



## REACH - Registration Evaluation and Authorisation of Chemicals

### HAMAMELIS VIRGINIANA, DISTILLATE Non-Alcoholic (EINECS 283-637-9)

In accordance with Article 6(1) of REACH, a registration shall be submitted to the Agency by manufacturers or importers for all substances manufactured or imported in quantities of 1 tonne or more per year (unless they are explicitly exempted from the scope of registration by other provisions of the Regulation).

This obligation applies to substances on their own or in preparations and in specific cases also for substances in articles. Therefore manufacturers or importers of preparations have to register **individual substances** which are components of the preparations, if the quantity of these substances is 1 tonne or more per year per manufacturer or importer.

#### **Preparations themselves do not need to be registered.**

As explained in the section 4.2.1 of *the Guidance on substance identification* available on the ECHA website ([http://reach.jrc.it/docs/guidance\\_document/substance\\_id\\_en.pdf](http://reach.jrc.it/docs/guidance_document/substance_id_en.pdf)), a mono-constituent substance is a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w).

In contrast, a multi-constituent substance is a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration >10% (w/w) and < 80% (w/w) (section 4.2.2 of the same Guidance document). A multi-constituent substance is the result of a manufacturing process.

The difference between a preparation and a multi-constituent substance is that a preparation is gained by the blending of two or more substances without chemical reactions, whereas a multi-constituent substance is the result of a chemical reaction.

Therefore Hamamelis Virginiana Distillate is a preparation not a multi constituent substance

Taking all the foregoing into consideration it is not our intention to pre-register any of the substances comprising non-alcoholic versions of witch hazel distillates.

The reasoning behind this is that

- i) Hamamelis Virginiana, as an individual substance in the various preparations, is a steam distilled natural product and as such is exempt from the requirements of REACH.
- ii) Hamamelis Virginiana, Non-Alcoholic is a preparation and, as stated previously, preparations do not need to be registered.
- iii) The preservatives used in all the varieties of non-alcoholic preparations are all imported by us as individual substances of the various preparations in quantities of less than 1000 kilos per year and as such are not required to be registered under the requirements of REACH.

Grateful thanks is extended to the ECHA helpdesk for their assistance in formulating and clarifying the position on steam distilled natural products and the position vis-a-vis preservatives in these preparations and the absence of a requirement to pre-register, or register, under the auspices of REACH..

**Note:** Hamamelis Virginiana Distillate USP/BPC contains Ethanol (14-15%).

Ethanol, as an individual substance of a preparation, requires registration under the requirements of REACH and this has been done. (See separate information sheet)

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