Helsinki, 21/Jun/2013

Safety Assessment
[SA9501203A]

Evaluation of the potential risks of a cosmetic product in accordance to the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products

Location of the Safety Assessment - Part A

Regulation 1223/2009 complying "Part A" of this assessment is kept on file at Oy TeamPac Ab and will be promptly made available to competent authorities to inspect if such an official and substantiated request is made.

Product: Teampac Refresher Bulk
Formula: 9501203
Type of Product: Wet Wipe for Body
Manufacturer: Oy TeamPac Ab
Country of Origin: FINLAND

Cosmetic Product Safety Report
Part B

1. Assessment Conclusion

Taking into consideration

- The quantitative and qualitative composition of the finished product,
- The physicochemical characteristics of the raw materials,
- The chemical structure of the raw materials,
- The available toxicological information of the raw materials,
- The margins of safety of exposure to the raw materials used,
- The possible interactions of the substances contained in the finished product,
- The physicochemical characteristics of the finished product,
- The consumer exposure to the finished product,
- The European Community regulations and recommendations,
- The possible undesirable adverse effects,
- The experience gained with marketing,

And based on the professional and scientific knowledge and literature accessible to us at the time of completing this safety assessment we conclude that the cosmetic product

Teampac Refresher Bulk
9501203

evaluated on a preliminary level, can be reasonably considered **NOT TO REPRESENT ANY UNDUE RISK TO THE HUMAN HEALTH** in accordance to the Regulation 1223/2009 if used under normal and foreseeable conditions.

2. Labeling, Mandatory Warnings and Instructions of Use

2.1. Mandatory Labeling Precautions to be Observed in Use

None.

2.2. Arbitrary Labeling Precautions

"Keep away from the children."
"Not to be swallowed."

3. Reasoning

This is a typical cosmetic formulation, the ingredients of which are all well-known with a long history of safe use in cosmetic products of this type. The ingredients are used at levels that have been seen and assessed in similar products by Cosmarts Ltd with no significant reports of irritation. The product is formulated and manufactured by a company with a long history of safety and quality.

The formulation contains no substances which are listed on the list of restricted substances (Annex III) of the Regulation (EC) No. 1223/2009.

Fragrance is provided by an IFRA Standard 46th Revision conforming fragrance supplier who performs quantitative risk assessment (QRA) for the fragrances.

The finished product is preserved with substances listed in the Annex V of the Regulation (EC) No. 1223/2009 and are in full compliance with the product type, maximum concentration and other conditions. This further substantiates the safe use of these preservatives, as they all belong to a positive list which has been published by the EU.

Systemic Exposure Doses (SED) and Margins of Safety (MoS) were calculated for each substance present in the cosmetic product, including carryover traces from raw materials and possible allergens from fragrance compound.

For substances where NO(A)EL value was not available the relationship between LD50 and SED was calculated with a further uncertainty factor. We understand the significant

scientific difference between acute toxicity (LD50) and chronic toxicity (NOAEL) and this relationship was used as a part of alternative risk assessment that also included evaluating the skin irritation, sensitization and mucous membrane irritation potentials. Summaries of the evaluated data are located in Section 8.3 of the confidential Safety Assessment Part A.

NOAEL's present in Section 8.1 of the confidential Safety Assessment Part A are always sub-chronic or chronic toxicity data, where available. Unavailable data is clearly identified as such.

Substances present as carryover traces under the TTC (Threshold of Toxicological Concern) threshold dose generally accepted by European Authorities such as EFSA, 2.5 ng/kg bw/day (0.15 µg/person/day), were considered to be toxicologically not a safety concern in this type of product, although their Systemic Exposure Dose were calculated. None of these analysed substances is aflatoxin-like-, azoxy-, or N-nitroso- compound or polyhalogenated- dibenzodioxin, -dibenzofuran, or -biphenyl.

All Margin of Safety (MoS) derived were higher than 100. This very conservative MoS value is used to extrapolate from a group of test animals to an average human being, and subsequently from average humans to sensitive subpopulations.

Margin Of Safety extrapolation approach includes both interspecies and intraspecies uncertainty factors and taking into account kinetics and dynamics as shown in the figure below, so sensitive human subpopulations (e.g., children, people with "sensitive skin") are covered. In general, there is no need for an additional uncertainty factor for children when intact skin is involved.

