Prepared for
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Project Number
**0442160A**

Date
**September 2017**

# TALL OIL FATTY ACIDS

## REVIEW OF DERMAL SENSITIZATION HAZARD

RAMBOLL ENVIRON

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## EXECUTIVE SUMMARY

Ramboll Environ US Corporation (Ramboll Environ), on behalf of Kraton Polymers LLC (Kraton), independently and critically evaluated information related to the dermal sensitization potential of tall oil fatty acids (TOFA; Chemical Abstracts Services Registry Number 61790-12-3). TOFA is a substance of variable composition consisting predominantly of oleic and linoleic acids, with minor amounts of other fatty acids and unsaponifiable matter.[1] TOFA is obtained by distilling crude tall oil (CTO) derived from pine tree pulp used in the kraft paper process. Kraton wants to ensure that its GHS classification of TOFA is accurate and correct. Therefore, Kraton requested that Ramboll Environ perform an assessment of TOFA's dermal sensitization hazard potential.

In summary, Ramboll Environ reviewed three animal studies of TOFA products performed in accordance with international guidelines, a peer-reviewed published review of human studies of TOFA sensitization potential in soaps, one animal study of a DTO product, and the main chemical constituents of TOFA. With the exception of the disregarded study in 1992, the information demonstrated that TOFA, its main components, and a closely related product, are not sensitizers. The only study that suggests that TOFA is a sensitizer is the 1992 study that cannot be relied upon because it cannot be confirmed that TOFA was the test substance and the study owner had rejected the study. Therefore, based on the weight of the evidence, Ramboll Environ concludes that TOFA is not a skin sensitizer according to GHS and GHS-aligned classification criteria.

The following summarizes Ramboll Environ's assessment:

1. A skin sensitization study of TOFA on guinea pigs commissioned in 1992 by Bergvik Kemi's European Union (EU) Regulatory Affairs Department reported that TOFA was a skin sensitizer.[2] Upon completion and review of the study, Bergvik Kemi determined that the test sample was not TOFA and disregarded the study. Bergvik Kemi was the European operating base of Arizona Chemical, which is now a subsidiary of Kraton. Ramboll Environ reviewed an affidavit of the Bergvik Kemi (Arizona Chemical) employee that explained the reasons for disregarding the study in 1992.
2. Two skin sensitization studies of TOFA on guinea pigs commissioned in 1998 by Arizona Chemical demonstrate that TOFA is not a skin sensitizer.[3]

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[1] Pine Chemicals Association. HPV Test Plans and Robust Summaries for Tall Oil and Related Substances and Tall Oil Fatty Acids and Related Substances. Atlanta, Ga: Pine Chemicals Association; 2001.

[2] BEVACID™ 2 Skin Sensitisation in the Guinea-Pig Study [Confidential Report]; Huntingdon Research Centre; 1992; Report number 920168D/BGV 5/SS.

[3] SYLFAT™ Tall Oil Fatty Acid - Test for Delayed Contact Hypersensitivity using the Guinea Pig Maximization Test; Scantox; 1998; Lab No 30888. SYLFAT™, Tall Oil Fatty Acid - Test for Delayed Contact Hypersensitivity using the Buehler Test; Scantox; 1999; Lab No 30889.

3. In 1999, apparently unaware of the conclusion previously made by Bergvik Kemi, Arizona Chemical's US Regulatory Affairs Department submitted the study under Section 8(e) of the Toxic Substances Control Act (TSCA) to the United States Environmental Protection Agency (USEPA) as part of a voluntary TSCA Compliance Audit Agreement. However, Arizona Chemical's US Regulatory Affairs Department did not provide USEPA a subsequent supplemental submission after they discovered that the study had been disregarded. Kraton reported to Ramboll Environ that the study was submitted to USEPA out of an abundance of caution.
4. A skin sensitization study of distilled tall oil (DTO) on guinea pigs commissioned in 1992 by Bergvik Kemi reported that DTO, a substance which is also obtained as distillation stream from CTO and which is chemically similar to TOFA, is not a skin sensitizer.[4]
5. A 2009 peer-reviewed article by a Cosmetics Review Panel reported that liquid soaps containing up to 12% TOFA did not cause dermal irritation, sensitization, or photosensitization in human subjects.[5]
6. Ramboll Environ reviewed the Globally Harmonized System for the Classification and Labeling of Chemicals (GHS) and related GHS-aligned frameworks such as those in the EU, US, and Canada for the classification requirements of sensitization hazards.[6]
7. Ramboll Environ reviewed publicly accessible information regarding the sensitization hazards of the major components of TOFA, including oleic acid, linoleic acid, palmitic acid, and stearic acid. Based on available information, Ramboll Environ concluded that none of the major TOFA components are skin sensitizers.

This assessment supports the conclusion that TOFA is not a skin sensitizer according to GHS and GHS-aligned classification criteria.

[4] 1992 BEVACID™ 25/30 Skin Sensitization in the Guinea-Pig Study; Huntingdon Research Centre; 1992; Report number 920169D/BGV 5/SS.

[5] Robinson V, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, Alan Andersen F. 2009. Amended safety assessment of tall oil acid, sodium tallate, potassium tallate, and ammonium tallate. Int J Toxicol. 28(6 Suppl 2):252S-8S. doi: 10.1177/1091581809354652.

[6] Globally Harmonized System for the Classification and Labelling of Chemicals Sixth Revised Edition, the European Union Classification, Labeling, and Packaging Regulation (EC) No 1272/2008, and the US Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR 1910.1200, Appendix A.