COSMETIC RAW MATERIAL

TOXICOLOGICAL EVALUATION

SAFETY ASSESSMENT ESTABLISHED BY THE EXPERT TOXICOLOGIST:

DR STEPHANE PIRNAY

BASED ON THE REGULATION (CE) N° 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF NOVEMBER 30, 2009 AND IN ACCORDANCE WITH THE FORMALIZED QUALITY PROCESS BASED ON THE RECOMMENDATIONS OF THE SCCS'S (SCIENTIFIC COMMITTEE ON CONSUMER SAFETY) NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 12TH EDITION MAY 15TH, 2023.

RAW MATERIAL

Organic virgin Plum oil (PRHBVI)
&
Virgin Plum oil (PRHUVI)

LABORATORY : PERLES GASCOGNE

SPONSOR : 3 ALLEE DE VIDALOU
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DATE : 25/03/2026

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1. CONTEXT

The present report aims to assess the safety of a virgin plum oil, both organic and non-organic, as a whole and specifically with regard to the presence of benzaldehyde present at maximum 0,25% in leave-on cosmetic products, (worst case based on body lotion, amount of product based on the SCCS 12th edition guidance for the assessment of cosmetic products: 7,82 g) for use at concentrations of up to 100%.

2. POINT CONCERNING THE IFRA STANDARD

The IFRA Standards form the basis for the globally accepted and recognized risk management system for the safe use of fragrance ingredients and are part of the IFRA Code of Practice.

Fragrance or Fragrance mixture: A mixture of fragrance ingredients and functional components formulated to impart an odor/flavor or for its malodor coverage/taste masking purposes.

Fragrance ingredient: Any basic substance (raw material) used for its odor properties or malodor coverage as a component of a fragrance mixture. [IFRA GUIDANCE FOR THE USE OF IFRA STANDARDS June 30, 2023].

Benzaldehyde is naturally present at 0,25% in the virgin vegetable oil that is not a fragrance ingredient.

Although IFRA standards provide conservative limits for fragrance applications, **these limits are not applicable for a vegetable oils used as cosmetic emollients**.

For reminder, IFRA is an industry association, as stated on its website https://ifrafragrance.org/ ("IFRA represents the international fragrance community, ensuring quality, safety, and sustainability in every scent"). Importantly, IFRA Standards are not legally binding within the framework of Regulation (EC) No 1223/2009 and are not formally referenced by the SCCS as regulatory criteria. They constitute a voluntary risk management tool primarily intended for fragrance mixtures. In practice, they may be used by safety assessors when dealing with complex fragrance compositions, particularly when the full qualitative and quantitative composition is not disclosed for reasons of confidentiality (e.g. proprietary perfume mixtures). However, this situation does not apply in the present case, where benzaldehyde is naturally occurring in a vegetable oil matrix and not used as a fragrance ingredient or within a fragrance mixture. Therefore, the direct application of IFRA limits in this context is not scientifically or regulatorily justified.

A quantitative risk assessment was therefore conducted according to SCCS 12th edition guidance for the evaluation of cosmetics safety.

3. PRUNUS DOMESTICA SEED OIL PHYSICO-CHEMICAL PROPERTIES:

3.1. General properties based on the literature:

Properties and constituents	*Prunus domestica* seed oil[134,135]
Appearance	
Specific gravity	
Refractive index	
Iodine value	90-108
Saponification value	
Peroxide value, mEq/kg	10.0 max
Melting point (°C)	
Unsaponifiable matter (%)	
Free fatty acids (%)	2.0 max as oleic acid
Titer (°C)	
Acid value	

[CIR afety Assessment of Plant-Derived Fatty Acid Oils – 2017].

