

Claims Substantiation

'Hypoallergenic'

For WaterWipes the term 'hypoallergenic' means the product is less likely than other cosmetics to cause allergic reactions. It also means that the product will be gentle for sensitive, delicate and allergy-prone and reactive skin.

This has been supported and verified by the following data

1. The allergenic potential of the product has been identified and minimised
2. The product in question is less allergenic than other similar products available for sale
3. These benefits can be evidenced by product testing or formulation.

1. Formulation

WaterWipes baby wipes contain only two ingredients; water and a drop of fruit extract, (which contains a trace of benzalkonium chloride). This extremely low number of ingredients dramatically reduces the potential for an allergic reaction. There are no other preservatives or fragrances present in the product. Preservatives and fragrances are the most frequent allergens found in personal care products.

2. Less allergenic

Similar products on the market often contain fragrances and sometimes a mix of preservatives as well as a number of botanical extracts, emulsifying, surfactant and buffering agents. All of these have the potential to cause an allergic reaction in susceptible individuals. With less ingredients and no fragrance, WaterWipes baby wipes are less likely to cause an allergic reaction.

3. Product testing

WaterWipes baby wipes have undergone numerous safety testing with excellent skin compatibility results all skin types including sensitive and allergy-prone skin.

- A clinical study using WaterWipes Baby Wipes, demonstrated the product had very good skin compatibility after a single application to the skin of the back under a semi occlusive patch for 48 hours, in 40 adult subjects who had a positive allergic case history.
- A clinical study using WaterWipes Baby Wipes, demonstrated the product had very good skin compatibility after a 21-day cumulative irritation test in 20 adult subjects.
- A clinical study using WaterWipes Baby Wipes, demonstrated the product was non-irritating and non-sensitising to the skin in a repeated insult (semi-occlusive) patch test (RIPT) carried out on 100 adult subjects.
- A clinical study to evaluate the phototoxicity potential of WaterWipes Baby Wipes by UV-A irradiation was carried out on 20 adult subjects. No adverse effect or unexpected reactions were observed on any of the subjects. The product was considered non-phototoxic.

- A clinical in-use study using a similar formulation daily for 14 days on 21 volunteers with dry and sensitive skin demonstrated very good dermatological tolerance for facial skin including and a very good cosmetic acceptability.
- A clinical study using a similar formulation, demonstrated the product can be considered as non-irritant after application for 48 consecutive hours on 22 volunteers with sensitive skin and reactive skin.

Additional information

WaterWipes baby wipes have been approved by Allergy UK and have been assessed as "unlikely to cause a reaction" and "may be of benefit" when used by an allergy sufferer.

Note:

In the EU, Annex IV of the Technical Document on Cosmetic Claims focuses on 'hypoallergenic' claims, stating they should be supported by verifying and confirming a very low allergenic potential of the product through scientifically robust and statistically reliable data. These data could be from a review of post-marketing surveillance data, and from a solid rationale for the selection of the ingredients of the formulation to minimise the allergenic potential of the finished product. There are currently no federal regulations that govern the use of the term 'hypoallergenic' in the USA.

Conclusion

Based on the evidence outlined in terms of formulation, comparison to other product and the product safety testing, WaterWipes Baby Wipes can be considered hypoallergenic and are unlikely to cause a reaction in allergy-prone individuals.

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