

Summary of the dossier: Mineral salt containing potassium and magnesium (Trade name: Salona®)

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This is an application for authorisation of mineral salt containing potassium and magnesium (Salona®) to be placed on the market as novel food ingredient according to Art. 35 (2) Regulation 2015/2283 and amending the Union list of novel foods (Regulation (EC) 2017/2470). Salona® is a natural mineral salt produced in a multi-step crystallization process from dead sea water with solar-energy in evaporation ponds.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.

Salona® consists mainly of carnallite, a hydrated double salt with the chemical formula $[KCl MgCl_2 \times 6 H_2O]$ consisting of potassium, magnesium, chloride and approximately 7 % of sodium chloride. In addition, Salona® contains several natural trace elements, such as bromide, strontium and barium.

Table salt (sodium chloride) is an important ingredient used in most food products for taste, flavour enhancement, preservation and other functions. According to the WHO the average daily intake of sodium by processed food is too high. A high sodium intake is considered to be linked to raised blood pressure and cardiovascular diseases. This has created a need for ingredients used in formulating sodium reduced food products. As a reduced sodium mineral salt, Salona® might be an effective tool for the replacement of salt in food. It is intended to be supplied to food business operators only.

The food categories listed below have been identified to have a significant impact regarding salt intake of the population in the European Union: (i) Leavened bread and similar: max. 0,4%; (ii) Raw cured meat: max. 1,05%; (iii) Cooked cured or seasoned meat: max. 0,7%; (iv) Preserved or partly preserved sausages: max. 0,7%; (v) Deep-frozen pizza: max. 0,6%. The given values show the maximum proposed use levels of Salona® in these food categories. The target groups are adults and the elderly who want to reduce their salt intake. It is not intended to be consumed by infants, toddlers or children.

A risk assessment was performed based on publicly available toxicological information comparing the exposure of the components of Salona® with the health-based guidance values established by scientific bodies like EFSA and WHO. The intake assessment shows that the estimated daily intake of Salona® for adults is at most 2,3 g. Considering this estimated daily intake the components like potassium and magnesium and the trace elements like bromide, strontium and barium are much lower than the established health-based guidance values: The estimated daily intake of Salona® of 2,3 g per day could lead to an exposure of up to 205 mg magnesium for adults in the course of the day which would be significantly lower than the tolerable upper intake level (UL) of 250 mg per day. For potassium the exposure lead to 313 mg per day. This value is ten-times lower than the reference

value of the Norwegian Scientific Committee for Food Safety (VKM, 2014). The exposure level of bromide will maximum 10,6 mg per day for adults. This corresponds to 0,15 mg bromide /kg bw /day, which is notably below the ADI of 0,4 mg/kg bw day. The tolerable daily intake (TDI) of strontium was established by Canada Health in 2018 with 1,417 mg/kg bw per day. The exposure level of strontium in Salona® is 46 µg resulting in 6,5 µg/ kg bw which is factor 2169 lower than the TDI. For barium the calculated value of 0,085 µg/kg bw is significantly lower than the established TDI of 0,21 mg/kg bw (WHO).

Other trace elements are also well below the health-based guidance values. The analysis of heavy metals and contaminants show that these are absent or occur only in non-concerning traces. Therefore, no health risk could be identified. The labelling of the salt content is an obligatory particular of the nutrition declaration of Regulation (EU) 1169/2011. Therefore, the consumer will be informed about a significant change in the nutritional value of a food. Hence, there is no risk of consumers being misled. As a result of the exposure and risk assessments mentioned above, the novel food ingredient “mineral salt containing potassium and magnesium - Salona®” is safe for all population groups and in the proposed food categories with the proposed levels of intake.