

## Cosmetic product safety report in accordance with Regulation (EC) No 1223/2009 on cosmetic products Article 10

### Product

Trade name: Aloe Vera Rescue Spray  
Formula ref. no.: 385035/4  
Article no: 12031  
Type of product: skin care product  
Version: --  
Responsible person: Verway World S.L.U.  
Calle Salobrar, NUM 11, EDIFICIO 3,B,D  
ES-07180 Calvia (Santa Ponsa)

### Part A – Cosmetic product safety information

#### 1. Quantitative and qualitative composition

The present assessment is based on the preparation method and the itemised qualitative and quantitative composition located in the Annex.

#### 2. Physical/chemical characteristics and stability

The physico-chemical properties of the raw materials can be taken from the safety data sheets and technical specifications, which should be included.

The finished product has the following physico-chemical properties:

form: liquid  
colour: beige  
pH-value: 5,5 - 6,5  
viscosity: n.av.  
flashpoint: n.app.

#### Storage conditions:

There are no special storage conditions required.

#### Durability:

Period of use after opening according to the manufacturer: 12 months

#### Results from storage trials:

An accelerated stability test was carried out (Test period minimum 3 months) and the product was judged to be stable under the conditions used.

### 3. Microbiological quality

The stability of the product against microbiological contamination was checked in a preservative efficacy testing.

For the evaluation following documents are available:

- microbiological specifications of the cosmetic product,
- result of the preservative efficacy testing.

### 4. Purity of raw materials, information about the packaging material

The purity of the raw materials can be taken from the technical specifications, which should be included and is to be checked by the manufacturer.

*PET bottle:* The packaging material was tested according to U.S. 21 CFR FDA Regulation part 177.1630 (Chloroform-soluble extractive residues) and complies with the requirements.

Additional information:

None.

### 5. Normal and reasonably foreseeable use

The product is used as a facial treatment und a body treatment several times a day and remains on the skin.

The product is not intended for use especially for children under 3 years of age, for the eye area, or on mucous membranes.

### 6. Exposure to the cosmetic product

The scale of exposition yields from the conditions of use, as determined in the directions for use or from the product design.

Application site:	entire body, face
Surface area (A):	15670 cm <sup>2</sup>
Amount of product used (M):	3,5 g
Duration of application:	Left on
Retention factor (R):	1
Frequency (f):	2,28 /d
Foreseeable routes of exposure:	dermal
Target market:	no specific target market
Body weight(G):	60 kg

$$\text{exp}_{\text{dermal}} = \frac{(M \cdot f \cdot R)}{G} \quad 0,133 \text{ [g/kg/d]}$$

## 7. Exposure to the substances

The systemic exposure dose (SED) is calculated for the components contained in the highest possible concentrations. This is the amount which could enter the bloodstream and therefore could be systemically available.

The margin of safety (MoS) is determined on the basis of the NOAEL (no observed adverse effects level), if appropriate toxicological data are available.

When calculating the SED an average body weight of 60 kg is assumed in general.

If no data is available for percutaneous permeation, a value of 100% is assumed.

component	% (finished product)	% permeation (skin)	SED (component) [mg/kg/d]	NOAEL [mg/kg/d]	MoS = NOAEL / SED
Alcohol	25	25	8,31	2400	289
Glycerin	5	100	6,65	2200	331
Citric Acid	1	100	1,33	1200	902
(P) Citral	0,1	100	0,13	30	226
(P) Benzyl Salicylate	0,1	100	0,13	125	940
(P) Geraniol	0,1	100	0,13	500	3759
(P) Linalool	0,1	100	0,13	117	880

For components which have a MoS of at least 100 in the present formulation system toxic effects are not expected to present state of knowledge.

Some of the ingredients have already been examined by the SCCS (Scientific Committee on Consumer Safety) and have been classified as safe for cosmetic use - possibly, under certain conditions of use.

