DWECK DATA

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Consultant on Natural Products to the Cosmetic and Toiletry industry

SAFETY ASSESSMENT FOR A COSMETIC PRODUCT

PRODUCT SAFETY REPORT

Statement No:	15072015/
Date of Issue:	15th July 2015
Client name:	TBT Solutions Ltd
Product name:	Niugini Organics Pure Unscented Soap
Formula ref:	as shown

I, Anthony C. Dweck, am a Chartered Chemist duly authorised according to the Regulation of the European Parliament and of the Council on cosmetic products (recast) 2008/0035 (COD) dated 10 November 2009 (finally as 1223/2009 on 30 November 2009) and all subsequent additions which replace all other regulations.

We have taken into consideration the general toxicological profile of each ingredient used, the chemical structure, the CIR panel evaluation where available, the level of exposure (full technical data and/or toxicology files are held for each ingredient) and a total daily exposure has been calculated along with the margins of safety for each ingredient. As a result of our evaluation the product has been classified as: **SAFE**.

We have independently assessed the product declared above and confirm that a PIF (Product Information File formerly PIP) has been completed and is summarised in the attached PIF (Excel) booklet by the parties involved. A full evaluation of the product has been compiled that includes stability testing, microbiological testing and pack compatibility testing and as a result this product safety report has been issued. The product fully complies with the legislation listed above and complies with the various Annexes relating to banned, CMRs, and restricted ingredients; colours, preservatives and sunscreens. The product has been produced by a company certified to have good proven GMP and tested to ensure good microbiological quality. There are no impurities or trace materials in the raw materials or packaging that would give any rise for concern. All the documentation relating to these tests can be made available from the supplier upon request. Where specific tests have been conducted these will be listed separately.

Signature of safety assessor: ……..

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CPNP Download Information
Cosmetic Products Notification Portal

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CAS	Ingredients	%w/w
	as shown	
61789-31-9	Sodium Cocoate	100.0000%

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Ingredients
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Sodium Cocoate

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CAS	Ingredients	
	as shown	Banding
61789-31-9	Sodium Cocoate	75-100

HELPFUL DATA
Date: 15/07/2015
Customer: TBT Solutions
Formula code: as shown
Product type: Soap
Exposure mg/day: 5000
Surface Area cm2: 840
Applications/day: 6
mg/cm2/day: 0.057
Dilution value: 100
IFRA Category: 9
PAO months: 12
Frame formulation number: 2,8
Nanomaterials: 0
Carcinogenic, mutagenic or toxic for reproduction CMR 1A or 1B: 0
Total level of VOCs 0

The Product Information File contains numerous documents that are summarised as follows:

- This product is a soap and requires no challenge test 3
- The packaging is suitable for cosmetic use without migration of harmful substances or presence of impurities.
- The raw materials are of Cosmetic or Pharmaceutical grade and are low in impurities.
- The Cosmetic Ingredient Review panel opinion on raw materials can be seen on the USA legal tab in the PIP Booklet.
- The ingredients are legally permitted according to the Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient "Hotlist") 2005 as amended. See USA tab in the PIP Booklet.
- The status of raw materials according to AICS can be seen on the Australia tab in the PIP booklet.
- The method of manufacture is in the PIF file and available on request.
- The specification of the product is in the PIF file and available on request.
- The product has been stability tested and a report is available on request.
- The California Proposition P65 is on Toxicology and USA tab #N/A
- Number of alerts for Norway - see toxicology tab 0
- REACH CoRAP (Community Action Rolling Plan) materials under investigation- see toxicology tab 0