Composition comparison with other vegetable oil used in cosmetics:

Fatty acids	*Perilla ocymoides* seed oil (perilla)[3]	*Persea gratissima* (avocado) oil[3]	*Pistacia vera* seed oil (pistachio)[65]	*Plukenetia volubilis* seed oil (sacha inchi)[188]	*Prunus amygdalus* (sweet almond) oil[3,63,128–130,189]	*Prunus armeniaca* (apricot) kernel oil[33]	*Prunus avium* (sweet) cherry seed oil[9,131,132]	*Prunus domestica* seed oil (prune/ plum)[134,135]
Caproic (C6)								
Caprylic (C8)								
Capric (C10)								
Lauric (C12)								
Myristic (C14)			0.09	0.02	1			
Myristoleic (C14:1)								
Palmitic (C16)		13-17	7.4	4.72	4-9	4.6-6	4-10	4-9
Palmitoleic (C16:1)		3-5.1	0.7	0.04	0.8	1-2		1
Heptadecanoic (C17:0)				0.12	0.2			
Stearic (C18)			0.9	3.33	2-3	0.5-1.2	1-4	3
Oleic (C18:1)	14-23	67-72	58.2	10.46	62-86	58-65.7 (total 18:1)	23-55	60-80
Linoleic (C18:2)	16	10 to 12	30.3	37.64	20-30	29-33; 28.5 (undef 18:2)	30-55	15-25
Linolenic (C18:3)	63-70		0.4	48.96	0.4	05-1.0 (undef 18:3)	13	1
Arachidic (C20)			0.6	0.09	0.2	0.2	2	
Eicosenoic (C20:1)			0.6	0.3	0.3			
Eicosadienoic (C20:2)								
Arachidonic (C20:4)								
Behenic (C22)			0.3		0.2			
Erucic (C22:1)			0.6		0.1			
Docosadienoic (C22:2)								
Docosahexaenoic (C22:6)								
Lignoceric (C24)								

Fatty acids	*Brassica oleracea* Acephala seed oil (kale)[78]	*Brassica oleracea* Italica (broccoli) seed oil[79]	*Butyrospermum parkii* (shea) oil[4]	*Butyrospermum parkii* (shea) butter[3,80-82]	*Camelina sativa* seed oil (false flax)[165]	*Camellia japonica* seed oil[166]	*Camellia kissi* seed oil[166]	*Camellia oleifera* seed oil (tea seed)[84,85]	*Camellia sinensis* seed oil[166]
Caproic (C6)									
Caprylic (C8)									
Capric (C10)									
Lauric (C12)									
Myristic (C14)				0.5					
Myristoleic (C14:1)									
Palmitic (C16)	4.4	0-5	3.8-4.1	3-9	7.8	7.9		6.1-15	8-10
Palmitoleic (C16:1)						0.16			
Heptadecanoic (C17:0)									
Stearic (C18)	0.7	0-5	41.2-56.8	30-50	2.96	2.46		0.8-2	1.5-3.5
Oleic (C18:1)	11.3	10-20	34.0-46.9	38-50	16.77	84.99	80	72-87	78-86
Linoleic (C18:2)	12.6	10-20	3.7-6.5	3-8	23.08	3.76		5.3-14.3	7-10
Linolenic (C18:3)	10.2	5-10		0.5 max	31.2				0.2-0.8
Arachidic (C20)	8.2		1-2	2.5-3		0.49			
Eicosenoic (C20:1)	0.4	5-10			11.99				
Eicosadienoic (C20:2)									
Arachidonic (C20:4)									
Behenic (C22)									
Erucic (C22:1)	51.8	40-50			2.8				
Docosadienoic (C22:2)									
Docosahexaenoic (C22:6)									
Lignoceric (C24)									

[CIR Safety Assessment of Plant-Derived Fatty Acid Oils – 2017].

