

## Potassium-based salt substitutes are not without health risks

Potassium chloride (KCl) products used as a substitute for sodium chloride or table salt (NaCl) are intended for patients requiring a low-salt or "salt-free" diet. However, their consumption may not always be safe for this population, because these individuals often suffer from high blood pressure, heart failure, kidney failure or diabetes, all of which are risk factors for abnormal serum potassium levels, either directly (due to the disease itself or its complications) or indirectly (side effects of treatments). For this population, therefore, consuming these substitute salts can aggravate a situation of hyperkalaemia, with potentially high health risks.



### The alert

In October 2018, a cardiologist alerted ANSES to a risk of severe or even fatal hyperkalaemia associated with the consumption of potassium chloride (KCl) as a substitute for sodium chloride or table salt (NaCl), as advocated with a low-salt diet. The cardiologist believed that these salt substitutes currently on sale over the counter, sometimes without any precautionary statement for the consumer, should at least be sold in pharmacies where advice can be obtained from the pharmacist, or even be dispensed on medical prescription. ANSES immediately undertook an expert appraisal to assess the risks associated with the consumption of these products.

### Causes and risks of hypokalaemia and hyperkalaemia

Potassium is an essential mineral for the body, found in all our cells. In particular, it plays a fundamental role in nerve transmission, muscle contraction and heart function. It is also involved in insulin secretion, carbohydrate and protein metabolism and the body's acid-base balance.

Hypokalaemia (a serum or plasma potassium concentration of less than 3.5 mmol/L) is characterised by heart rhythm disorders, cramps and asthenia (severe fatigue). It can be caused by increased potassium loss, due for example to diarrhoea or

vomiting, or to excessive loss from the kidneys. Hypokalaemia resulting from inadequate dietary intake is unusual and is only rarely encountered in the context of very low-calorie diets or malnutrition.

The clinical manifestations of mild to moderate hyperkalaemia (serum or plasma potassium concentration greater than 5.5 mmol/L in adults) are generally non-specific (fatigue, decreased strength of certain muscles, paraesthesia, nausea, vomiting, even diarrhoea). When the concentration is greater than 6.5 mmol/L, hyperkalaemia can lead to variable clinical signs depending on the cause and the patient's condition: the most dangerous are potentially fatal heart rhythm disorders.

### Sources of potassium in the diet and recommended intakes

According to data from EFSA [1] and the French Information Centre on Food Quality (CIQUAL<sup>1</sup>) – which is part of ANSES – chocolate, bananas, vegetables and dairy products are the common foods with the highest potassium content.

In a 2016 opinion [2], ANSES estimated that a potassium intake of 3500 mg/d had a beneficial effect on blood pressure in adults and that potassium intakes below 3500 mg/d were associated with an increased risk of stroke.

1. <https://ciqual.anses.fr/>

The data available at the time were insufficient for determining an average requirement (AR<sup>2</sup>) for potassium, but were sufficient for defining an adequate intake (AI<sup>3</sup>) of 3500 mg/d for both men and women.

On the other hand, like EFSA [3], ANSES considered that there were insufficient data to propose a tolerable upper intake level (UL) for potassium

### Risk factors for hyperkalaemia

EFSA [3] pointed out that adverse effects, particularly on heart function, have been observed in patients with impaired renal function and reduced urinary potassium excretion when the intake of potassium salts was equivalent to 1 g/d in addition to normal dietary intake. It considered that the risk of adverse effects was low with dietary intakes of the order of those observed in European countries (5-6 g/d in adults) but indicated that gastrointestinal effects had been seen in healthy adults taking potassium supplements at doses of 1-5 g/d. It also identified individuals engaging in activities leading to dehydration (sports, working in hot conditions, etc.), diabetic patients, people suffering from impaired kidney function, undergoing cardiovascular treatment, or suffering from metabolic disorders affecting potassium balance, as being at greater risk of hyperkalaemia, as well as the elderly, due to reduced kidney function.

In the United States, the National Kidney Foundation (NKF) recommends limiting the daily dietary intake of potassium to no more than 2 to 4 g in patients with mild to moderate kidney failure. A lower intake (< 2 g/day) is recommended in the event of end-stage renal disease. These situations concern 4% of the American population, and this prevalence can be extrapolated to France. In addition, in 2005 and 2006 [3-4], ANSES considered that the consumer should be informed, when purchasing food supplements containing potassium or salt substitutes, that they are contraindicated in cases of kidney failure or a low-potassium diet.

An international database (Vigilyze) has recorded all cases of hyperkalaemia worldwide since 1986. Out of more than

23,000 cases (including about 1000 with a fatal outcome), just under 3000 were recorded in France. The cause was mainly medication-related, especially in patients with diabetes (type 2), heart failure or kidney failure treated with drugs that decrease renal excretion of potassium (e.g. ACE inhibitors, ARBs, NSAIDs, anti-aldosterone, etc.) or are sources of potassium (e.g. Diffu-K<sup>®</sup>).

