



## INFORMATION NOTE UPDATE

### The classification and labelling of pigment preparations containing colophony

Colophony (a.k.a. rosin) has had for a number of years, under the classification and labelling legislation within the EU<sup>1</sup>, a legally binding classification as a skin sensitizer.

As a consequence and unless there is irrefutable evidence to the contrary, colophony-containing pigments products must also be labelled.

The concern about possible colophony-induced sensitizing properties of rosinated pigments motivated ETAD in 1992 to carry out a corresponding project, and a series of Buehler tests were commissioned in order to determine if rosin containing pigment products also show skin sensitization effects.

None of the products showed any sensitization potential and, based on these studies, ETAD recommended that pigment products containing colophony need not to be labelled.<sup>2</sup>

The need to review this recommendation was triggered by the availability of data within the framework of REACH. Colophony, as a phase 1 substance, was registered in 2010 and the toxicological data submitted may now be viewed on the ECHA website.

The submitted data indicated that the skin sensitization potential of colophony can vary with time and storage conditions, which has also been confirmed by several scientific articles.<sup>3</sup>

On the basis of this information, ETAD has critically re-evaluated its earlier studies and concluded that they are not robust enough to justify not labelling colophony containing products; *inter alia* they do not cover any aging effects. Therefore, in compliance with its responsible care approach, ETAD withdraws the former recommendation not to label pigment products containing colophony.

### Conclusion

In consideration of the whole set of information currently available on colophony, ETAD recommends manufacturers and importers of colophony-containing pigments to label them accordingly to Directive 2008/1272/EC, which foresees:

- For a colophony content **0.1% ≤ X < 1%**:
  - o disclose the presence of colophony in the MSDS section 3;
  - o no classification as Skin Sens. 1;
  - o Label with Supplemental Label Information Code EUH208 'Contains colophony. May produce an allergic reaction'.
- For a colophony content **above ≥ 1%**:
  - o disclose the presence of colophony in the MSDS section 3;
  - o classify as Skin Sens. 1;
  - o Label with GHS07, Warning, Hazard Statement Code H317 'May cause an allergic skin reaction'.

<sup>1</sup> Directive 1272/2008/EC, with amendments, as for 18.10.2011

<sup>2</sup> The 1993 ETAD Information Note can be downloaded at <http://www.etad.com/lang-en/publications/information-notice.html>

<sup>3</sup> Downs A. M., Sansom J. E., 1999, Contact Derm., 41(6): 305-310.

**Note**

According to Directive 2008/1272/EC, which introduced the GHS system, colophony has to be classified as Skin sensitizer 1 and must be labelled with the Hazard Statement Code H317 'May cause an allergic skin reaction'. The specific substances covered by the labelling are:

|                             | <b>EINECS No</b> | <b>CAS No.</b> |
|-----------------------------|------------------|----------------|
| Rosin, colophony            | 232-475-7        | 8050-09-7      |
| Tall oil rosin              | 232-484-6        | 8052-10-6      |
| Resin acids and Rosin acids | 277-299-1        | 73138-82-6     |

In the REACH Dossier a fourth substance is mentioned and all 4 EINECS No. are merged into 232-475-7. ETAD strongly recommends labelling it accordingly.

|                                       |           |            |
|---------------------------------------|-----------|------------|
| Resin acids and Rosin acids, tall oil | 302-657-1 | 94114-23-5 |
|---------------------------------------|-----------|------------|

With the implementation of REACH the rosin industry has decided to register only one CAS No. for rosin: 8050-09-7. This way no distinction is made anymore in the way rosin can be obtained: tapping live trees (gum rosin), extracting wood stumps (wood rosin) or in the pulping process (tall oil rosin). The same approach has been taken for rosin derivatives. As a consequence, the CAS Nos. 8052-10-6, 73138-82-6 and 94114-23-5 should be used with care in the EU, as these CAS Nos. have NOT been registered under REACH.