



PRESERVATIVES

Are they safe?

31 May 2010

Piotr Kozarewicz
European Medicines Agency

An agency of the European Union 



Key Principles - Excipients

Most experts agree that formulations for the paediatric population may need to be different to those for adults:

- Formulations should be as simple as possible
- Number of excipients should be reduced to a minimum
- No unnecessary additives
- Excipient levels should be reduced to a minimum



Key Principles - Preservatives

According to *Guideline on Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product* (Doc. Ref. **EMA/CHMP/QWP/396951/2006**):

“Antimicrobial preservatives are normally added to prevent microbial proliferation arising under in use conditions. The properties are due to certain chemical groups which are usually harmful to living cells and might therefore be associated to certain risks when used in man.”



Key Principles - Preservatives

“Inclusion of antimicrobial preservatives or antioxidants in a finished product needs special justification.

The use of these substances should be avoided in general, especially when considering the suitability of related formulations to the paediatric population.”



Problem?

We have the Guideline ...

so what is the problem?

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.