4329100G – HAMAMELIS RAIN

Version: 22 - 05/APR/2018

1. PRODUCT IDENTIFICATION

Trade Name:	HAMAMELIS RAIN
Manufacturer:	PROVITAL
Responsible for the Safety Assessment:	Lourdes Mayordomo
Tf./Fax:	3493-7192350/7190294
e-mail:	l.mayordomo@weareprovital.com
Kind of Raw Material:	Active Ingredient
Function of the Ingredient (PCPC Inventory):	Cosmetic Astringents, Skin-Conditioning Agents - Miscellaneous
Function of the Ingredient (UE Inventory):	Skin Conditioning, Astringents

2. PRODUCT COMPOSITION

Components Breakdown (INCI). Including actives, solvents, preservatives, antioxidants and other additives:

[EU]		CAS	EINECS
Hamamelis Virginiana Leaf Water	98,5 - 100 %	84696-19-5	283-637-9
Preservatives			
Sodium Benzoate	0,3 - 0,5 %	532-32-1	208-534-8
Potassium Sorbate	0,05 - 0,15 %	24634-61-5 590-00-1	246-376-1
Additives			
Gluconolactone	0,5 - 0,7 %	90-80-2	202-016-5
Calcium Gluconate	0,005 - 0,015 %	299-28-5	206-075-8

PCPC [CTFA]		CAS	EINECS
Hamamelis Virginiana (Witch Hazel) Leaf Water	98,5 - 100 %	---	---
Preservatives			
Sodium Benzoate	0,3 - 0,5 %	532-32-1	208-534-8
Potassium Sorbate	0,05 - 0,15 %	24634-61-5 590-00-1	246-376-1
Additives			
Gluconolactone	0,5 - 0,7 %	90-80-2	202-016-5
Calcium Gluconate	0,005 - 0,015 %	299-28-5	206-075-8

3. TOXICOLOGICAL INFORMATION

Data obtained in our own toxicological tests and/or bibliographical research

Animal testing:

This product has not been the subject of animal testing or retesting for cosmetic purposes by or on behalf of this company.

General information:

The external application of hamamelis preparations can be regarded as safe and has been accepted as a medicines for human use. (EMA-European Medicines Agency, Evaluation of Medicines for Human Use, HMPC-Commitee on Herbal Medicinal Products, Report EMA/HMPC/114585/2008 published on 12 November 2009)

There is a CIR Final Report on Safety Assessment of Hamamelis virginiana concluding its safety in cosmetic use. (CIR Final Report, February 9, 2018)

American Herbal Products Association: Hamamelis virginiana L. leaves - Herbs that can be safely consumed when used appropriately (Class 1)

Direct food substances affirmed as generally recognized as safe: Gluconolactone (21CFR184.1318), Calcium gluconate (21CFR184.1199)

Gluconolactone is a permitted food additive in Europe (E575) and in the USA it is considered a safe substance (GRAS) which can be used directly in the food (21CFR184.1318).

The CIR Final Report on Safety Assessment of Sodium Benzoate (IJT, 20(S3):23-50, 2001, reopened 06/10) exists and includes all the toxicological data.

The CIR Final Report on Safety Assessment of Potassium Sorbate (JACT 7 (6): 837-80, 1988, confirmed 04/06) exists and includes all the toxicological data.

Classification according to Council of Europe (*):

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*(1)- Non-recommended ingredients (2)-Ingredients which could not be assessed (3) –Recommended ingredients

Cytotoxicity:

No data available.

Skin Irritation:

Preparations containg Hamamelis distillate are used in therapies for atopic eczema due to its anti-irritant properties. The low toxicity of hamamelis and the absence of adverse effects supports this therapeutic use. (EMA-European Medicines Agency, Evaluation of Medicines for Human Use, HMPC-Commitee on Herbal Medicinal Products, Report EMA/HMPC/114585/2008 published on 12 November 2009)

Skin Sensitization:

Hamamelis Virginiana (Witch Hazel) Water was not irritating or sensitizing in HRIPTs at up to 25.80%. (CIR Final Report, February 9, 2018)

Eye Irritation:

Test performed with other products of Provital: Hamamelis Extract H.G.(Cod. 43000) : In-vitro Irritation Index (HET-CAM, 5% solution) = 7.3 +/- 0.8.

