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SAFETY ASSESSMENT/ TOXICOLOGICAL RISK ASSESSMENT

Product Name: QUAT FREE SURFACE DISINFECTANT WIPE

our ref: M1752

This Safety Report/Assessment is conducted for the assessment for safety of a Food Contact surface wipe.

The Assessment is conducted in accordance with the principles of Good Laboratory Practice referred to in Article 1 of Council Directive 2004/10/EC on the applications of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

This assessment takes account of:

a) the general toxicological profile of each ingredient used:
b) the chemical structure of each ingredient:
c) the level of exposure of each ingredient;
d) the specific exposure characteristics of the areas on which the product will be applied;

REVIEW OF INGREDIENTS

All of the ingredients have a history of use in Consumer products. Ingredients that are:

- Prohibited under EU REACH Regulations
- Restricted when used beyond the allowed authorised conditions
- With toxicological data incompatible with the intended concentration and use
- Which have insufficient toxicological data nor safety in use experience
- Which are not properly characterised with regard to purity and analytical composition

: are excluded.

ASSESSMENT

Assessment is based on ingredient safety review and information on the final formulation, including the intended and reasonably foreseeable use, the physico-chemical and microbiological specifications of the raw materials and the finished product, stability and a history and record of any reported undesirable effects linked to the use of the product.

DESCRIPTION OF THE PRODUCT

The product is intended for surface disinfecting. It is recognised that traces of liquid may remain and come into contact with foods.

DESCRIPTION OF INTENDED AND REASONABLY FORESEEABLE USE

The product may reasonably be typically used as required.

QUANTITATIVE COMPOSITION OF THE PRODUCT

Ingredients are listed below. Detailed information on the safety and toxicology of ingredients is presented below.

Deionised Water
Isopropyl Alcohol
Didecyldimonium chloride
Decylglucoside
Tetrasodium EDTA
DMDM Hydantoin
Iodopropyl Butylcarbamate

Wipe Manufacture
The liquid is applied to a Polypropylene, Viscose
nonwoven fabric, sheet size 20 x 20 cm with a loading of approx. 41g liquid / sqm fabric.

The above ingredients have been reviewed for potential to be skin irritants, sensitisers or photo-sensitisers.
In the context of a Food surface wipe, specific attention was directed to residues that may be ingested with foods.
Hence systemic and sub-chronic toxicity has been taken into account.
A review of the literature and of the structural chemistry has been made for each ingredient to estimate the likely potential for genotoxicity, reproductive effects and carcinogenicity.
No animal testing has been conducted on this formulation. All safety data is taken from existing published sources.

CALCULATION OF POTENTIAL HUMAN EXPOSURE

Human exposure resulting from trace carry over after use of the wipe can only be estimated.
A 20x20 cm wipe contains 41/25 grams liquid, ie 1.64gm
Assuming that 20% remains on a surface, ie 0.33gm
Based on a residue of 330 mg in contact with 200 gm foods

It can be estimated that for any person, there may be a daily intake of 330 mg of liquid.

QUANTITATIVE EXPOSURE

Deionised Water	= 292 mg
Isopropyl Alcohol	= 33 mg
Didecyldimonium chloride	= 3.3 mg
Decyl glucoside	= 0.99mg
Tetrasodium EDTA	= 0.132 mg
DMDM Hydantoin	= 0.462mg
Iodopropyl Butylcarbamate	= 0.0198 mg

EXPOSURE AS MG/KG BODYWEIGHT

For a 60 kg Adult the above exposures are calculated as:

Deionised Water	= 4.87 mg/kg
Isopropyl Alcohol	= 0.55 mg/kg
Didecyldimonium chloride	= 0.055 mg/kg
Decyl glucoside	= 0.0165mg/kg
Tetrasodium EDTA	= 0.0022 mg/kg
DMDM Hydantoin	= 0.0077 mg/kg
Iodopropyl Butylcarbamate	= 0.00033 mg/kg

MARGINS OF SAFETY

Based on the available toxicological literature or on “read-across” data Margins of Safety have been calculated for both topical and systemic effects based on published NOAEL data.

It was concluded that all ingredients, when considered both individually and in combination have an adequate Margin of Safety, ie > 100.

GOOD MANUFACTURING PRACTICE

The product is to be manufactured to adequate standards of Good Manufacturing Practice and there to be are adequate controls in regards to Microbial quality.

STABILITY

The product is deemed stable under normal and foreseeable conditions of use.

MICROBIAL QUALITY

INGREDIENTS

It is a requirement that all raw materials/ ingredients meet a microbial quality of < 1000 cfu/ gram for Adult products

FINSHED PRODUCT

It is a requirement that the Finished Product meets a microbial quality of < 1000 cfu/ gram for Adult products and zero harmfuls.

