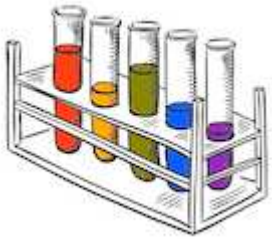

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Product Safety Assessment

NovaPure Naturals - Baby Powder

NovaPure Naturals

Reference	NPN001
Issue	1
Issue Date	12-Oct-20

NovaPure Naturals - Baby Powder

Sponsor NovaPure Naturals

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Maranta Arundinacea Root Powder (Arrowroot)	n/a	70.560
Avena Sativa (Oat) Kernel Meal	84012-26-0	17.690
Zinc Oxide	1314-13-2	3.130
Rosa Canina Flower (Rosehip) Powder	84696-47-9	2.350
Matricaria Recutita (Chamomile) Flower Extract	84082-60-0	2.350
Kaolin	1332-58-7	2.350
Calendula Officinalis Powder	84776-23-8	1.170
Lactobacillus	n/a	0.200
Bifidobacterium	n/a	0.200

Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.

Fragrance allergens are quoted as additional items so percentages may not add up to 100.

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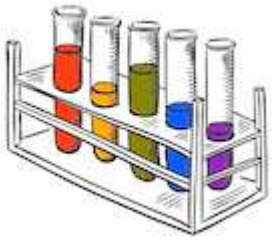


Product Safety Assessment

NovaPure Naturals - Baby Powder

NovaPure Naturals

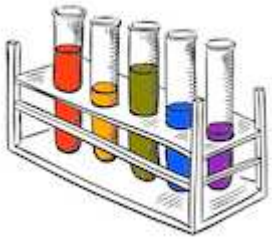
Reference	NPN001
Issue	1
Issue Date	12-Oct-20

Section 2 - Product Characteristics

Ingredient List

Maranta Arundinacea Root Powder (Arrowroot), Avena Sativa (Oat) Kernel Meal, Zinc Oxide, Rosa Canina Flower (Rosehip) Powder, Matricaria Recutita (Chamomile) Flower Extract, Kaolin, Calendula Officinalis Powder, Lactobacillus, Bifidobacterium

Frame Formulation Number	Perfumed Powder (Loose Or Pressed) 8.2
IFRA Category	Baby Powder and Talc
Adult or Child	Baby



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Reference NPN001
Issue 1
Issue Date 12-Oct-20

Section 3 - Microbiological Quality

This product is non-aqueous and consequently raises no microbiological issues. The reasoning behind this statement is detailed in ISO 29621 Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products.

Section 4 - Impurities and packaging

This formulation does not contain any ingredients with toxicologically relevant impurities.

There are no known or likely interactions with the pack that have any safety implications.

Section 5 - Normal and Foreseeable Use

This product is intended for topical application to a limited body area in small quantities.

Section 6 - Exposure

Where Used This product is applied to the skin

Estimated Daily Amount Used 2 g

Calculated relative daily exposure mg/kg 200

Frequency Of Use Daily

Assumed Body Weight 10 Kg

Rinse Status Leave On

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Maranta Arundinacea Root Powder (Arrowroot)	n/a	70.560	2.000	1.120		

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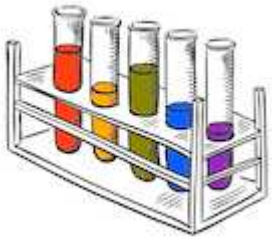

Product Safety Assessment

NovaPure Naturals - Baby Powder

NovaPure Naturals

Reference NPN001
Issue 1
Issue Date 12-Oct-20

Avena Sativa (Oat) Kernel Meal	84012-26-0	17.690	2.000	5.380		
Zinc Oxide	1314-13-2	3.130	2.000	6.260		
Rosa Canina Flower (Rosehip) Powder	84696-47-9	2.350	2.000	4.700		
Matricaria Recutita (Chamomile) Flower Extract	84082-60-0	2.350	2.000	4.700		
Kaolin	1332-58-7	2.350	2.000	4.700		
Calendula Officinalis Powder	84776-23-8	1.170	2.000	2.340	1000	427.350
Lactobacillus	n/a	0.200	2.000	0.400		
Bifidobacterium	n/a	0.200	2.000	0.400		

The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed (the NOAEL). If the MoS is 100 then the use level is one hundredth the level at which any effect is observed. Any level above 100 is considered to be acceptable.