CPNP Rule 18. Other Ingredients. Number to declare. **0**

CPNP Rule 17. Camphor, menthol, cineole (eucalyptol) total present **0.0000**

- Camphor 0.0000
- Menthol 0.0000
- Cineole 0.0000

Ingredients as shown **Toxicology comments**

Sodium Cocoate The Food and Drug Administration (FDA) permits Coconut Oil to be used as a direct food additive as a substitute for cocoa butter. Coconut Oil, Coconut Acid and Coconut Alcohol are permitted for use as indirect food additives as defoaming agents in the manufacture of paper and paperboard used for food packaging. Coconut oil is also listed as a substance Generally Recognized as Safe (GRAS) by the FDA for use in cotton and cotton fabrics used in dry food packaging. The safety of Sodium Cocoate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Coconut Oil and Coconut Acid and the other ingredients made from Coconut Oil and Coconut Acid were safe for use as cosmetic ingredients. CIR summary: Cocos Nucifera (Coconut) Oil is the cosmetic ingredient name for the oil pressed from the dried fruit of coconuts. Coconut Oil is often composed of 90% saturated triglycerides and low in nonglyceride impurities. Coconut Oil may function as a fragrance ingredient, hair conditioning agent, or skin-conditioning agent and is reported in 626 cosmetics at concentrations from 0.0001 to 70%. Cosmetic ingredients can consist of fatty acids derived from Coconut Oil, hydrogenated forms of these fatty acids, corresponding fatty alcohols, simple esters and inorganic salts, and sulfated salts, all of these fatty acids. While most Coconut Oil derivatives are skin conditioning agents, a wide variety of other cosmetic functions are described. Oral toxicity studies indicate Coconut Oil and Hydrogenated Coconut Oil are relatively nontoxic by ingestion, and as a single 5 g/kg dose to rats, neither compound caused deaths. Rats fed 25% Coconut Oil for 90 d had only slight fatty change of the liver. Hydrogenated Coconut Oil (15%) had no effect on the life span of mice. Hydrogenated Coconut Oil was nontoxic as a single 3 g/kg dermal dose, was non-irritating to the skin in single-insult occlusive patch tests in guinea pigs, and was not a sensitizer. Coconut Oil did not cause skin irritation in rabbits in a 24-h single-insult occlusive patch test. Undiluted Coconut Acid caused minimal irritation in rabbits when assayed in a 24-h single-insult occlusive patch test. Some studies suggested low eye irritation potential in Coconut Oil and Hydrogenated Coconut Oil. Coconut Oil significantly reduced the increase in prostate weight and prostate weight to body weight ratio related to benign prostatic hyperplasia induced by testosterone injections in rats. Clinical tests of bar soap containing Coconut Oil up to 13% resulted in no irritation to mild irritation, with neither phototoxicity nor photosensitivity. A tanning butter containing 2.5% Coconut Oil did not cause reactions in a 6-wk repeat insult predictive patch test. Potassium Cocoate was an irritant in less than 1% of subjects with pre-existing dermatitis. Lipstick containing 10% Hydrogenated Coconut Oil caused no irritation after a single patch application and no indication of sensitization in retests performed 14 d later. Coconut Oil was not an allergen at 100% concentration in 12 subjects. The salts and esters of this large group of ingredients derived from Coconut Oil are expected to have similar toxicological profiles as the Oil, its hydrogenated forms, and its constituent fatty acids. In solution, the salts are expected to dissociate in any product formulation independent of whether the salt is sodium, ammonium, magnesium, or potassium. The esters likely will break down into their component parts, none of which present any safety issues, e.g. lauryl alcohol and coconut fatty acids for Lauryl Cocoate. The Expert Panel recognizes that use concentration data are not available for all ingredients in this group and that some ingredients in this group are not in current use. The Panel considers that the concentrations for the ingredients that are in use would apply to those with similar functions, but not those in current use. In the absence of inhalation toxicity data, the Expert Panel determined that Coconut Oil and its

derivatives can be used safely in hair sprays, because the product particle size is not respirable. The Expert Panel stressed that the cosmetics industry should continue to limit pesticide residues and heavy metals that may be present in botanical ingredients before blending into cosmetic formulation. In addition, aflatoxin should not be present in Coconut Oil and ingredients derived from Cocos nucifera. With these limitiations, Coconut Oil and the other ingredients derived from Cocos nucifera are safe as cosmetic ingredients in the practices of use and concentration described in this safety assessment.

Please note that the allergens are displayed as 0% because they are a part of the essential oil or perfume percentage. The actual figures are calculated out on the INCI tab of the PIP booklet.