Additionally Cosmarts Ltd has confidential data regarding certain substances used in this formulation that also provide further weight of evidence for the safety of the product.

Calculated Margins of Safety for the substances in the finished product provide weight of evidence that the product is generally having a good margin of safety and use levels of the substances are optimal even for sensitive subpopulations.

The amount of skin irritating and/or eye irritating ingredients is very low and provides mildness for the product even in leave-on application.

Effects of the product as supplied on the skin

Under normal conditions of use exposure will be low and the likelihood of causing skin irritation will be low. Repeated exposure to the product is unlikely to produce allergy by skin contact. Exposure to the product is unlikely to result in phototoxic effects. Exposure to the product is unlikely to cause damage to internal organs following absorption through the skin.

Effects of the product as supplied on the eye

Like all cosmetic products containing surfactants, accidental exposure of the eye to the formulation as supplied may result in slight eye irritation. Unlikely to cause damage to the eye. If product is in contact with eye, rinse thoroughly with water.

Effects of inhaling the product

Inhalation is an unlikely route of exposure.

Infants under 6 months of age

This product is not primarily targeted for children under 3 years of age. Infants have a higher body surface area to body mass ratio compared to older children and adults, which may be a cause of higher exposure per kg body weight to dermal applied compounds. Different absorption and distribution factors due to the immaturity of physiological functions of young children may cause ineffective inactivation and elimination kinetics and thus higher internal exposure to the same external dose of certain chemicals in young children compared to adults. This inter individual variation is already taken into account by the uncertainty factor of 100, which is composed of 10 for interspecies variations (animal to man) and 10 for inter individual variations. Thus substances with Margin of Safety greater than 100 there is no general scientific justification for adding an extra uncertainty factor due to a larger exposure surface area.

3.1 SAFETY ASSESSMENT CONCLUSION

Based on all the presented facts the normal and foreseeable usage of this cosmetic product it is considered to provide the high degree of safety that would be reasonably expected by the consumer. As a result of our preliminary evaluation the finished cosmetic product has been classified as **SAFE** under normal and foreseeable conditions.

3.2 LOCATION OF THE SAFETY ASSESSMENT - PART A

Regulation 1223/2009 complying "Part A" of this assessment is kept on file at Oy TeamPac Ab, Dunkavägen 4, 07880 Liljendal. A copy will be stored with the safety assessor as well. Safety Assessment – Part A will be promptly made available directly to competent authorities to inspect if such an official and legally substantiated request is made.

4. Assessor's credentials and approval of part B

4.1 Safety Assessor

Mr. Alex Westerberg FRSPH
Safety Assessor

Cosmarts Ltd
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FINLAND

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Email info@cosmarts.com

4.2 Proof of Qualifications of Safety Assessor

- Safety Assessment of Cosmetics, Vrije University, Brussels, Belgium
- Degree in Cosmetic Science, De Montfort University, Leicester, The United Kingdom
- Diploma in Cosmetics Sciences, Society of Cosmetic Scientists, the United Kingdom
- Complying with the European Legal Requirements, Dr. Roberto Ciaff, London, The United Kingdom
- Member of Safety and Regulatory Toxicology Committee (SRTC), Personal Care Products Council (former CTFA)
- Fellow of Royal Society for Public Health (RSPH), The United Kingdom

A full statement is available on request.

4.3. General Notes

This assessment constitutes a formal notification of cosmetic product safety as required by the Cosmetic Regulation 1223/2009 of the European Parliament and of the Council.

This assessment is based on information supplied by manufacturers and from recognized sources and, whilst endeavors have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied to it and used for preparing this assessment.

In supplying this safety assessment Cosmarts Ltd makes no assurances that the individual substances are registered or exempt under REACh. Importers of products containing any botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions.

It must be ensured by the manufacturer that ingredients are of cosmetic grade or higher and meet the relevant purity criteria at all times.

The safety of a cosmetic product is also dependent on its microbiological quality and it is up to the Responsible Person to have systems in place to control it.

The toxicological risk with accidental, improper and/or unforeseeable application is excluded from this safety assessment.

Each subsequent change of formula, change or addition of relevant data to the safety assessment leads to invalidity of this assessment.

If this cosmetic product is reported to cause adverse reaction amongst consumers, the safety assessor must be informed at once and a new safety assessment made.

4.4 Approval of Part B

Helsinki 21/Jun/2013

Signature on File

Alex Westerberg FRSPH
Safety Assessor