4553100G – BLACK BACCARA ROSE

Version: 24 - 15/JAN/2021

1. PRODUCT IDENTIFICATION

Trade Name:	BLACK BACCARA ROSE
Manufacturer:	PROVITAL
Responsible for the Safety Assessment:	Lourdes Mayordomo
Tf./Fax:	3493-7192350/7190294
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Kind of Raw Material:	Active Ingredient
Function of the Ingredient (PCPC Inventory):	Colorants
Function of the Ingredient (UE Inventory):	Skin-Conditioning; Tonic

2. PRODUCT COMPOSITION

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

[EU]		CAS	EINECS
Aqua	40 - 60 %	7732-18-5	231-791-2
Glycerin	40 - 60 %	56-81-5	200-289-5
Rosa Hybrid Flower Extract	1 - 3 %	93062-88-5	296-844-4
Preservatives			
Sodium Benzoate	0,2 - 0,3 %	532-32-1	208-534-8
Potassium Sorbate	0,2 - 0,3 %	24634-61-5	246-376-1
		590-00-1	

PCPC [CTFA]		CAS	EINECS
Water	40 - 60 %	7732-18-5	231-791-2
Glycerin	40 - 60 %	56-81-5	200-289-5
Rosa Hybrid Flower Extract	1 - 3 %	93062-88-5	---
Preservatives			
Sodium Benzoate	0,2 - 0,3 %	532-32-1	208-534-8
Potassium Sorbate	0,2 - 0,3 %	24634-61-5	246-376-1
		590-00-1	

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:

Traditionally, Rose (flowers,roots and leaves) have been used to treat burns, injuries and rheumatic arthritis.(International Journal of Food Studies, 2018, vol. 7, no 2.)

The following substances have the GRAS status ('Generally Recognized As Safe'): Glycerin (21CFR182.1320)

The CIR Expert Panel concluded that glycerin is safe in the practices of use and concentration described in the Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014, which include 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.

The Cosmetic Ingredient Review (CIR) Expert Panel concluded that the ingredient Sodium Benzoate is safe in the present practices of use and concentration described in this safety assessment. (Safety Assessment of Benzyl Alcohol, Benzoic Acid and its Salts, and Benzyl Benzoate. IJT 36(Suppl. 3):5-30, 2017)

Classification according to Council of Europe (*):

Non-classified.

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

Cytotoxicity:

No data available.

Skin Irritation:

Glycerin (RTECS no. MA8050000): Draize Test in the skin of rabbit, 500 mg, 24h, mild.

Glycerin (50% in water) was not irritating to subjects with dermatitis (n=420) when administered for 20-24h under occlusion. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Skin Sensitization:

In a sensitization study, natural and synthetic glycerin were not sensitizing to white male guinea pigs (n=12). A moisturizer containing glycerin (65.9%) was not sensitizing in a modified Draize test (n=48). There were no reaction during either the induction or challenge phase. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Eye Irritation:

Test performed with other products of Provital: Rose Extract H.G. (4945):In-vitro Irritation Index: HET-CAM (con.100%) :2.5

Glycerin (RTECS no. MA8050000): Draize Test eye rabbit = 500 mg/24h, mild.

Mutagenicity:

Glycerin was not genotoxic in multiple Ames tests using multiple strains of Salmonella typhimurium up to 50mg/plate. It was not genotoxic in a cytogenetic assay, in a HGPRT assay, sister chromatid exchange assay using CHO cells, unscheduled DNA synthesis assay using rat hepatocytes, or a in vitro chromosome aberration test using CHO cells, up to 1.0mg/mL was tested in these studies. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Moreover in two in vivo chromosome aberration assays, glycerin was not genotoxic when administered orally to rats at 1mg/kg or by injection into the abdomen at 1000/mg/kg. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Acute toxicity:

Rosa hybrida Hort., flower, methanol extract (RTECS nº: VL0361000): TDLo oral mouse = 200 mg/kg.

Glycerin (RTECS no. MA8050000): TDLo oral in human = 1428 mg/kg.

Glycerin (RTECS no. MA8050000): LD50 in rat: p.o. = 12600 mg/kg, i.p. = 4420 mg/kg, s.c. = 100 mg/kg, i.v. = 5566 mg/kg. LDLo in rat i.m. = 10 mg/kg, TDLo in rat i.m. = 5 g/kg.

