

Cosmetic Product Safety Report

Conforming to
Regulation (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30
November 2009 on Cosmetic Products

Product Line	Alcohol Hand Rub
Name of Product	Community Spirit Hand Sanitiser
Product Category	Hand Cleansing
Manufacturer	Conker Spirit Limited. Unit 3, 16A Inverleigh Road, Southbourne, BH6 5HA
Responsible Person	Conker Spirit Limited. Unit 3, 16A Inverleigh Road, Southbourne, BH6 5HA

Report Part A

Quantitative Formulation
Final Product characteristics (including stability, microbiology etc.) Packaging Warnings
Normal and reasonably foreseeable use
Target Population
Undesirable effects and serious undesirable effects
Product and substance exposure characteristics & margin of safety summary
Substance toxicity profiles – see additional sheets

Report Part B

Data review
Assessment summary
Warnings and instructions of use
Reasoning
Assessment conclusion

Cosmetic product safety Report Part A

%	Product category	Amount per application (g)	Frequency of application	G/day applied	Retention factor	G/day exposure	Exp. Surface area cm ³	Systemic exposure dose (mg/kg) based on 60kg	Specific exposure mg/cm ³	MOS summary
100	Hand rub	2	5	10	1%	0.1	12895	1.67	0.0078	>100
1.45	Glycerine	0.03	5	0.15	1%	0.0015	12895	0.03	1.6x10 ⁻⁵	>100
80	Alcohol	1.6	5	8	1%	0.08	12895	1.33	0.0062	>100
0.125	Hydrogen Peroxide	0.0025	5	0.0125	1%	0.000125	12895	0.0002	9.7x10 ⁻⁷	>100
18.43	Water	0.3675	5							

Quantitative and qualitative composition

Final Product characteristics

Liquid

Physical And Chemical Properties

pH – expected range 9.5-10.5

Stability and Reactivity

Interaction of substances –

No major interactions are expected

Generally stable at ambient storage conditions – nominally stable for 30months+ in sealed or unsealed container.

Ingredient Purity

Specific purity criteria (e.g. secondary amine content) are not applicable in this formulation. General ingredient purity remains the responsibility of the manufacturer – specifically prohibited ingredients as defined by Annex II (REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL) must be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

Microbiological Purity

Product does not support microbial growth under normal storage conditions due to high alcohol content.

Packaging

No specific requirements (e.g. absence of nitrosating agents)

Warnings

For external use only. Do not drink.

Normal and reasonably foreseeable use

Used as per typical liquid hand cleanser

Target Population

Marketed as a product for general population – not specifically marketed for infant use. The scale of manufacture appropriate to this type of safety report (small / artisanal with a typical customer base of 100-10000 sales per annum) indicates limited population exposure.

Undesirable effects and serious undesirable effects

None declared at the time of preparation of this document – a separate file must be made to record any declared incidences of undesirable effects – any serious undesirable effects must be notified to the competent authority and or local poison control agency

Cosmetic product safety Report Part B

The report validity conditions detailed in Part A must be adhered to by the manufacturer; otherwise this report is null and void and may not be used in relation to the criteria set out in REGULATION (EC) No 1223/2009 relating to the safety of cosmetic products placed on the market in the EU.

A review of the information contained within this report, taking into account the requirements of Article 3 of REGULATION (EC) No 1223/2009 and including, at least the following considerations

Relating to the final product

Physical and Chemical Properties

Stability and Reactivity

Microbiological Purity

Packaging

Normal and reasonably foreseeable use

Target Population

And in general

The general toxicological profile of each ingredient used:

The chemical structure of each ingredient:

The level of exposure of each ingredient;

The specific exposure characteristics of the areas on which the cosmetic product will be applied;

The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Warnings and instructions of use

Standard usage instructions associated with this type of product – for external use only - not to be used around the eyes, mucous membranes or on broken skin. If irritation occurs discontinue use.

Additional Reasoning

Nil additional

Local toxicity

Phototoxic materials are not included in this formulation.

CMRs

Not included in this formulation

Nano materials

No nano materials are included in this formulation

Dermal irritants / sensitizers

no significant exposure (leave on), however compatibility testing is advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations, or if new ingredients (without supplier confirmation of dermal compatibility) are used by the manufacturer.

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation

CALCULATION OF THE MARGIN OF SAFETY

Maximum amount of ingredient applied (mg) I

Typical body weight of human (kg) 60

Maximum absorption through the skin (%) A

Systemic Exposure Dose (mg/Kg Bw) SED = I x A / 60

Margin of Safety NOAEL / SED

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate repeated dose toxicity studies.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100)

Product Category – Liquid cleanser

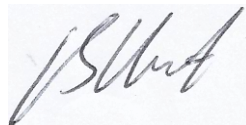
product comprising denatured alcohol, glycerine and hydrogen peroxide

Products –Alcohol hand rub

Responsible person – Conker Spirit Limited – United Kingdom Assessment

Conclusion

The data review indicates no significant risk under normal and foreseeable conditions of use, and the product fulfils the required criteria to be marketed in the EU.



Dr Liam Scott Hirt MBBS MRCP 27/03/2020