FINISHED PRODUCT SAFETY

The above formulation is based on known ingredients with history of safe use in consumer products.
The product is considered to be protected from microbial growth.
The microbial content (Total Viable Count) at time of manufacture must be within recognised limits (nmt 1000cfu and zero harmfuls /gm).

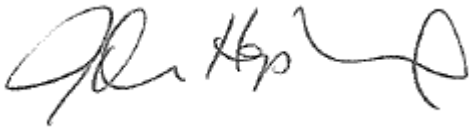
This Safety Assessment has taken account of:

1. The Quantitative/Qualitative composition of the product,
2. The intended and reasonably foreseeable use of the product,
3. Margins of Safety for all ingredients considered both individually and in combination.

likely safety hazards from normal use of this product and when used as directed or from foreseeable conditions of misuse.

The product is considered safe for sale in EU Countries.

Dated: September 15th 2015



Dr. JOHN HOPKINS BSc. PhD. MRSB. C Biol.
Safety Assessor

Note: This assessment is made on the basis of current legislation and current knowledge of chemical safety. If there is a change in either of these factors, the Assessment should be reviewed

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JOHN HOPKINS

CURRICULUM VITAE

Academic Qualifications.

BSc (Honours) Biochemistry/Chemistry.
University of St Andrews, UK.
PhD Pharmacology/Toxicology.
University of Dundee, UK.

Membership of Societies

Member Royal Society of Biology. **MRSB. C Biol.**
Membership number 004007934

A Founder member of British Toxicology Society 1979.

Member Company of CTPA

Qualifications as a professional Toxicologist in respect of Directive 93/35/EEC Art 7a(1)(e) and Regulation EC 1223/2009

The Diploma **C Biol**. is within the meaning of Regulation 2 (1) of the European Communities (Recognition of Professional Qualifications) Regulations, 1991(b).
The holder is recognised under European Community law to be a Safety Assessor for products under the Cosmetics Directive.

Relevant Experience

2000- current, Director and Principal of **Innovant Research Ltd**, an independent Consultancy in Toxicology, Risk Assessment and Product Safety. Emphasis on the safety of chemicals, cosmetics and medical device products.

1976-1999. Employed by **Johnson and Johnson**.
Several positions from Toxicology head, Head of Medical Dept, and R&D Director in UK and Director in the USA.

1974-1976. Toxicologist for **Smith Kline Beecham Pharmaceuticals**, Responsible for antibiotic safety program.

At Smith Kline Beecham Pharmaceuticals, developed methods for rapid evaluation of potential renal damage due to cephalosporin and penicillin antibiotics. Also developed methods to assess safety of anti-depressant medicines.

At Johnson & Johnson, was responsible for safety of both medical devices and skin and hair care products in the European business. Developed methods for cell culture evaluation of shampoo and detergent products as an alternative to the rabbit eye test.
Also cell culture methods for safety evaluation of implantable medical devices.

Also developed methods for human dermal evaluation of skin-care products to assess for potential irritation and sensitisation.

Developed methods for safety evaluation of bone repair plates, carbon fibre and polyester ligament repair systems, prior to human clinical studies.
In positions of Research Director in Johnson & Johnson, was responsible for new product development for both adult and infant care areas of business.

PUBLICATIONS

Hopkins J and Tudhope GR. Glutathione peroxidase in Human Red Cells in Health and Disease. British J. Haematol. 25:563 (1973).
Hopkins J and Tudhope GR. Red Cell Glutathione in Anaemia. Scottish Medical Journal 18:177 (1973)
Hopkins J and Tudhope GR. Glutathione Peroxidase deficiency with increased susceptibility to erythrocyte Heinz Body formation. Clin Sci. & Mol.Med.47: 643 (1974)
Tudhope GR and Hopkins J. Plasma tocopherol levels and the susceptibility of Erythrocytes to Heinz Body formation. Clin.Sci.& Mol.Med. 46: 635 (1974)
Tudhope GR and Hopkins J. Lipid Peroxidation in Erythrocytes. Acta Haematologica 51: 29 (1974)
Hopkins J and Tudhope GR. The effects of Drugs on erythrocytes in vitro. Brit. J. Clin. Pharmac. 1:191 (1974)
Hopkins J. Baby Powder- exploring the Myths and Realities. Brit.J. Midwifery 9 (9) 545-547 (2001).
Hopkins J. The safe and effective use of baby powder. RCM Midwives Journal 4 (9) 285-286 (2001).
Bertin C, Zunino H, Pittet J-C, Beau P, Pineau P, Massonneau M, Robert C, Hopkins J. A double-blind evaluation of the activity of an anti-cellulite product containing retinol, caffeine and ruscogene by a combination of several non-invasive methods. J.Cosmet. Sci 52, 199-210 (2001).