3.2. Properties based on the raw material data

Composition	Concentration
Fatty acids	
Saturated Fatty Acids	5-10%
Mono Unsaturated Fatty Acids	65-80%
Poly Unsaturated Fatty Acids	15-25%
Trans fatty acids	<0,1%
Details for fatty acids:	
C14:0	<0,5%
C16:0	4-9%
C16:1 (n-7c)	<1%
C17:1 (n-7c)	<0,2%
C18:0	1-2%
C18:1 (n-7c)	<2%
C18:1 (n-9c)	60-80%
C18:2 (n-6c)	15-25%
C18:3 (3t)	<0,1%
C18:3 (n-3c)	<1%
C20:0	<0,3%
C20:1 (n-9c)	<0,2%
Tocopherol et tocotrienols total	600-900 mg/kg
Alpha-tocopherol	40-140 mg/kg
Bête-tocopherol	<10 mg/kg
Gamma-tocopherol	550-750 mg/kg

Delta-tocopherol	20-60 mg/kg
Alpha-tocotrienol	<10 mg/kg
Bêta-tocotrienol	
Gamma-tocotrienol	
Delta-tocotrienol	
Vitamine E	10-25 mg/kg
Peroxyde indice	<10 meq O2/Kg
Allergens (mg/kg)	
Benzyl alcohol	<150
Benzaldehyde	<2500
Vanillin	<30

Impurity (mg/kg)	**Concentration (ppm)**
Cyanides (total HCN)	<10
Mercure	<0,005
Arsenic	<0,05
Cadmium	<0,01
Copper	<0,4
Tin	<1
Iron	<5
Nickel	<0,15
Lead	<0,04
Ochratoxin A	<1
Aflatoxins B1,B2,G1,G2	<4
Aflatoxins B1	<1
Benzo(a)pyrene	<0,5
4 PAHs	

[Fiche de spécification huile vierge de prune biologique 19/10/2023 et Fiche de specification huile vierge de prune biologique 09/06/2025 – PERLES DE GASCOGNE].

4. TOXICOLOGICAL PROFILE

PRUNUS DOMESTICA SEED OIL

*** CIR conclusion:** Many of the fatty acid oils in this assessment are edible, and exposure to the oils from food use would result in a much larger systemic dose than that resulting from use in cosmetic products. Consequently, their systemic toxicity potential, except as discussed below relating to carcinogenicity, is not addressed in this report. The safety focus of use of these oils as cosmetic ingredients is the potential for irritation and sensitization.

The Panel concluded that the 244 plant-derived fatty acid oils (including prunus domestica seed oil) are safe in the present practices of use and concentration described in the assessment.

*** Chronic toxicity:** Fatty acid ingredients contains in the prunus domestica seed oil are ubiquitous in food as components of dietary fats. The US FDA determined that several of the fatty acids and salts of fatty acids are approved as food additives permitted for direct addition to food for human consumption. Daily consumption of these ingredients would result in much larger systemic exposures than what is expected from use in cosmetic products, even if there was 100% absorption. [CIR Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics – 2019].

*** Dermal absorption**: Previous research on plant oils have demonstrated that, when applied topically, mostly remain at the surface of skin, without deep penetration into the first upper layers of the stratum corneum. [Lin, T. K., Zhong, L., & Santiago, J. L. (2017). Anti-Inflammatory and Skin Barrier Repair Effects of Topical Application of Some Plant Oils. *International journal of molecular sciences*, *19*(1), 70. https://doi.org/10.3390/ijms19010070].

*** Sensitization:** According to the prediction model of the KeratinoSens™assay (OECD Guideline 442D), the test substance is rated as a non-sensitizer. [Plum, ext. ECHA REACH registered substance factsheets].

*** Biodegradation :** Ready biodegradability [Plum, ext. ECHA REACH registered substance factsheets].

*** CMR hazard :** The results of an Ames test, performed according to OECD guideline 471 and GLP principles, showed that Plum concentrate is not mutagenic in the Salmonella typhimurium reverse mutation assay and in the Escherichia coli reverse mutation assay. [Plum, ext. ECHA REACH registered substance factsheets].

*** Cutaneous irritation :** Not irritant. [Perles de Gascogne. FDS - RF6-013/1.001]. Slight irritation of the skin (abrasive effect) if intense friction. [Perles en Gascogne safety data sheet PRCQT3_FDS_FR].

- BENZYL ALCOHOL :

*** NOAEL :**100 mg/kg/day

*** Ref. NOAEL :** [RIFM Update to RIFM fragrance ingredient safety assessment, benzyl alcohol, CAS Registry Number 100-51-6 - 2025].

