

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 06/29/2015 Revision date: 06/29/2015

Version: 1.0

PRODUCT: NUTRASEB FACIAL CREAM (4801680)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Name : NUTRASEB facial cream

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Medical device

1.3. Details of the supplier of the safety data sheet

ISDIN

Provencals 33

Barcelona, 08019 - Spain

T +34 93 240 20 20

www.isdin.com

1.4. Emergency telephone number

Emergency number : +34 93 240 20 20

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Eye Irrit. 2A H319

Full text of H-statements: see section 16

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



GHS07

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H319 - Causes serious eye irritation

Precautionary statements (GHS-US) : P305+P351+P338 - If in eyes: Rinse cautiously with water for several

minutes. Remove contact lenses, if present and easy to do. Continue

rinsing

P337+P313 - If eye irritation persists: Get medical advice/attention

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

None



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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
N-2-Hydroxyethylacetamide	(CAS No) 142-26-7	5 - 7	Skin Irrit. 2, H315 STOT SE 3, H335
1,2-pentanediol	(CAS No) 5343-92-0	1 - 3	Eye Dam. 1, H318

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. If eye irritation persists: Get

medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after eye contact : Eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Reactivity : The product is non-reactive under normal conditions of use, storage and

transport.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-

contained breathing apparatus. Complete protective clothing.



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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For

further information refer to section 8: "Exposure controls/personal

protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and

eyes. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands

after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

NUTRASEB facial cream	
ACGIH	Not applicable
OSHA	Not applicable

N-2-Hydroxyethylacetamide (142-26-7)	
ACGIH	Not applicable
OSHA	Not applicable



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1,2-pentanediol (5343-92-0)	
ACGIH	Not applicable
OSHA	Not applicable

8.2. Exposure controls

: Ensure good ventilation of the work station. Appropriate engineering controls

: Protective gloves. Hand protection Eve protection : Safety glasses.

: Wear suitable protective clothing. Skin and body protection

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

: Avoid release to the environment. Environmental exposure controls

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel-cream Colour : Almost White Odour : Aromatic and Mild Odour threshold : No data available : No data available Hq Melting point : Not applicable : No data available Freezing point Boiling point : No data available : No data available Flash point Relative evaporation rate : No data available (butylacetate=1)

Flammability (solid, gas) : No data available **Explosion limits** : No data available : No data available Explosive properties : No data available Oxidising properties : No data available Vapour pressure Relative density : No data available Relative vapour density at 20 °C : No data available : No data available Solubility : No data available Log Pow Log Kow : No data available : No data available Auto-ignition temperature : No data available Decomposition temperature



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Viscosity : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

N-2-Hydroxyethylacetamide (142-26-7)	
LD50 oral rat	27660 mg/kg (Rat)
LD50 dermal rabbit	> 20000 mg/kg (Rabbit)
ATE US (oral)	27660,000 mg/kg bodyweight

1,2-pentanediol (5343-92-0)	
LD50 oral rat	> 5000 mg/kg (Rat; OECD 401: Acute Oral Toxicity; Experimental value)
LD50 dermal rabbit	> 2000 mg/kg bodyweight (Rabbit; Experimental value; OECD 402: Acute Dermal Toxicity)

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified



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Reproductive toxicity : Not classified Specific target organ toxicity (single : Not classified

exposure)

Specific target organ toxicity (repeated: Not classified

exposure)

Aspiration hazard : Not classified Symptoms/injuries after eye contact : Eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

1,2-pentanediol (5343-92-0)	
LC50 fish 1	> 1000 mg/l (LC50; 96 h; Salmo sp.)
EC50 Daphnia 1	> 500 mg/l (EC50; EU Method; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)
LC50 fish 2	> 1096 mg/l (LC50; OECD 203: Fish, Acute Toxicity Test; 96 h; Danio rerio; Static system; Fresh water; Experimental value)
EC50 Daphnia 2	500 mg/l (EC0; EU Method; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)
Threshold limit algae 1	9334,69 mg/l (EC50; DIN 38412: German standard methods for the examination of water, waste water and sludge; 72 h; Desmodesmus subspicatus; Static system; Fresh water; Experimental value)
Threshold limit algae 2	6944,99 mg/l (EC50; DIN 38412: German standard methods for the examination of water, waste water and sludge; 72 h; Desmodesmus subspicatus; Static system; Fresh water; Experimental value)

12.2. Persistence and degradability

N-2-Hydroxyethylacetamide (142-26-7)	
Persistence and degradability	Biodegradability in soil: no data available.

1,2-pentanediol (5343-92-0)	
Persistence and degradability	Readily biodegradable in water. Highly mobile in soil. Photooxidation in the
	air.

12.3. Bioaccumulative potential

N-2-Hydroxyethylacetamide (142-26-7)	
Bioaccumulative potential	No bioaccumulation data available.



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1,2-pentanediol (5343-92-0)	
Log Pow	0,2 (0.06; Experimental value; 25 °C)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

12.4. Mobility in soil

1,2-pentanediol (5343-92-0)	
Log Koc	Koc, PCKOCWIN v1.66; 1; Calculated value; log Koc; PCKOCWIN v1.66; 0; Calculated value

12.5. Other adverse effects

Effect on global warming : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT Not regulated for transport

Additional information

Other information : No supplementary information available.

ADR

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available



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Classification according to Regulation (EC) No. 1272/2008 [CLP]

Eye Irrit. 2 H319

Full text of H-statements: see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Full text of H-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure,
	Category 3, Respiratory tract irritation
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product