Hopkins J., Baby Powder – Dusting off the Myths. Chemist & Druggist, 15th Dec 2001. pp 32-33 (2001)
Hopkins J. The Safe use of Fragrance in Cosmetics. Chemist & Druggist, 3rd August.2002, p 30 (2002).
Hopkins J. Essentials of newborn skin care. Brit. J. Midwifery 12 (5) 314-317. (2004).

PUBLISHED PROCEEDINGS

Meeting of the Scottish Society for Experimental Medicine. Reported as Hopkins J and Tudhope GR. Erythrocyte Glutathione Peroxidase in patients with anaemia. Scot. Med. J. 17:376 (1972).

Meeting of the Scottish Society for Experimental Medicine. Reported as Hopkins J and Tudhope GR. Vitamin E and the Red Blood Cell. Scot.Med.J.18: 216 (1973)

PATENTS

Application filed 1998: Composition for the Treatment of Prickly Heat Rash in Infants.
Application filed 1999: Composition for the treatment of seborrheic dermatitis and dandruff in infants and children.
Application filed 1999: Composition for a body wash with skin moisturising benefits.

POSTERS /ORAL PRESENTATIONS

Johnson and Johnson Skin Care Symposium, Hamburg, Germany. 1992. Role of D- Panthenol and Phytantriol when combined to increase the strength of human hair (poster). Hopkins 1992.

Johnson & Johnson Skin Care Symposium, New Brunswick, USA. Role of Zinc oxide in the treatment of Nappy rash, studies in a rat model and human infant evaluation (poster). Hopkins J. 1994.

European Soc. Dermatology. June 1999, London. Efficacy of the association of retinol and lactose and hydroxy acid on the signs of skin ageing. Clinical study with comparison to placebo (poster). Bertin C, Hopkins J.

21st Congress of International Federation of the Societies of Cosmetic Chemists, Berlin 2000. An original *in-vivo* method using uv spectroscopy to evaluate the performance of a new broadband uv filter (poster) Issachar N, Bruere V, Cambon M, Castelli D, Robert C, Hopkins J. 2000.

Congress of the Polish Neonatal Society, Mikolajaki, Poland, 2001. Infant Skin (lecture). Hopkins J. 2001.

COMMITTEE MEMBERSHIPS AND TEACHING

A Member of several Trade Association technical committees including CTPA (UK Trade Association) and Colipa (European Trade Association).

Member of Colipa Committee, Brussels to present support to European Commission SCCNFP for use of salicylic acid at higher-than-preservative amounts in skin and hair care products (2001-2002).
Member of Colipa Committee to present data to EU Scientific Steering Committee (SSC) for approval of azoles in non-drug applications in skin and hair care (2003).

Member of Colipa Zinc Oxide task force to present safety data and support to European Commission SCCNFP for continued use of zinc oxide in skin care products (1999-2004).

Member of Colipa Cosmetovigilance Task Force, Brussels 2005-06.

Member of UK CTPA Scientific Advisory Committee (1999-current).

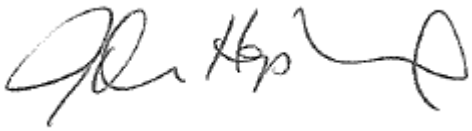
Member of UK CTPA Toxicology Advisory Panel (2000- current)

Member of COLIPA Committee, Brussels, representing CTPA (2010 – 2012) to draft Colipa Guidelines for format of Safety Assessment/Safety Report under new legislation Regulation EC 1223/2009 .

Lecturer at University of Surrey MSc Course in AppliedToxicology 2012.
Lecturer for Product Safety Evaluation at CTPA Conference March 2014
Lecturer for Toxicology at Society of Cosmetic Chemists Conference, UK March 2014.

EXPERT WITNESS

Have acted as Expert Witness in United States court cases (2004, 2006, 2012, 2013) for talc litigation matters re talc safety/toxicology.
Have presented Expert Witness statements on behalf of Oxford (UK) Trading Standards in court case.



Dated: July 30th 2015.

Institute of Biology

Incorporated by Royal Charter

To certify that

John Hopkins

has been admitted as a

Member

by resolution of the Council and
is entitled to employ the designation
Chartered Biologist

Membership Number 004007934

Honorary Secretary

Election Date 25 March 1999

Registered Charity Number 277981

THE UNIVERSITY OF DUNDEE

In exercise of the powers granted by the Royal Charter and with the authority of the Senatus Academicus the University has conferred the Degree of Doctor of Philosophy

upon

JOHN HOPKINS

James Drever.
Principal and Vice-Chancellor

J. P. Duguid
Dean of the Faculty of Medicine

In witness whereof the Common Seal of the University is affixed hereto

12 July 1974

R Lister
Secretary