Section 8 - Toxicological Profile of Ingredients

Avena sativa (Oat) kernel meal 84012-26-0

Avena Sativa Kernel Meal is a coarse meal obtained by the grinding of the kernels of the Oat, Avena sativa L., Poaceae, commonly known simply as oats.

It is listed on the EU's CosIng database without any restrictions on its use.

The inclusion of oatmeal, a common foodstuff, into a product of this kind raises no toxicololgical issues.

Bifidobacterium n/a

Bifidobacterium is one or more species of the microorganism, Bifidobacterium, Bifidobacteriaceae.

It is listed on the EU's CosIng database without any restrictions on its use. It has been pre-registered with ECHA under the REACH regulations.

It has been investigated for its skin benefits without unanticipated adverse effects coming to light.

The incorporation of small numbers of 'friendly' bacteria intended to favourably modulate the skin flora has been a practice in cosmetic products for several decades. It is not expected to and in practice has not been associated with adverse effects.

Given the nature of the material no margin of safety calculation is appropriate.

Guéniche, Audrey et al. "Bifidobacterium Longum Lysate, A New Ingredient For Reactive Skin". Experimental Dermatology, vol 19, no. 8, 2009, pp. e1-e8. Wiley, doi:10.1111/j.1600-0625.2009.00932.x. Accessed 12 Oct 2020.

J Cosmet. Sci., 55,473-479 (September/October 2004) Topical application of Bifidobacterium-fermented soy milk extract containing genistein and daidzein improves rheological and physiological properties of skin KOUJI MIYAZAKI, TOMOKO HANAMIZU, TOSHIRO SONE, KATSUYOSHI CHIBA, TAKASHI KINOSHITA, and SATOSHI YOSHIKAWA,

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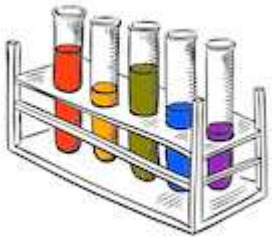

Product Safety Assessment

NovaPure Naturals - Baby Powder

NovaPure Naturals

Reference	NPN001
Issue	1
Issue Date	12-Oct-20

Calendula Officinalis Powder 84776-23-8

Calendula Officinalis Powder is the extract of the whole plant of the Calendula, Calendula officinalis L., Compositae.

The cosmetic ingredient review has reviewed the scientific data on calendula based ingredients and concluded that they are safe as used in cosmetic ingredients.

In addition to safety data Calendula and its components have been extensively studies for their medical applications without any safety concerns emerging. As an example a study has been carried out indicating a counter irritant effect of calendula in combination with rosemary.

Calendula is permitted as a cosmetic ingredient in the European Union. There is no suitable NOAEL available, but a study has been carried out that titrated up to 1000mg/Kg/day without finding any adverse effects at any dose. This figure has been used to carry out the margin of safety calculation. Since this is acceptable, the true margin must be even more so.

Int J Toxicol. 2010 Nov-Dec;29(6 Suppl):221S-43 Final report of the Cosmetic Ingredient Review Expert Panel amended safety assessment of Calendula officinalis-derived cosmetic ingredients Andersen FA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW.

Skin Pharmacol Physiol. 2005 Jul-Aug;18(4):195-200. Protective effects of different marigold (Calendula officinalis L.) and rosemary cream preparations against sodium-lauryl-sulfate-induced irritant contact dermatitis.Fuchs SM, Schliemann-Willers S, Fischer TW, Elsner P.

Kaolin 1332-58-7

Kaolin occurs naturally as a mineral and is found in every region of the world. It is a dry form of clay that is mined for a very wide range of applications from pottery through to pharmaceuticals. It is widely used in cosmetics particularly in face masks which contain a very high level of it. It is composed mainly of aluminium silicate.

The Cosmetic Ingredient reviewed kaolin as part of a general review of clays, and concluded that they were safe as used in cosmetics.