The limit values and restrictions for use specified by the cosmetic regulation are met for the following ingredients:

Sorbic Acid
Potassium Sorbate
Sodium Benzoate

A further consideration is therefore not necessary.

## Assessment of further ingredients:

component	% (finished product)	% permeation (skin)	SED (component) [mg/kg/d]
Aqua	100	100	133,00
Aloe Barbadosensis Leaf Juice	50	100	66,50
Polyglyceryl-10 Laurate	1	100	1,33
Disodium Cocoyl Glutamate	1	100	1,33
Sodium Lactate	1	100	1,33
Punica Granatum Extract	0,1	100	0,13
Maltodextrin	0,1	100	0,13
Sodium Cocoyl Glutamate	0,1	100	0,13
Tripleurospermum Maritimum Extract	0,1	100	0,13
Sodium Hydroxide	0,1	100	0,13
Ruscus Aculeatus Extract	0,1	100	0,13
Ectoin	0,1	100	0,13
Mentha Piperita Extract	0,1	100	0,13
Viscum Album Leaf Extract	0,1	100	0,13
Vaccinium Macrocarpon Extract	0,1	100	0,13
Melissa Officinalis Extract	0,1	100	0,13
Spiraea Ulmaria Extract	0,1	100	0,13
Centaurea Cyanus Flower Extract	0,1	100	0,13
Hamamelis Virginiana Extract	0,1	100	0,13

Based on the currently available toxicological data, these substances are not likely to be hazardous in the given concentrations.

Parfum
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The safety of the perfume in the present concentration and the intended use is confirmed by the manufacturer. (Safety assessment in the Annex)

If the perfume contains one or more of 26 specified substances, these substances must be listed in the "ingredients list" on the label if the concentration exceeds 0,001% in ,Leave-on'-products or 0,01% in ,Rinse-off'-products.

The used perfume oil contains the following of these substances in relevant concentrations:

(P) Citral
(P) Benzyl Salicylate
(P) Geraniol
(P) Linalool

#### 8. Toxicological profile of the substances

In order to create the profiles, information of the raw material manufacturers, available scientific literature, publications of the SCCS, BfR and other organizations were consulted.

The toxicological profiles of the materials and the underlying data sources are available in the archives of "CoSiChem AG" and can be reviewed there.

#### 9. Undesirable effects

Data on undesirable effects and customer complaints is not available.

#### 10. Further information on the cosmetic product

None.

## Part B – Cosmetic product safety assessment

### 1. Assessment conclusion

*Aloe Vera Rescue Spray* is suitable for cosmetic purpose, based on the toxicological data, not regarding unavailable information.

Health injuries are not known or expected under normal and foreseeable use.

### 2. Labelled warnings and instructions of use

None.

### 3. Reasoning

This assessment is based on the toxicological profile of the ingredients, the chemical structure, available toxicological / dermatological documentation of the raw materials and studies of final products including microbiological tests legal settlements, general obliging international assessments, recommendations of authorities and associations and experiences of commercialisation.

The product contains no substances classified as hazardous to health in concentrations which should be taken into account under normal and foreseeable use.

Sensitisation, exceeding the expected reactions of sensitive people, is not likely.

The product is stable against microbial contamination.

In terms of permitted ingredients and maximum allowable concentrations of constituents the legal standards of the EU Regulation 1223/2009 on cosmetics are met.

Possible interactions of the substances contained in the cosmetic product have been assessed and led to no particular findings.

The consideration of the toxicological profiles of the different substances have been described and duly justified in part A.

Impacts of the stability on the safety of the cosmetic product have been duly considered and described in part A.

## Appendices and Documents taken into consideration

- Quantitative composition
- Microbiological tests and specification
- Toxicological short profiles of the components
- Specification and safety assessment of the perfume oil
- Information about packaging material
- Qualifications of the safety assessor

19.12.2018

Responsible for the safety assessment:



Ezme Hopkins

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