ALWAYS CHECK MANDATORY WARNINGS ON THE EU LEGAL TAB.
Number of warnings to add = 0
Suggested warnings

Use only as directed
In the unlikely event of rash or irritation, discontinue use
In the event of contact with the eye. Wash with copious volumes of water
For external use only
Avoid contact with eyes

CPNP Rule
None

Perfume NOAEL values are shown, but the calculation for perfume margin of safety and their allergens is performed using the IFRA guidelines where set limits have been set. Please see the IFRA QRA table included in this report. The PIP workbook also has proposed new allergens (see INCI tab).

MARGINS OF SAFETY

Raw Material	MOS	NOAEL	<100
Sodium Cocoate	712	2,000	0

Shampoo, Rinse-Off Conditioners, Bar Soap, Feminine Hygiene Pads & Liners, Other Aerosols (including air fresheners sprays but not including deodorant/antiperspirants, hair styling aids spray)			IFRA QRA		
Allergens from perfume	**0.01% Rinse-off**	**0.001% Leave-on**	**9**	**IFRA Status**	**%w/w**
Amylcinnamyl Alcohol	ok	ok	5.00	safe	0.0000
Amyl Cinnamal	ok	ok	5.00	safe	0.0000
Anise Alcohol	ok	ok	5.00	safe	0.0000
Benzyl Alcohol	ok	ok	5.00	safe	0.0000
Benzyl Benzoate	ok	ok	5.00	safe	0.0000
Benzyl Cinnamate	ok	ok	5.00	safe	0.0000
Benzyl Salicylate	ok	ok	5.00	safe	0.0000
Cinnamyl Alcohol	ok	ok	0.40	safe	0.0000
Cinnamal	ok	ok	0.05	safe	0.0000
Citral	ok	ok	5.00	safe	0.0000
Citronellol	ok	ok	5.00	safe	0.0000
Coumarin	ok	ok	5.00	safe	0.0000
Eugenol	ok	ok	0.50	safe	0.0000
Farnesol	ok	ok	5.00	safe	0.0000
Geraniol	ok	ok	5.00	safe	0.0000
Hexyl Cinnamal	ok	ok	5.00	safe	0.0000
Hydroxycitronellal	ok	ok	1.00	safe	0.0000
Isoeugenol	ok	ok	0.02	safe	0.0000
Butylphenyl Methylpropional	ok	ok	5.00	safe	0.0000
Limonene	ok	ok	2.00	safe	0.0000
Linalool	ok	ok	2.00	safe	0.0000
Hydroxyisohexyl 3-cyclohexene Carboxaldehyde	ok	ok	0.20	safe	0.0000
Methyl 2-Octynoate	ok	ok	0.01	safe	0.0000
Alpha-isomethyl Ionone	ok	ok	5.00	safe	0.0000
Evernia Prunastri (Oakmoss) Extract	ok	ok	0.10	safe	0.0000
Evernia Furfuracea (Treemoss) Extract	ok	ok	0.10	safe	0.0000
The status rinse off or leave on status has been decided, but both allergen options are shown					
Special IFRA essential oils					
Angelica Archangelica Root Oil	#N/A				
Camellia Sinensis Leaf Extract	#N/A				
Cananga Odorata Flower Oil	#N/A				
Citrus Aurantifolia (Lime) Oil Expressed	#N/A	#N/A			
Citrus Aurantium Amara (Bitter Orange) Peel Oil	#N/A	#N/A			
Citrus Aurantium Bergamia (Bergamot) Peel Oil Expressed	#N/A	#N/A			
Citrus Limon (Lemon) Peel Oil Expressed	#N/A	#N/A			
Citrus Paradisi (Grapefruit) Peel Oil	#N/A	#N/A			
Colophonium	#N/A				
Commiphora Erythrea Glabrescens Gum Oil	#N/A				
Commiphora Erythrea Gum Extract	#N/A				
Cuminum Cyminum Seed Oil	#N/A				
Jasminum Grandiflorum (Jasmine) Flower Extract	#N/A				
Jasminum Sambuc (Jasmine) Flower Extract	#N/A				
Liquidambar Styraciflua Oil	#N/A				
Melissa Officinalis Leaf Oil	#N/A				
Myroxylon Pereirae (Balsam Peru) Oil	#N/A				
Tagetes Minuta Flower Oil	#N/A				

