

4077100G – PASSION FRUIT EXTRACT H.GL. - M.S.

Version: 20 - 20/09/2009

Exclusive N.A. Distributor
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1. PRODUCT IDENTIFICATION

Trade Name:	PASSION FRUIT EXTRACT H.GL. - M.S.
Manufacturer:	PROVITAL,S.A.
Responsible for the Safety Assessment:	Lourdes Mayordomo
Tf./Fax:	3493-7192350/7190294
e-mail:	l.mayordomo@provitalgroup.com
Kind of Raw Material:	Active Ingredient
Function of the Ingredient (CTFA Handbook):	Not reported
Function of the Ingredient (UE Inventory):	Skin Conditioning
Maximum Suggested Concentration:	100%
INCI approved in:	Registered in EU, USA
Japanese Name:	---

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
Passiflora Edulis Fruit Extract	1 - 3 %	91770-48-8	294-833-9
Preservatives			
Potassium Sorbate	0,2 - 0,3 %	24634-61-5	246-376-1
Sodium Benzoate	0,2 - 0,3 %	532-32-1	208-534-8

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

Impurities:

Heavy Metals (as Pb)	Less than 20 ppm.
Pesticides	Non applicable.

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 fruit of Pasiflora edulis is considered safe. The fruit can be grown to eat or for its juice, which is often added to other fruit juices to enhance aroma.

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

Classification according to Council of Europe (*):

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Non-classified.

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

Cytotoxicity:

No data available.

Skin Irritation:

Glycerin (RTECS n°MA8050000): Draize Test in the skin of rabbit , 500 mg, 24 h, Mild

Skin Sensitization:

No data available.

Eye Irritation:

Glycerin (RTECS n°MA8050000): Draize Test in the eye of rabbit ,126 and 500 mg, 24 h, Mild

Mutagenicity:

Glycerin: DNA inhibition in human lymphocyte, 200 mmol/l (PNASA 6 79, 1171, 1982) Cytogenic Analysis rat p.o., 1 g/Kg (TGANAK 19, 436, 1985)

Acute toxicity:

Fruit juice of Passiflora edulis: LD50 mouse p.o. = 21471 mg/kg (An Fac Med Lima 2006; 67(3)).

Glycerin (RTECS n° MA8050000):LD50 in mouse:p.o.=4090 mg/kg, i.p.=8700 mg/kg, s.c.=91 mg/kg, i.v.= 4250mg/kg. LD50 in rabbit: p.o.=27 g/kg, skin>10g/kg, i.v.=53 g/kg

Glycerin (RTECS n° 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

Subchronic and chronic toxicity:

Glycerin (RTECS n° MA8050000): TDLo p.o.= rat 16800mg /Kg/28D-C; rat 96 g/Kg/90D-I; mouse 560 g/Kg/8W-C; mouse 2800 mg/Kg/25W-C

Reproductive effects:

Glycerin:(RTECS n° MA8050000) rat, i.t. TDLo = 280 mg/Kg, 2 Days, male ; rat o. TDLo=100 mg/Kg, 1 Day, male ;rat, i.t., TDLo=862 mg/Kg, 1 Day, male

Other data:

Glycerin (RTECS n° MA8050000): LC50 rat inhalation > 570/mg/m³/1H

Glycerin (RTECS n°MA8050000): TDLo oral in human = 1428 mg/kg

4. ECOLOGICAL DATA

Biodegradability:

Glycerin (HSDB n°492,Revisión:20050624).Activated sludge test:220 mg/l resulted in a COD of 97%;Test in a 5 days:BOD= 82%. Glycerin is considered a substance easily degraded

Aquatic Toxicity:

Glycerin:Inhibition multiplication test in algae (Microcystis aeruginosa) and protozoa (Entosiphon sulcatum) Toxicity threshold=2900 mg/l and 3200 mg/l (HSDB n°492,Revision:20050624)

Glycerin (HSDB n°492,Revision:20050624):LC50 goldfish > 5000 mg/l/24 h

Other data:

No data available.

5. CONCLUSION

The components of this product have registered adverse effects neither in its traditional 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 and at the maximum recommended concentration, involves no risk for consumers.