*** Population at risk :** Premature new-born babies represent a population with elevated risk.[Arrow, R.C. (Writer). Medical toxicology. Third Edition, Lippincott Williams and Wilkins. Philadelphia, Pa. 2004. , p. 1231].

*** Subacute and Chronic toxicity :** In a subchronic toxicity study, groups of 10 F344/N rats/sex/dose and 10 B6C3F1 mice/sex/dose were administered benzyl alcohol via gavage (vehicle: corn oil) at doses of 0, 50, 100, 200, 400, or 800 mg/kg/day for 13 weeks (5 days/week). NOAEL for both rats and mice was determined to be 100 mg/kg/day based on reduced bodyweight gain. [RIFM Update to RIFM fragrance ingredient safety assessment, benzyl alcohol, CAS Registry Number 100-51-6 - 2025].

*** CIR conclusion :** Considered sure for a use in all the cosmetic formulations up to 1% [Annex V CE 1223/2009 reglementation] sure for a use in the capillary dyeings up to 10%; [IJT 20 (S3): 23-50, 2001].

*** Genotoxicity :** Mutation in micro-organisms. [National Toxicology Program Technical Carryforward Series. (Research Triangle Park, NC 27709) No.206: NTP-TR-343,1989].

*** Ocular irritation :** Vapor: Irritating for the eyes. Liquid: Irritating for the eyes. [American Coastguard, Ministry for Transport. CHRIS - Dangerous Chemical data. Volume II. Washington, D.C. : American HMSO, 1984-5].

*** Acute toxicity in animals :** LD50 - Lethal dose, kill 50% Rodent Oral percent - rat 1230 mg/kg Behavior - somnolence (reduced general activity) [Food and Cosmetics Toxicology. (London, the U.K.) V.1-19, 1963-81. For publisher information, see FCTOD7: 2,327,1964].

*** Toxic effects on wildlife :** Other informations: Short term toxicity to aquatic invertebrates - A study on Daphnia sp. during 48 hours showed an EC50 = 8.012 mg/L. Other informations: Short term toxicity to aquatic invertebrates - A study on Daphnia magna during 48 hours showed an EC50 <= 36.9 mg/L. [BENZYL ALCOHOL - ECHA registered factsheet - 13-Jul-2023].

*** Study of the effects on microorganisms :** ISO 8192 (Water quality - Test for inhibition of oxygen consumption by activated sludge for carbonaceous and ammonium oxidation): Toxicity to micro organisms - A study on activated sludge during 3 hours showed an IC50 = 640.0 mg/L. Other informations: Toxicity to micro organisms - A study on activated sludge during 28 days showed an NOEC = 100.0 mg/L. [BENZYL ALCOHOL - ECHA registered factsheet - 13-Jul-2023].

*** Cutaneous irritation :** Ordinary test of Draize administration by the skin. Human - man 16mg/48H. Light irritation. [Cosmetics and Toiletries. (Allured Pub. Corp., POB 318, Wheaton, IT 60189) V.91- 1976 : 94 (8), 41.1979].

*** Additional informations :** Maximum concentration in ready for use preparation : 1 % . [Annex 5 of the european legislation of cosmetic products : list of preservatives allowed in cosmetic products].

*** Evaluation of the skin permeation :** The percutaneous absorption of benzyl acetate and five other benzyl derivatives (benzyl alcohol, benzyl benzoate, benzamide, benzoin and benzophenone) has been determined in vivo in monkeys. Absorption through occluded skin was high for all compounds (approximately 70% of the applied dose in 24 h) and no significant difference between the values ??of the different compounds was observed [Bronaugh RL et al., In vivo percutaneous absorption of fragrance ingredients in rhesus monkeys and humans.Food Chem Toxicol. 1990 May;28(5):369-73].Benzyl alcohol as a fragrance ingredient in cosmetics and other products is lipophilic and therefore has the potential to be rapidly absorbed by the skin. Cutaneous passage was determined in rhesus monkeys. Absorption on occluded skin is between 56-80% in 24 hours. In non-occlusive condition the penetration conditions are reduced to 32% taking into account the evaporation of the substance. [https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/14748/7/2/3 30-03-2017].