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Overall Product Rating
SAFE

Introduction
The raw materials used to formulate this product are all well-known ingredients with a long history of safe use. They are used at levels that have been seen and assessed in similar products held in our data base with no reports of irritation. The formulation is typical of its type and formulated by a company with a long history of safety and quality. The toxicology statements relate to the material when used at 100% and we have taken into account the lower amounts used in this product. Different countries have different requirements and this section relates solely to European sales.
Effects of the product as applied on the skin
The formulation may cause only minimal skin irritation even if exposure is prolonged and /or repeated. The product is unlikely to produce phototoxic reactions. There is unlikely to be any systemic reaction caused by absorption through the skin. We have calculated the margin of safety for all ingredients and found the safety factor to be acceptable. Our calculations had considered the total exposure of raw materials used in this product.
This is a rinse off or product that is used diluted, we have calculated the effect of that dilution and applied a suitable factor
This product is not a nail polish or remover, there are no special considerations with respect to the nails.
The margin of safety is above a value of 100 and there are no causes for concern. Fragrances are considered separately.
This product contains little or no alcohol and no stinging would be expected
Effect of ingestion
The formulation as supplied is unlikely to cause any problems if ingested.
This product does not contain oils or materials expected to exhibit a laxative effect.
Spilt product or residual product is unlikely to cause a physical hazard.
Internal use or ingestion of this product is not expected
There are no solvents or diluents that would give rise for concern.
Effect of the product on the eye
This product contains no particles or particles too small to be of concern should they enter the eye
This product contains surface active agents (e.g. soap or detergent) that may also cause transient irritation should they come into contact with the eye.
This product is an aqueous solution of active materials that is unlikely to cause irritation should it come into contact with the eye.
Rinsing the eye will quickly remedy any irritation or discomfort. Suitable warnings should be employed in these cases.
This product is not an emulsion and has been evaluated under a different category.
The risk of this product entering the eye is minimal, an eye warning is at the client's discretion. As assessors we would say that although it is not mandatory to have an eye warning in today's world of litigation an eye warning would be prudent.
This product contains little or no alcohol and no stinging would be expected
Effect of Inhalation
Inhalation is not considered an issue as there are no dust particles.
Inhalation is not considered an issue because there are no solvents to give concern.

Sunscreen Labeling
No SPF has been claimed
No special instructions are required with reference to SPF values
There are no special instructions in relation to sun protection
There are no special precautions to be advised with respect to sun protection.
There are no special warnings with relation to sun exposure required.
Suggested product warnings are covered in an earlier section.
The advice to get medical help or contact a Poison Control Center right away in the event of ingestion is good for any product.
Alpha Hydroxy Acids (AHAs)
The level of AHAs or BHAs in this product is not a concern
This is not a professional peel product and the level of AHAs gives no concerns.
Legal compliance
The preservatives, colours and UV sunscreens have all been checked against the limits set in the various annexes as defined in the Regulation of the European Parliament and of the Council on cosmetic products (recast) 2008/0035 (COD) dated 10 November 2009. All necessary warning have been checked and are in place. The 26 potential allergens present in the Parfum and essential oils have been calculated and declared where required. The company has demonstrated that it produces to Good Manufacturing Practice. **Take notice of any warnings in the Toxicology Assessment and legal sections. Ensure that all perfume allergens found in the INCI section are accounted for in the ingredient listing.** (This is the final responsibility of the client). Mandatory warnings are shown in the Excel workbook and have been highlighted on the relevant country legal tab. The need and number of European warnings are highlighted above the suggested warnings of this report (the client must ensure these are in place)..
We have taken into account the toxicology of each and every raw material and on the basis of those calculations shown on this page have made an assessment with a rating as shown above.
Specific Warnings
See the PIP Booklet for mandatory warnings under specific country legislation.
Arbitrary Warnings
Children should be supervised. We suggest this because the product may cause damage to furnishings and fabrics etc.
Qualification of the Safety Assessor
Anthony C. Dweck
BSc CChem CSci FLS FRSC FRSPH
Chartered Chemist, Chartered Scientist, Fellow of the Linnean Society, Fellow Royal Society of Chemistry, Fellow Royal Society for Public Health. Worked in the personal care industry since 1971 as a chemist, production manager, technical director, technical editor and technical consultant. Also acts as expert witness to the Trading Standards Office.
Notification.
Now that the safety assessment has been carried out and before you place the product on the UK market, if the UK is the first market in the EU, please ensure your Responsible Person is registered with the European Commission Authentication Service (ECAS) by going to https://webgate.ec.europa.eu/aida/selfreg and following the instructions. Once you have registered with ECAS you must go to the Cosmetic Products Notification Portal (CPNP) at https://webgate.ec.europa.eu/aida/cpnp where you can create your organisation. At this stage you can follow the instructions given in the CPNP User manual to register your product. Dweck Data regret that this is a service that we are unable to offer.

