

Environment and Climate Change Canada

Health Canada

June 2019

8.1.3 Rosin

Rosin (CAS RN 8050-09-7) and the related substance resin acids and rosin acids (CAS RN 73138-82-6) are considered a single substance on the basis of information provided by industry and will be evaluated together (personal communication from Pine Chemicals Association to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). A search of SDS for CAS RN 73128-82-6 revealed no products, which is consistent with the limited information submitted under section 71 notices.

Rosin has not been approved for use in Canada as a food additive. Furthermore, there is no indication that rosin (CAS RN 8050-09-7) or resin acids and rosin acids CAS RN 73138-82-6 are used as food flavouring agents, flavourings, or other ingredients added to foods. Both substances may be used in food packaging (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated July 4, 2017; unreferenced). CAS RN 8050-09-7 (rosin) is a component in coatings for cans and paper, adhesives, can end cement and corrugated boxes, while CAS RN 73138-82-6 (resin acids and rosin acids) has been identified as a component in printing inks with no direct food contact (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). There is the potential for direct food contact from rosin (CAS RN 8050-09-7), but the human exposure potential is considered to be low based on the properties of the substances (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced).

According to notifications submitted under the Cosmetic Regulations to Health Canada, rosin is used in certain cosmetic products in Canada, but CAS RN 73138-82-6 (resin acids and rosin acids) is not. For rosin, the categories of adhesive, depilator, epilator, makeup and nail polish account for over 94% of products. Adhesives and depilator and epilator products can contain a high concentration, up to 100%, of rosin (personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). These solid or semi-solid gels or cakes are applied to large areas of the body (legs) for hair removal. The rosin is not expected to absorb through the skin as the material is designed to be applied and physically removed from the skin surface to facilitate hair removal. Systemic exposure is therefore expected to be minimal.

Exposures to rosin can occur from nail polishes, makeup/adhesives for the face and eyes, and lipsticks. In adults, exposure through dermal deposition from the use of nail polish containing up to 10% rosin, assuming that two coats are applied to fingernails and toenails, was estimated at 0.23 mg/kg bw/event.

Environment and Climate Change Canada

Health Canada

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The internal dose, estimated on the basis of 11% dermal absorption, is 0.024 mg/kg bw/day (Hoelgaard 1982). Eye makeup can contain up to 3% by weight of rosin and may be applied daily to the eyelid area. The dermal deposition over the course of the day was estimated to be 0.013 mg/kg bw/event and average daily deposition of 0.015 mg/kg bw/day was determined with an internal dose of 0.0065 mg/kg bw/day based upon the absorption of 19.2 µg/cm² from 24 cm² use area. Lipsticks contain between 0.1% and 3% of rosin by weight, with ingestion from the lip area during the day. An upper-bounding estimate of daily oral exposure to lipstick was determined to be 0.01 mg/kg bw/day.

Rosin is listed in the Natural Health Products Ingredient Database with a non-medicinal role for use as a base, binder, coating agent, emulsifying agent, encapsulating agent, and film former (NHPID [modified 2019]). Rosin is also present as a non-medicinal ingredient in authorized products listed in the Licensed Natural Health Products Database (LNHPD) (personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Rosin appears in many dental varnishes to treat sensitive teeth in both adults and children at concentrations of up to 59% rosin. The suggested frequency of application to the teeth is very infrequent, i.e., a few times per year. At the suggested amount of 1.6 mL, this gives a potential oral ingestion of 0.944 mL of rosin or 1.05 grams (0.944 mL × 1.115 g/mL) per application. This results in a per event dose of 33.9 mg/kg bw for children and 14.8 mg/kg bw for adults. This is expected to be slowly released from the tooth surface over a period of months. Assuming release over a period of 90 days followed by re-application, this would result in an average daily dose of 0.38 mg/kg bw/day for children and 0.164 mg/kg bw/day for adults.

Rosin also appears in therapeutic products as a non-medicinal ingredient. Topical therapeutic treatments, typically marketed for pain relief, in the form of a patch or plaster can contain rosin likely formulated as an adhesive. Little information is available on the amount of rosin present in these products, which have a suggested use of 3 to 4 times daily, with warnings to limit use beyond 7 days (personal communication, email from the Therapeutic Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Given the suggested short duration of use, exposure is not expected to be greater than exposures previously determined for cosmetics.

A limited number of over-the-counter allergy and cold relief products contain rosin as a non-medical ingredient, with an upper limit of 7 mg per tablet. Assuming 2 tablets are taken per day, this would result in an average daily dose of 0.20 mg/kg bw/day for adults (personal communication, email from the Therapeutic Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced).

Draft Screening Assessment - Resins and Rosins Group

Official title: Draft screening assessment - Resins and rosins group

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Products available to consumers containing rosin include various sealants and construction materials, electronics solder or flux, adhesives, paint, printing inks and various manufacturing process aids for other consumer products (AGDH 2017). International work completed by Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) estimated concentrations in these products to be up to 30% (AGDH 2017). Inhalation exposures from solder/flux as it is heated are not expected to be from the rosin itself but rather from the combustion products, which are beyond the scope of this assessment.

Some resin products containing nearly pure rosin are used by amateur sports players, dancers and violinists. Rosin is used in sports for improved grip in tennis and baseball and is liberally applied to the hands. Inhalation and ingestion of this solid material is not expected, but dermal exposure of the palms to pure powdered rosin can routinely occur. The deposition on both hands for this scenario was based on the US EPA high-end soil adhesion factor for adults in a residential setting (0.07 mg/cm²), due to the similarities in powdered rosin and particulate soil (US EPA 2007). The estimated applied mass for the palms of both hands (455 cm²) was 31.45 mg, resulting in an applied dose of 0.45 mg/kg bw/event for adults, with an internal dose of 0.047 mg/kg bw/event assuming 11% dermal absorption. It is considered that up to 10 such exposure events could occur in a given day, but that exposure would not occur at all on other days, leading to a combined internal dose of 0.47 mg/kg bw/day on days of exposure. It is noted that the thickness of the palm may further limit dermal uptake; the dose presented is therefore likely an overestimation. This exposure is expected to cover incidental dermal exposures resulting from any infrequent uses of adhesives, inks or paints.