# Product Assessment Against Criteria: Antiperspirants

Classification: Cosmetic

Date of Decision: Spring 2009

Revised: Summer 2016

## Summary of Classification:

Aluminum-based antiperspirant preparations are regulated as cosmetics provided that the requirements (e.g. claims, directions for use, etc.) are as outlined in the conclusion, and that the product is represented as intended for the reduction of normal underarm perspiration. This decision is based primarily on its mechanical mode of action (composition) and to a lesser degree its representation (e.g. to minimize body odour). Antiperspirants indicated for hyperhidrosis are regulated as drug products.

## Evaluation Against Criteria

### Representation:

*Is the product represented in a manner suggesting it is used for treating,*

*diagnosing, preventing, or curing disease or restoring, correcting or modifying organic functions in human beings?*

Perspiration is recognized as a regular body function necessary to maintain human body temperature. Antiperspirants have a similar purpose as deodorants (which are classified as cosmetics) as both are intended to minimize body odour. Furthermore, antiperspirant products reduce the extent of sweating with or without the presence of perfumes, as well as the occurrence of unsightly sweat marks on clothing. These products are represented as temporarily reducing the extent of normal sweating, minimizing body odour, and decreasing the occurrence of unsightly sweat marks on clothing.

The exemption to this understanding would be products intended for use in hyperhidrosis, or that imply protection based on a mechanism of action that modifies organic function. By definition, hyperhidrosis is an overproduction of sweat. As products used for this condition are represented as correcting a disorder, they are regulated as drugs.

*Is the product likely to be understood by consumers to have characteristics of a drug?*

Most antiperspirants are used for aesthetic reasons and not for the prevention or treatment of any disease or the alleviation of their symptoms. They behave in the market place in every way as cosmetics. The representation for sale of the product is inherently cosmetic in nature and the associated acceptable claims are not prophylactic. However, the product would likely be understood to be therapeutic if it is advertised or intended for use in cases of a disorder, such as hyperhydrosis.

## Composition:

*Does the product's composition suggest it is an agent for treating, diagnosing, preventing, or curing disease or restoring correcting or modifying organic functions in human beings?*

Topical antiperspirants typically contain inorganic salts of aluminum or zirconium, usually as chlorohydrates that are in some cases complexed with organic moieties. In 1950, zirconium (IV) salts were patented in antiperspirants. Zirconium salts have similar chemistry to aluminum salts in that they form gels on hydrolysis. They tend to be slightly more efficient than aluminum salts because of the higher acidity and greater synergistic effect of zirconium-containing complexes. Zirconium salts, however, are too expensive to use as the sole antiperspirant active but incorporation of a small amount of zirconium oxydichlorohydrate ($ZrOCl_2$) or zirconium oxyhydroxychlorohydrate ($ZrO(OH)Cl$) in aluminum chlorohydrate (ACH) -based antiperspirants improves their efficacy by 30-50%. These zirconium/aluminum chlorohydrate (ZACH) salts are more acidic than ACH and therefore need to be buffered to reduce skin irritation. This led to the development of zirconium aluminum glycine (ZAG) salts; these are ZACH salts complexed with glycine(aminoethanoic acid), which buffers ZACH salts without hindering performance.

Aluminum and zirconium antiperspirants are sold as roll-ons, lotions, creams, pump sprays and aerosols. With the onset of sweating, the aluminum salt dissolves into the neck of the sweat duct. The average pH of axillary sweat is about 6, so the aluminum salts form polymeric aluminum hydroxide solids. These form a gel, which blocks the sweat gland duct thus reducing the amount of sweat secreted. The presence of gel plugs has been confirmed by using analytical methods, e.g. transmission electron microscopy.

Previously, antiperspirants were considered to be drugs because the definition of "drug" in the *Food & Drugs Act* includes: "...restoring, correcting or modifying an organic function ..." It was maintained that because antiperspirants interfere with the natural passage of sweat from the sweat glands, they too should be regarded as drugs. However, upon reassessment, it has been determined that the mode of action of antiperspirant ingredients is mechanical in nature, and any physiological effect of the aluminum and/or zirconium is minor, transient, and secondary to its primary cosmetic purpose of decreasing odour and unsightly sweat marks. Therefore, a typical antiperspirant meets the intent of the definition of "cosmetic".

