Peanut Chocolate Candies
91731060	M&M's Peanut Butter Chocolate Candies
91732000	Peanut bar
91732100	Planters Peanut Bar
91733200	Peanut Bar, chocolate covered candy
91734000	Peanut butter, chocolate covered
91734100	Reese's Peanut Butter Cup
91734200	Reese's Pieces
91734300	Reese's Sticks
91734400	Reese's Fast Break
91734450	Reese's Crispy Crunchy Bar
91734500	Peanut butter morsels
91746010	Sugar-coated chocolate discs
91746100	M&M's Milk Chocolate Candies (formerly M&M's Plain Chocolate Candies)
91746120	Sixlets
91746150	Easter egg, candy coated chocolate
91746200	M&M's Pretzel Chocolate Candies
91760100	Toffee, chocolate covered
91760200	Toffee, chocolate-coated, with nuts
91770000	Dietetic or low calorie candy, NFS
91770030	Dietetic or low calorie candy, chocolate covered
91726110	Nougat, with caramel, chocolate covered
91726410	Nougat, chocolate covered
91760100	Toffee, chocolate covered
91703050	Caramel with nuts and cereal, chocolate covered
91703060	Caramel with nuts, chocolate covered
91733200	Peanut Bar, chocolate covered candy

Sweet Sauces and Toppings

[Cocoa Butter Substitute] = 30%

91301120	Sugar, caramelized
91302010	Honey
91303000	Molasses
91303500	Sugar, brown, liquid
91303750	Chocolate gravy
91304010	Topping, butterscotch or caramel
91304020	Topping, chocolate, thick, fudge type
91304030	Topping, fruit
91304040	Topping, marshmallow
91304050	Hard sauce
91304060	Topping, nut (wet)
91304070	Topping, peanut butter, thick, fudge type
91304080	Topping, fruit, unsweetened
91304090	Topping, chocolate flavored hazelnut spread
91304250	Topping, milk chocolate with cereal
91304300	Topping, chocolate, hard coating
91351020	Topping, dietetic
91361020	Fruit sauce
91361040	Dessert sauce

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