*** Sensitization on human: Data** provided benzyl alcohol a No Expected Sensitization Induction Level (NESIL) of 5900 µg/cm2 for the skin sensitization endpoint. [RIFM Update to RIFM fragrance ingredient safety assessment, benzyl alcohol, CAS Registry Number 100-51-6 - 2025].

- BENZALDEHYDE :

*** NOAEL :**200 mg/kg/day

*** Ref. NOAEL :** [A.M. Api,et al, RIFM fragrance ingredient safety assessment, benzaldehyde, CAS Registry Number 100-52-7, Food and Chemical Toxicology, Volume 134, Supplement 2,2019]

*** CIR conclusion :** Based on the data presented in this safety assessment, the CIR Expert Panel concluded that Benzaldehyde is safe as used in cosmetic products. [Final Report on the Safety Assessment of Benzaldehyde, CIR 2006].

*** Ocular irritation :** For eye irritation existing study as performed by Thyssen has been supplemented by recent lab communications indicating a protocol design similar to OECD 405 was employed. This is suggestive that the substance is at most slightly irritant. [Benzaldehyde, ECHA REACH registered substance factsheets].

*** Sensitization :** There are several reports on contact urticaria after exposure to 5% the test substance in both workers (Schubert 2006) as well as in volunteers (1/5 positive, Forsbeck 1977). [Benzaldehyde, ECHA REACH registered substance factsheets]. Available data indicate that benzaldehyde has a low skin sensitization potential. In vitro results are variable (negative in DPRA, positive in some cellular assays), while in vivo studies generally show weak or no sensitization, with limited responses observed in some human studies.

A NESIL of 590 µg/cm² has been established. Overall, benzaldehyde is considered a weak skin sensitizer. [A.M. Api,et al, RIFM fragrance ingredient safety assessment, benzaldehyde, CAS Registry Number 100-52-7, Food and Chemical Toxicology, Volume 134, Supplement 2,2019].

*** Cutaneous irritation :** Based on the information available it can however be concluded that the test substance is moderately irritant to the skin. [Benzaldehyde, ECHA REACH registered substance factsheets].

*** Subacute and Chronic toxicity :** The repeated-dose toxicity of benzaldehyde has been extensively investigated in both rats and mice. In studies involving daily oral administration by gavage, the NOAEL was established at 200 mg/kg/day. This value is primarily based on decreased survival observed in male rats in a two-year carcinogenicity study. [A.M. Api,et al, RIFM fragrance ingredient safety assessment, benzaldehyde, CAS Registry Number 100-52-7, Food and Chemical Toxicology, Volume 134, Supplement 2,2019].

- VANILLIN :

*** NOAEL :**650 mg/kg/day

*** Ref. NOAEL :**[https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/2209/7/6/2].

*** Sensitization :** Vanillin was tested with other substance of urotropine process for the manufacturing of the Vanillin. 0/45 patients had positive results, so Vanillin was not sensitizing in this patch test study. [Vanillin, ECHA REACH registered substance factsheets].

*** Genotoxicity :** The in vitro genotoxic studies available indicated negative effects in gene mutations and chromosomal aberrations with and without metabolic activation system. The in vivo studies available on micronucleus assay and antimutagenic effect confirm the absence of genotoxic effect of Vanillin. [Vanillin, ECHA REACH registered substance factsheets].

*** Ocular irritation :** 0.1 mL of vanillin (purity unknown) undiluted was instilled into the conjunctivae sac of New Zealand White rabbits (6 animals) for 24 hours. Animals then were observed for 7 days. Irritation was scored by the method of Kay and Calandra, and in this study, vanillin is an eye irritant. Vanillin is irritating to the eyes, with reversibility within 8 days. [Vanillin, ECHA REACH registered substance factsheets].