Based on these observations and all the data in the literature, it therefore appears that the people most at risk of hyperkalaemia if potassium salts are used inappropriately are:

- patients with stage IV kidney failure, known as end-stage renal disease;
  - diabetic patients;
  - heart failure patients;
  - hypertensive patients;
- elderly subjects, who are more frequently treated for high blood pressure, diabetes, heart failure or decreased kidney function.

### ANSES's recommendations

Populations with one or other of these risk situations form a non-negligible part of the French population. Because of their health status, they should undergo rigorous and regular medical monitoring. If this is not the case, or if the individuals are unaware of their condition, the risk of hyperkalaemia is increased.

Faced with public health recommendations that encourage a reduction in sodium intakes and scientific organisations advocating an increase in potassium intakes, consumers may turn to products with a reduced salt content or replace traditional salt with potassium salts. However, KCl is already used in many food products as an additive and as a replacement for NaCl without this being clearly indicated on these products. As a result, total KCl intakes are difficult to determine and their estimation cannot be based solely on intakes resulting from the substitution of traditional salt by KCl.

2. The average requirement (AR) is the average daily need within the population, as estimated from individual intake data in relation to a criterion of nutritional adequacy in experimental studies. It is used to calculate a population reference intake (PRI), which expresses the daily intake that meets the nutritional needs of almost all (97.5%) the population.

3. The adequate intake (AI) is the average daily intake of a population or subgroup whose nutritional status is considered adequate. It constitutes a nutritional reference when an AR and therefore a PRI cannot be estimated.

#### Where should reports be sent?

Adverse effects can be reported on the [Adverse Health Event Reporting Portal](#) of the Ministry of Social Affairs and Health or directly by completing [the online reporting form](#).

ANSES therefore recommends that people who need to reduce their sodium intake or increase their potassium intake should be informed of the risks of hyperkalaemia due to drug interactions with KCl-based substitutes.

It alerts the public authorities to the hazards incurred by consumers due to a lack of information on labels concerning the use of potassium salts. This is especially true for people with one of the conditions that increase the risk and who are receiving inadequate or no medical attention.

ANSES also draws the attention of the public authorities to the existence of three health claims authorised by Regulation EC 1924/2006 for potassium, one of which states that "potassium helps to maintain normal blood pressure". This claim could encourage hypertensive individuals to turn to foods offering KCl and thus expose themselves to a health risk.

In addition, ANSES notes that dietary potassium intakes are difficult to quantify due to food manufacturing processes (sodium salt substitutes, potassium enrichment of foodstuffs, additives and processing aids). It recommends conducting a study to quantify the potassium intakes of the vulnerable populations mentioned in its latest opinion, in order to refine the assessment of their risk of hyperkalaemia.

Lastly, ANSES stresses the importance of rigorous and regular medical monitoring of people at risk, in order to significantly reduce their risk of hyperkalaemia.

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### **References**

[1] EFSA (2016). Scientific opinion on dietary reference values for potassium. *EFSA Journal* 2016; 14(10):4592, 56 pp. doi 10.2903/j.efsa.2016.4592.

[2] ANSES (2016). ANSES Opinion on the Updating of the PNNS guidelines: revision of the dietary reference values for vitamins and minerals for the general adult population.

[3] EFSA (2006). Tolerable upper intake levels for vitamins and minerals: Scientific Committee on Food (SCF)-Panel on Dietetic Products, Nutrition and Allergies (NDA)

[4] AFSSA (2005). Avis 2004-SA-0295 relatif à l'évaluation des justificatifs d'un sel diététique pour régime hyposodé modéré à teneur réduite en sodium, enrichi en calcium et magnésium [Opinion 2004-SA-0295 on the assessment of supporting evidence for a sodium-reduced diet salt for a moderate low-salt diet, fortified with calcium and magnesium].

[5] AFSSA (2006). Avis 2005-SA-0004 relatif à une demande d'évaluation des justificatifs concernant l'utilisation d'un substitut de sel (composé d'un mélange de chlorures de sodium et de potassium, de sulfate de magnésium et de lysine) en vue d'une incorporation dans des denrées alimentaires destinées à l'alimentation courante [Opinion 2005-SA-0004 on a request to assess supporting evidence for the use of a salt substitute (consisting of a mixture of sodium and potassium chlorides, magnesium sulphate and lysine) for incorporation into foodstuffs intended for human consumption].

**POUR EN SAVOIR PLUS, VOUS POUVEZ CONSULTER:**

[ANSES Opinion on the characterisation of hazards associated with the use of potassium salts as a substitute for sodium chloride in food for populations at risk \(in French\)](#)