Mutagenicity:

Genotoxicity studies on Hamamelis Water performed by the National Toxicology Program of the National Cancer Institute in USA. The product was negative in the following assays: chromosome aberrations in mice, in vitro cytogenetics (chromosome aberrations, sister chromatid exchange), sex-linked recessive lethal mutations in Drosophila, mouse lymphoma assay, Salmonella assay and sister chromatid exchage in mice. (http://ntp.niehs.nih.gov; EMA/HMPC/114585/2008)

Hamamelis Virginiana (Witch Hazel) water extract (concentration not specified) ,was not genotoxic in a Salmonella

mammalian microsome assay (stains TA97, TA98, TA100, and TA1535), with and without metabolic activation.

(Report, July 7, 2017, available from Safety Assessment of Hamamelis Virginiana (Witch Hazel)-Derived Ingredients as Used in Cosmetics - CIR)

Acute toxicity:

The oral administration of a single dose of a Hamamelis Virginiana plant (Witch Hazel) preparation from 10 to 20 g showed no toxic effect in mice and rats. (Report, July 7, 2017, available from Safety Assessment of Hamamelis Virginiana (Witch Hazel)-Derived Ingredients as Used in Cosmetics - CIR)

Were administered suppositories containing Hamamelis Virginiana ethanol extract (0, 20, 100, or 300 mg/kg) to a New Zealand White rabbits. The extract was characterized as having a minimum of 10% tannins and containing gallic acid. The rabbits were observed for 7 h after dosing and then daily for 2 weeks. There were no hematological effects observed. The no-observed-adverse-effects-level (NOAEL) was > 300 mg/kg. (Report, July 7, 2017, available from Safety Assessment of Hamamelis Virginiana (Witch Hazel)-Derived Ingredients as Used in Cosmetics - CIR)

Subchronic and chronic toxicity:

Hamamelis alcohol extract:(Europ. Bull. of Drug Research V.9 Suppl.nº1,2001) 200mg/Kg for 19 days rats, showed no toxic effects

Reproductive effects:

No data available.

Other data:

Hamamaelis virginiana distillate was one of the substances studied in the Carcinogenesis Bioassay Program by the National Toxicology Program of the National Cancer Institute in USA. Hamamelis water was considered showing no carcinogenic effects after dermal application in rats and mice. (Environ Health Perspect 1987, 74(10): 229-235)

In a multicenter, prospective pediatric cohort study, subjects suffering from superficial skin lesions, diaper skin rash, or other local inflammations of skin and mucous membranes were treated with an ointment containing either Hamamelis Virginiana (Witch Hazel) or dexpanthenol. Only two adverse events were potentially related to the Hamamelis virginiana (witch hazel; i.e.: erythema and burning sensation), which were resolved by the end of the treatment period. (Report, July 7, 2017, available from Safety Assessment of Hamamelis virginiana (Witch Hazel)-Derived Ingredients as Used in Cosmetics - CIR)

4. ECOLOGICAL DATA

Biodegradability:

No data available.

Aquatic Toxicity:

No data available.

Other data:

No data available.

5. CONCLUSION

The components of this product have registered adverse effects neither in its described uses nor in the historical marketing of this company. These data and the available toxicological information lead to the conclusion that the use of this product, under the normal conditions of cosmetic use, involves no risk for consumers.

The European cosmetics legislation (Regulation (EC) No 1223/2009) establishes the need to assess the safety of cosmetic products, taking into account the toxicological profile of the ingredients. To do this, in the case of possible systemic effects, it is necessary to obtain the NOAEL (no observed adverse effects level) for the calculation of MoS (margin of safety). The absence of these considerations shall be duly justified.

The NOAEL value, or else other data used for the same purpose (LOAEL, LD50, etc.), can only be calculated experimentally from toxicological studies that require the use of animals. Since Provital does not perform any animal testing, it has established a system to ensure the safety of its products without the need of NOAEL and the subsequent calculation of MoS. This systematic, in the case of natural complex substances (NCS) has been endorsed by international organisms and renowned toxicologists.

The safety of this ingredient is then established based on the following information: known uses of the active in different fields (medicine, food, cosmetics, etc.), profile of the chemical compounds of the ingredient and bibliographic toxicological information available for the active and its components. The integration and study of all these data allows for a conclusion on the safety of the ingredient.