Curriculum Vitae of Anthony C. Dweck BSc, CChem, CSci, FRSC, FLS, FRSPH.

Dweck has worked for Smith & Nephew, S.C. Johnson, Marks & Spencer, and Peter Black (now LF Beauty). In 1998 he formed Dweck Data in order to devote more time to the study of botanicals and their chemistry. He is author and compiler of the "Toxicology Assessments Software Programme", that will go on sale in 2015.

Past member of Council (1984-1986) Society of Cosmetic Scientists, Past President Society of Cosmetic Scientists (1996-1997), Past President Society of Cosmetic Scientists (2001 – 2002), Honorary Member of Society Cosmetic Scientists (awarded 2004), Technical Editor Personal Care Magazine (Asia Pacific 1999-2010) (Europe 2008-2010) now Technical Consultant (since 2010), Associate Editor International Journal of Cosmetic Science (2001-2003), Moderator and creator of the Formulators' Discussion Group (1998-2005), Honorary Organiser SCS Spring Conference 100% Natural in 2007, Member of the Scientific Advisory Committee of the CTPA (1992-1998). Member of the Advisory Board of Cosmetics & Toiletries Magazine (1997-1998), Member of the Advisory Board of International Society of Cosmetic Dermatology (2003-2013), Member of the Editorial Scientific Advisory Panel of SPC Magazine (1997-2001), Member of the Editorial Scientific Advisory Board of SOFW Journal (1988 - 1999), Member of the LCLN (Ingredient Nomenclature) of the C.T.P.A. (1994-1998), Member of the IFSCC Monograph Review Committee (1997 - 1999), External Examiner for Society of Cosmetic Scientists (since 1991), Referee (reviewer) for International Journal of Cosmetic Science (1992-2013), Chairman Sponsorship Committee of IFSCC Congress in 2002, Edinburgh (1998-2000), IFSCC listed conference speaker. Chairman of the SCS 50th Anniversary Book Committee, 1998. Joint Organiser of the Post Graduate Course in Cosmetic Science (1998, 2000, 2001, 2003, 2005, 2007), Council of Europe - Botanical Task Force (Committee of Experts) (appointed 1998). Consultant and expert witness (listed) to the Trading Standards Office. Member of the Scientific Advisory Board to Union Swiss (since 2008). Consultant Member IFRA (since 2014). 43 years in the industry.

Author of over a hundred articles and papers on various aspects of the Cosmetic and Toiletry industry and numerous book chapters, Anthony is also a frequent lecturer on his favourite topic of botanicals/medicinal plants and has presented over 80 papers at conferences all over the world. He was a regular organiser of the conference programme for PCIA (Personal Care Ingredients Asia) and the honorary organiser for the SCS Spring Symposium 13-15th May 2007 "the 100% Natural Conference" at Staverton Park, Northants. He is Co-Organiser of "Making Cosmetics" (2012, 2013). His data base on naturals and natural derivatives is one of the largest in the world. A full list of publications may be found at www.dweckdata.com

He has written four books.

- Handbook of Cosmetic Ingredients - their use, safety and toxicology. 4th ed. Is temporarily unavailable.
- Handbook of Natural Ingredients. 3rd ed. eBook is temporarily unavailable
- Formulating Natural Cosmetics. ISBN: 978-1-932633-75-7. Allured Business Media. 2nd ed in July 2014.
- Handbook of Natural Ingredients" Not for sale. Book only available to clients of CLR. Chemisches Laboratorium Dr. Kurt Richter GmbH