*** Acute toxicity in animals :** LD50 oral (rat): 3978 mg/kg bw. Vanilline is not harmful by ingestion. LD50 dermal (rat): > 2000 mg/kg bw (no mortality observed at this dose). Vanilline is not harmful by dermal route. [Vanillin, ECHA REACH registered substance factsheets].

*** Cutaneous irritation :** New Zealandwhite rabbits (6 animals) were dermally exposed to0.5 g of vanillin (purity unknown) for 24 hours. In this study, vanillin was not a dermal irritant. [Vanillin, ECHA REACH registered substance factsheets].

*** Subacute and Chronic toxicity :** In a subchronic study by oral route, no effect related to vanillin was observed. The NOAEL determined was 650 mg/kg/day. Other studies by dermal and inhalation route were poorly described and were not taken into account for assessment. [Vanillin, ECHA REACH registered substance factsheets].

5. EXPOSURE TO SUBSTANCES

The Systemic exposure dose (SED) is defined as the dose of the component which is absorbed in a systemic way during the use or misuse of the product. It is calculated based on the daily exposure:

Systemic exposition dose (SED) = C x Q x F x R x PT

with :
C = Concentration of the substance in the final product (%)
Q = Quantity of the final product used per application (mg)
F = Frequence of application (day^{-1})
R = Factor of retention based on the rinsing, or the dilution of the final product
PT = Skin penetration*

The avereage weight of an adult is 60 kg (SCCNFP 0690/03), the avereage weight of a child is 20 kg and the avereage weight of a baby is 5 kg (Institut national de la Santé et de la recherche médicale 06/13).

SEE **ANNEX 2**. CALCULATION OF EXPOSURE DOSES

* **Dermal absorption, justification for 50% :**

Dermal absorption values should consider the vehicle and formulation; default values may overestimate exposure when experimental data or physicochemical considerations indicate lower bioavailability. **The SCCS 12th edition advised to use a default value of 50%.**

Dermal absorption was not assumed to be 100%, as recommended by SCCS Notes of Guidance when formulation-specific considerations apply. Benzaldehyde is naturally present within a triglyceride-rich vegetable oil matrix, which is expected to reduce dermal bioavailability compared to the neat substance.

Considering physicochemical properties (volatility, moderate lipophilicity) and vehicle effects, a conservative dermal absorption value of 50% was applied.

6. CALCULATION OF MARGINS OF SECURITY

In order to exclude a possibility of systemic toxicity, the margins of security of each ingredient should be **higher than 100.** The margin of security is defined as the ratio between the maximal tolerated dose without side effects (NOAEL) and the daily dose of systemic exposure, both expressed in mg/kg of weight. The absorbed dose (mg/kg weight) is divided by the average weight of 60 kg in adults 20 kg in children or 5 kg in babies.(SFP 0690/03).

In accordance with the IKW proposals, the NOAEL used for the calculation of the margin of security is referred to the results of sub acute or chronic toxicological tests when those data exist.

MS (margin of security) = NOAEL/SED

SEE ANNEX 3. CALCULATION OF MARGINS OF SECURITY

Regarding the substances for which the margins of security have not been calculated, they do not show any major toxicological concern given the usual use of this product and as explained for each one in the additional information and/or CIR conclusion paragraphs in section A.11.

7. LOCAL TOLERANCE OF BENZALDEHYDE

According to the SCCS 12th edition, the surface area for body lotion is 15670 cm², and the amount of product apply for body lotion is 7,82g, so 0,000499043 g/cm², equivalent to 499 µg of oil/cm².

As a result, the oil containing a maximum of 0,25% of benzaldehyde, it represents 1,25 µg/cm² of benzaldehyde, significantly lower than the NESIL of 590 µg/cm², indicating a wide margin of safety for skin sensitization.

8. CONCLUSION

Based on the available toxicological data and the exposure assessment performed, Organic virgin Plum oil (PRHBVI) and Virgin Plum oil (PRHUVI) can be considered safe for use in cosmetic products, including leave-on applications, with a body lotion worst case scenario (7,82 g per day), at concentrations up to 100%.