No suitable NOAEL is available in the literature for this material, but given that aluminium and silicates are regular components of the diet to which the body is exposed to much greater levels there are no toxicological concerns arising from the topical application of this material and no margin of safety calculation has been carried out.

Int J Toxicol. 2003;22 Suppl 1:37-102.Final report on the safety assessment of aluminum silicate, calcium silicate, magnesium aluminum silicate, magnesium silicate, magnesium trisilicate, sodium magnesium silicate, zirconium silicate, attapulgite, bentonite, Fuller's earth, hectorite, kaolin, lithium magnesium silicate, lithium magnesium sodium silicate, montmorillonite, pyrophyllite, and zeolite. Elmore AR; Cosmetic Ingredient Review Expert Panel.

Lactobacillus n/a

Lactobacillus is one or more species of the microorganism, Lactobacillus.

The incorporation of small numbers of 'friendly' bacteria intended to favourably modulate the skin flora has been a practice in cosmetic products for several decades. It is not expected to and in practice has not been associated with adverse effects.

Given the nature of the material no margin of safety calculation is appropriate.

Maranta Arundinacea Root Powder (Arrowroot) n/a

Maranta Arundinacea Root Powder is the powder obtained from the dried, ground roots of the West India Arrow Root, Maranta arundinacea L., Marantaceae. It was a popular food ingredient in Victorian and early Twentieth Century Britain, and is still the basis of a well known biscuit. It is used in cosmetics as an absorbant material in body powders.

It is listed on the EU's CosIng database without any restrictions on its use.

Although not identical, its chemistry is very similar to that of other starches such as corn starch, which have been used very widely with no reported adverse effects. It can therefore be concluded that it raises no toxicological issues.

There is no published NOAEL for this material, but given its nature and use as a foodstuff it is not necessary to carry out a margin of safety calculation in order to conclude that it is safe as used in this product.

Matricaria Recutita (Chamomile) Flower Extract 84082-60-0

Matricaria Recutita Flower Oil is the extract from the flowers of the plant, Matricaria recutita, Compositae (syn: Chamomilla recutita, Compositae)

It is listed on the EU's CosIng database without any restrictions on its use.

This is an aqueous extract of a well known plant that is generally recognised as safe. It is present at a vanishingly low level in the formulation. It has therefore no toxicological significance and does not need to be considered in assessment of the overall safety of the formulation.

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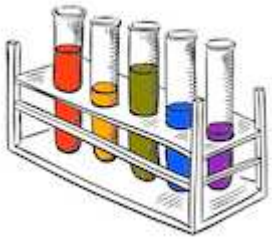

Product Safety Assessment

NovaPure Naturals - Baby Powder

NovaPure Naturals

Reference	NPN001
Issue	1
Issue Date	12-Oct-20

Rosa Canina Flower (Rosehip) Powder 84696-47-9

Rosa Canina Flower Powder is the powder obtained from the flowers of the Hip Rose, Rosa canina L., Rosaceae

It is listed on the EU's CosIng database without any restrictions on its use.

This is a powdered extract of an edible plant that is generally recognised as safe. It is present at a vanishingly low level in the formulation. It has therefore no toxicological significance and does not need to be considered in assessment of the overall safety of the formulation.

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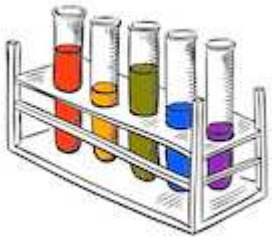

Product Safety Assessment

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Reference	NPN001
Issue	1
Issue Date	12-Oct-20

Zinc Oxide 1314-13-2

Zinc Oxide is listed on the CosIng database for use as both a colourant and a UV filter without restrictions on its use in cosmetics.

The EU's Scientific Committee on Consumer Safety has issued several opinions on Zinc Oxide.

The SCCP considers that on basis of the dossier reviewed in 2003 the use of Zinc Oxide in its non-nano form (pigment grade, with particle sizes above 100 nm) is considered safe in cosmetic products as a UV-filter up to 25%. The concern expressed in the SCCNFP opinion 0693/03 with regard to phototoxicity is not relevant for this form of Zinc Oxide due to the absence of dermal penetration.

Zinc Oxide is also used as a colorant in cosmetic products. In view of the similar toxicity of both nano-sized and fine Zinc Oxide, it is considered that Zinc Oxide is safe when used as colorant in cosmetics for dermal application.