Glycerin (RTECS no. MA8050000): LD50 oral mouse = 4090 mg/kg, LD50 i.p. mouse = 8700 mg/kg, LD50 s.c. mouse = 91 mg/kg, LD50 i.v. mouse = 4250 mg/kg, LD50 oral rabbit = 27 g/kg, LD50 i.v. rabbit = 53 g/kg, TDLo i.m. rat = 4 mL/kg, TDLo i.m. rat = 4000 mg/kg.

Subchronic and chronic toxicity:

Rosa hybrida Hort., flower, methanol extract (RTECS nº: VL0361000): TDLo oral mouse = 1400 mg/kg/7D-I

Glycerin (RTECS no. MA8050000): TDLo oral rat = 96 g/kg/30d-I, TDLo oral mouse = 560 g/kg/8w-C, TDLo oral mouse = 2800 mg/kg/25w-C.

The NOAEL of glycerin in rats was between 115 and 2300 mg/kg when orally administered in water for 44days.The NOEL in dogs was 950 when orally administered for 3 days. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

In repeated dose toxicity studies with humans there were no signs of toxicity or effects on blood or urine production when subjects (n=14) were orally administered glycerin (1.3 - 2.2 g/kg/day) for 50 days.(Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

There were no treatment effects when glycerin (100%; 0.5 - 4mL) was administered to 30% of the body surfaces of rabbits for 45 weeks.(Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

The inhalation NOAEL was 0.167 for glycerin administered nose only for 5h/day, 5day/week for 13 weeks in rats.

(Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Reproductive effects:

Glycerin (RTECS no. MA8050000): rat, i.t. TDL0 = 280 mg/kg, 2 days, male; rat oral TDL0 = 100 mg/kg, 1 day, male; rat, i.t., TDL0 = 862 mg/kg, 1 day, male.

In a two-generation reproductive study in rats (n=10/sex), the administration of glycerin (0,20%; 2000mg/kg/day in drinking water) for 8 weeks before mating until weaning of pups produced no adverse effects on the reproductive efficiency of the parents (F0) or the development of the offspring (F1). (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

When glycerin was administered orally to rats and mice on days 6 through 15 of gestation, there were no adverse effects observed in the dams. The NOAEL for maternal toxicity and teratogenicity was 1310 mg/kg/d for rats and 1280 mg/kg/d for mice. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

When glycerin was administered orally to rabbits (n=25) on days 6 through 18 of gestation, there were no adverse effects found in the dams. The NOAEL for maternal toxicity and teratogenicity was 1180 mg/kg/d. (Safety Assessment of Glycerin as Used in Cosmetics, Final Report, December 2014)

Other data:

A study performed with the flowers of Rosa hybrida showed an anti-inflammatory effect in several models of inflammation induced in mice after an oral dose of 200 mg/kg. Also it showed an analgesic effect and the inhibition of type IV allergic reaction. These results support the use of Rosa hybrida in relieving inflammatory pain and insight into the development of new agents for treating inflammatory diseases. (J Ethnopharmacol. 2003 Nov;89(1):171-5)

There have been no reports in the literature of toxicity as such of rose plant parts including pollen or rose products. (The Biology of Hydrid Tea Rose (Rosa x hydrida), Australian governement, version 2, March 2009)

The American Academy of Allergy Asthma and Immunology (AAAAI) suggests that respiratory reactions to rose pollen are rare, probably because of the fact that rose pollen is heavy and sticky, and designed for insect pollination rather than wind dispersal. (The Biology of Hydrid Tea Rose (Rosa x hydrida), Australian governement, version 2, March 2009)

4. ECOLOGICAL DATA

Biodegradability:

None test of biodegradability have been performed on this product. However we have been able to conclude that this product can be considered as easily biodegradable due to his composition and the raw material used, considering that ingredients from vegetal origin and the solvents are biodegradable and the raw material from synthetic origin are in a very low concentration.

Glycerin (HSDB no. 492, revision: 20050624): Activated sludge test: 220 mg/l resulted in a COD of 97%; Test in a 5 days: BOD = 82%. Glycerin is considered an easily degradable substance.

Aquatic Toxicity:

Glycerin: Multiplication inhibition test in algae (Microcystis aeruginosa) and protozoa (Entosiphon sulcatum): Toxicity threshold = 2900 mg/l and 3200 mg/l (HSDB no. 492, revision: 20050624).

Glycerin (HSDB no. 492, revision: 20050624): LC50 goldfish > 5000 mg/l/24h.

Other data:

No data available.

5. CONCLUSION

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.

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.

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