The exemption to this understanding would be products intended for use in hyperhidrosis. As they imply a physiological action that is neither transient nor superficial, they are regulated as drugs.

## Level of action:

*Does the product exert solely a superficial effect?*

The product is applied topically with no evidence of percutaneous absorption.

## Other considerations:

In the United States, antiperspirants are classified as drugs. In New Zealand, Australia, and the European Union, they are cosmetics. Similarly, in South Africa, an antiperspirant "modifies a physiological function in that it inhibits the production of perspiration. Its purpose is the prevention of body odour that will occur if perspiration is unchecked. Although it acts by the modification of a physiological function, this modification is minor and is at a superficial level. This product is classified

as a cosmetic".

## Conclusion:

Based on its representation, mode of action (composition), level of action and classification in other jurisdictions, most antiperspirants are classified as cosmetics, including those with duration statements, and are regulated under the *Cosmetic Regulations*. However, antiperspirants intended for use in hyperhidrosis, or that imply protection based on a mechanism of action that modifies organic function are considered to treat or mitigate a disorder and therefore will remain classified as drug products, and are regulated under the *Natural Health Product Regulations* or the *Food and Drug Regulations*, depending on ingredient.

**The following outliness the classification parameters for cosmetic antiperspirant products.**

1. *Non-therapeutic claims*:
    - Antiperspirant
    - Any duration statement (e.g. 24, 48 hour)
    - Helps keep you dry
    - Protects against wetness
    - Reduces (or provides protection against) underarm perspiration
    - Extra effective
    - Clinical (qualified as clinical testing)
    - Clinical protection (must be qualified with "clinically proven extra effective wetness protection")
    - Clinically tested/proven/trials
    - Body responsive
    - Controls odour/Anti-odorant

2. *Therapeutic/health claims*:
    - Hyperhidrosis
    - Persistent protection based on a mechanism of action that modifies organic function
    - Problem /Excessive perspiration
    - References to perspiration from hormonal/endocrine changes or malfunction
    - Clinical (unqualified)
    - Clinical protection (unqualified)
    - Clinical/Therapeutic strength/effect/action
3. *Ingredients:*

**Table 1. Antiperspirant ingredients acceptable as Cosmetics [1], [2], [3]**

| Ingredient Name (International Nomenclature Cosmetic Ingredients - INCI) | Acceptable Concentration (weight for weight - w/w) |
|---|---|
| Aluminum chloride | ≤15% |
| Aluminum chlorohydrate | ≤25% |
| Aluminum chlorohydrex PEG | ≤25% |
| Aluminum chlorohydrex PG | ≤25% |
| Aluminum dichlorohydrate | ≤25% |
| Aluminum dichlorohydrex PEG | ≤25% |
| Aluminum dichlorohydrex PG | ≤25% |

| Ingredient Name (International Nomenclature Cosmetic Ingredients - INCI) | Acceptable Concentration (weight for weight - w/w) |
|---|---|
| Aluminum sesquichlorohydrate | ≤25% |
| Aluminum sesquichlorohydrex PEG | ≤25% |
| Aluminum sesquichlorohydrex PG | ≤25% |
| Aluminum zirconium trichlorohydrate | ≤20% |
| Aluminum zirconium trichlorohydrex GLY | ≤20% |
| Aluminum zirconium tetrachlorohydrate | ≤20% |
| Aluminum zirconium tetrachlorohydrex GLY | ≤20% |
| Aluminum zirconium tetrachlorohydrex PEG | ≤20% |
| Aluminum zirconium tetrachlorohydrex PG | ≤20% |
| Aluminum zirconium pentachlorohydrate | ≤20% |
| Aluminum zirconium pentachlorohydrex GLY | ≤20% |
| Aluminum zirconium octachlorohydrate | ≤20% |
| Aluminum zirconium octachlorohydrex GLY | ≤20% |

## References:

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| 1 | Ingredients, concentrations or claims which fall outside acceptable cosmetic limits may require pre-market evaluation to obtain a Drug Identification Number (DIN)/Natural Product Number (NPN) |
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| 2 | The percentage of antiperspirant ingredient must exclude any water, buffer components or propellant (Food and Drug Administration, 2003a). |
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| 3 | Products containing aluminum chloride must be formulated in an aqueous solution non-aerosol form. Similarly, zirconium-containing ingredients cannot be used in products in aerosol form. |

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