

Cosmetic Product Safety Report Summary



Product Name: X Patch

Medex Ref No: MD201

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The above-named product has been independently safety assessed by Delphic HSE Solutions Ltd for and on behalf of Medex Scientific (UK) Ltd. The assessment is summarised below.

Formulation:

INCI Name	CTPA Name	Frame %	CAS No.	EINECS No.
Aqua	Water	> 25% - ≤ 50%	7732-18-5	231-791-2
Acrylates Copolymer	Acrylates Copolymer	> 25% - ≤ 50%	25133-97-5 / 25035-69-2 / 25212-88-8	n/a
Phenoxyethanol	Phenoxyethanol	>0.1% - ≤1%	122-99-6	204-589-7
Arginine HCl	Arginine HCl	>0.1% - ≤1%	1119-34-2	214-275-1
Avena Sativa Seed Extract	Avena Sativa Seed Extract	>0.1% - ≤1%	-	-
Epimedium Sagittatum Extract	Epimedium Sagittatum Extract	>0.1% - ≤1%	-	-
Lepidium Meyenii Root Extract	Lepidium meyenii (Maca) root extract	>0.1% - ≤1%	-	-
Ptychopetalum Olacoides Bark Extract	Ptychopetalum Olacoides Bark Extract	>0.1% - ≤1%	84929-46-4	284-529-4
Sodium Borate	Sodium Borate	>0.1% - ≤1%	1330-43-4 / 1303-96-4	215-540-4
Trichilia Catigua Bark Extract	Trichilia Catigua (Catuaba) Bark Extract	>0.1% - ≤1%	-	-
Urtica Dioica Leaf Extract	Urtica Dioica (Nettle) Leaf Extract	>0.1% - ≤1%	84012-40-8	281-685-5
Zinc Gluconate	Zinc Gluconate	>0.1% - ≤1%	4468-02-4	224-736-9
Tribulus Terrestris Fruit	Tribulus Terrestris	>0.1% - ≤1%	90131-68-3	290-381-1

Extract	Fruit Extract			
Acacia Senegal Gum	Acacia Senegal Gum	>0.1% - ≤1%	9000-01-5	232-519-5
Glycerin	Glycerin	≤ 0.1%	56-81-5	200-289-5
Cucurbita Pepo Seed Extract	Cucurbita Pepo (Pumpkin) Seed Extract	≤ 0.1%	89998-03-8	289-741-0
Maltodextrin	Maltodextrin	≤ 0.1%	9050-36-6	232-940-4
Capsicum Annuum Extract	Capsicum Annuum Extract	≤ 0.1%	84625-29-6	283-403-6
Silica	Silica	≤ 0.1%	7631-86-9 / 112945-52-5 / 60676-86-0	231-545-4 / 262-373-8 / 310-060-2
Potassium Sorbate	Potassium Sorbate	≤ 0.1%	24634-61-5 / 590-00-1	246-376-1 / -

Manufacturer's Instructions for Use:

Directions for Use:

Ensure skin is clean, dry and free of hair. Apply one patch directly onto any area of the body that is not covered in hair, avoiding the face, neck and genital area. Replace patches every 24 hours. Do not use more than a total 1 patch in any 24 hour period.

Safety:

For external-use only. Use only as directed. If you are receiving medical treatment or medication for a health problem, you should seek authorisation or supervision from your medical professional. Do not use on irritated or broken skin. If irritation occurs, discontinue use. Keep away from children. Store in a cool dry place. If contact with the eyes occurs, wash out with cold water and seek medical attention.

Statement:

This product is not intended to diagnose, treat, cure or prevent any diseases.

Delphic required Safety Labelling:

Canada only: "Do not use on broken or abraded skin, not to be used by children under three years of age"

Product Review

Cosmetic patch, intended to be used by adults.

No Observed Adverse Effect Levels (NOAELs) were not available for review for some materials. For those materials where a Margin of Safety (MoS) was not derived this is often due to the fact that they are polymers, and so have a very low dermal absorption and bioavailability, or due to either a history of safe use at similar levels in cosmetic products related to the product under review, lack of biological activity, the ingredient being a constituent of the human diet, or for a reason explained in the individual

ingredient toxicological summary in annex II.

For those substances where values were available, the MoS are above the typical recommended values (see preface to annexes), unless materials have recommended safe levels (as established by bodies such as the Scientific Committee on Consumer Safety (SCCS) or Cosmetic Ingredients Review (CIR) expert panel) or legal limits that are described in percentage terms. All such materials are present at or below the recommended safe levels or legal maximums, as indicated by the relevant MoS.

Most of the plant extracts used in this formulation are described as food grades, and therefore no adverse effects would be expected when used in cosmetics. All of these plants are also used in food and/or traditional medicines, leading to conclude that they are safe, despite limited toxicological data are available.

Due to the presence of sodium borate, label must bear the warning "Do not use on broken or abraded skin, not to be used by children under three years of age" in order to comply with Canadian regulation. Overall, considering potential adverse effects related to sodium borate when systemically available, this warning can be recommended for all regions. The level of sodium borate in the formulation complies with European and Canadian regulations. The manufacturer must ensure that all raw materials are of suitably safe cosmetic grade for all regions to be sold. Manufacturer / organisation responsible for placing the product on each market must ensure no additional registrations are required.

Skin Toxicity – neat product:

The product as supplied may cause slight skin irritation especially if exposure is prolonged and/or repeated. Exposure to this product is unlikely to result in photo-toxic effects. Unlikely to cause sensitisation following repeated skin contact. Unlikely to produce systemic toxicity following skin contact.

Eye Toxicity – neat product:

May cause significant eye irritation and discomfort.

Oral Toxicity – neat product:

All materials if swallowed in large amounts have the potential to cause injury. If incidentally swallowed in small amounts, the formulation as supplied may cause slight, transient irritation to the mouth and upper digestive tract. Not expected to produce systemic toxicity following ingestion. All materials if swallowed in large amounts have the potential to cause injury.

Inhalation Toxicity – neat product:

It is unlikely that inhalation will be the route of exposure.

Overall Safety & Compliance

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give consumers the level of safety they can reasonably expect. This product complies with the requirements of the EU Cosmetic Regulation (EC) No 1223/2009. The product must be manufactured according to Good Manufacturing Practice. The ingredients are legally permitted according to the Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic

Ingredient "Hotlist") 2005 as amended, and must comply with the regulatory requirements of the Food and Drugs Act, R.S.C. 1985, c.F-27, Cosmetic Regulations (C.R.C., c. 869) as amended, and the Consumer Packaging and Labelling Act. The product must be made in accordance with Canadian Good Manufacturing Practices.

This product meets the requirements of the Australian Department of Health and Ageing, NICNAS Cosmetic Guidelines 2007 as amended. (www.nicnas.gov.au)

The ingredients are legally permitted as per the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments. They must comply with the relevant purity standards. The product must be manufactured in accordance with FD&C guidance on Good Manufacturing Practice.

Signed on behalf of Medex Scientific (UK) Ltd

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