The PRUNUS DOMESTICA SEED OIL itself consists mainly of fatty acids that are widely present in the human diet and have a well-established safety profile. As highlighted by the CIR Expert Panel, systemic exposure from cosmetic use is negligible compared to dietary intake, and therefore systemic toxicity is not considered a concern. In addition, dermal absorption studies indicate that plant oils remain predominantly on the surface of the skin, further limiting systemic exposure.

The toxicological evaluation therefore focuses primarily on local effects (irritation and sensitization). The available data indicate that the oil is not irritating and not sensitizing.

Regarding naturally occurring constituents:

- Benzaldehyde (≤ 0,25%), benzyl alcohol and vanillin (trace levels) were specifically assessed.
- For all substances, the Margins of Safety (MoS) calculated under worst-case conditions (7,82 g/day, leave-on application) are above 100 (see ANNEXE 3 for calculation), including for infant exposure scenarios.
- In addition, the calculated dermal exposure levels of 1,25 µg/cm² for benzaldehyde remain significantly below their respective NESIL values (590 µg/cm²), indicating no concern for skin sensitization.

Other minor constituents such as benzyl alcohol and vanillin also present no safety concern, based on their toxicological profiles (MOS>100, absence of genotoxicity, low irritation and moderate sensitization potential).

Finally, the use of IFRA standards is not considered relevant in this context, as the ingredient is not used as a complex mix of fragrance but as a vegetable oil, and its safety assessment is therefore appropriately based on SCCS principles.

9. REFERENCES OF THE SAFETY ASSESSORS

Stephane PIRNAY, Pharm.D., Ph.D. in Toxicology, ERT, Recipient of the Award from the national Academy of Pharmacy, Recipient of the Award from the University René Descartes Paris V, Former Assistant Professor of the University of Paris V in Toxicology, Former Fellow at NIH, USA, Legal Expert at Court of Appeal of Paris, Certified Expert by the Court of Cassation, Expert Toxicologist of the **Agency EXPERTOX.**

And,

Lona GUILLEMIN, Graduate of the Master 'Research Method in Environment, Health, Toxicology and Ecotoxicology' from the University of Grenoble-Alpes, Toxicologist Evaluator from **Agency EXPERTOX**.

March 30th 2026

S. PIRNAY **L.GUILLEMIN**



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ANNEX – 1 FORMULA

CAS No	INCI name	Concentration
90082-87-4	PRUNUS DOMESTICA SEED EXTRACT	100
100-51-6	BENZYL ALCOHOL	0,015
100-52-7	BENZALDEHYDE	0,25
121-33-5	VANILLIN	0,003

ANNEX – 2 CALCULATION OF EXPOSURE DOSES

INCI name	C (%)	Q (mg)	F (day^{-1})	R (%)	PT (%)	DES (mg/day)	DES among adult (mg/kg/day)	DES among child (mg/kg/day)	DES among infant (mg/kg/day)
PRUNUS DOMESTICA SEED EXTRACT	100	7820	1	100	50	3910,000	65,167	195,500	782,000
BENZYL ALCOHOL	0,015	7820	1	100	50	0,587	0,010	0,029	0,117
BENZALDEHYDE	0,25	7820	1	100	50	9,775	0,163	0,489	1,955
VANILLIN	0,003	7820	1	100	50	0,117	0,002	0,006	0,023

ANNEX – 3 CALCULATION OF MARGINS OF SECURITY

INCI name	DES among adult (mg/kg/day)	DES among child (mg/kg/day)	DES among infant (mg/kg/day)	NOAEL (mg/kg/jr)	MS among adult	MS among child	MS among infant
PRUNUS DOMESTICA SEED EXTRACT	65,167	195,500	782,000	NI	/	/	/
BENZYL ALCOHOL	0,010	0,029	0,117	100	10230	3410	853
BENZALDEHYDE	0,163	0,489	1,955	200	1228	409	102
VANILLIN	0,002	0,006	0,023	650	332481	110827	27707