According to EU criteria, Zinc Oxide is a non-sensitiser to the skin and, as such, does not have to be classified for skin sensitisation.

It is a material with a low level of toxicity, with an LD50 > 2000 mg/kg.

Zinc Oxide has a NOEL of about 0.5 mg/kg/day for Humans giving a very adequate calculated margin of safety for this product.

As a food additive, zinc oxide is on the U.S. FDA's list of generally recognized as safe, or GRAS, substances.

SCCNFP/0649/03, final opinion concerning Zinc Oxide COLIPA n° S 76

SCCP/1215/09 Scientific Committee on Consumer Products SCCP Clarification on Opinion SCCNFP/0932/05 on Zinc oxide COLIPA n° S76

SCCS/1489/12 Revision of 11 December 2012 Scientific Committee on Consumer Safety SCCS OPINION ON Zinc oxide (nano form) COLIPA S 76.

Gekkan Yakuji. Pharmaceuticals Monthly. Vol. 22, Pg. 291, 1980.

Journal of Industrial Hygiene. Vol. 9, Pg. 88, 1927.

Microfine zinc oxide (Z-Cote) as a photostable UVA sunblock agent
Mitchnick MA ; Fairhurst D ; Pinnell SR. J. Am. Acad. Dermatol.; VOL 40 ISS Jan 1999, P85-90, (REF 35) [IPA]

Zinc absorption from zinc oxide, zinc sulfate, zinc oxide + EDTA, or sodium-zinc EDTA does not differ when added as fortificants to maize tortillas.
Hotz C; DeHaene J; Woodhouse LR; Villalpando S; Rivera JA; King JC
J Nutr. 2005, May; 135(5):1102-5. [The Journal of nutrition] [PubMed

Select Committee on GRAS Substances (SCOGS) Review 182.89911314-13-2 1973

Section 9 - Undesirable Effects

No undesirable effects are foreseen with this product when used under conditions of normal and foreseeable use.

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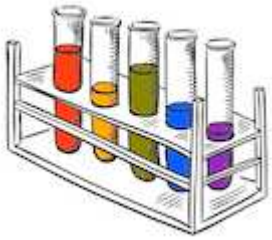

Product Safety Assessment

NovaPure Naturals - Baby Powder

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Reference	NPN001
Issue	1
Issue Date	12-Oct-20

Part B

Section 1- Assessment Conclusion

This product has been assessed and found to comply with the requirements of current EU and US cosmetic regulations. The ingredients selected have been reviewed and are used at levels suitable to ensure that the end user will experience the level of safety they can reasonably expect for this kind of product when used in accordance with the manufacturers instructions, and when manufactured following a suitable cosmetic GMP procedure.

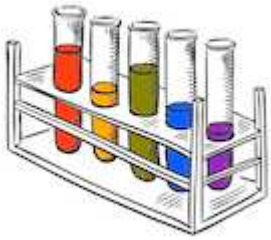
Section 2- Labels and Warnings

This product does not require any specific warnings over and above those customary for this category of product.

Period After Opening 12 Months

Section 3- Reasoning

This is a standard product using conventional ingredients at normal levels. This category of products has a good track record of safe use and so can be presumed to be safe under normal and foreseeable conditions of use. Interactions between ingredients are unlikely to be problematic in this kind of product.



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Signed

Colin Sanders  12/10/2020

Appendix - Credentials of Assessor

Colin Sanders Bsc(Hons) FRSB Dip SCS
Date of Birth 19.5.1960

Academic Qualifications

Bachelor of Science in Environmental Science from Leicester Polytechnic, lower second with honours awarded in 1983.

Diploma in Cosmetic Science awarded by the Society of Cosmetic Science awarded in 1985

Membership of Professional Bodies

Society of Cosmetic Scientists

Fellow of the Royal Society of Biology

Experience

Development Chemist at Intergen Cosmetics 1983-1987
Quality Assurance W.M.Stills 1987-1990
Formulation Scientist/Formulation Laboratory Manager Stiefel Laboratories 1990-2004
Head of Product Formulation Medex/Montagne Jeunesse 2004-2013