We provide solutions for the pharmaceutical industry

Niacet’s products are used in various applications for the pharmaceutical industry. There is a strong focus on quality control and product excellence and all of our products conform to USP and/or European Pharmacopoeia. In addition, calcium acetate and sodium acetate trihydrate are produced under c-GMP conditions and Niacet is a registered API producer of these products.

• Our acetates are used in the production of insulin (mainly sodium acetate but also ammonium acetate, potassium acetate and zinc acetate).
• Our acetates play an important role as regulators of the pH level of dialysis solutions (such as sodium acetate, sodium diacetate, magnesium acetate and potassium acetate).
• Calcium acetate is an Active Pharmaceutical Ingredient (API) in phosphate binders, which are used in the treatment of hyperphosphatemia to reduce the absorption of phosphate into the human body.
• Other applications are the production of penicillin, antibiotics, hormones, enzymes and oral cleansers to treat breath odor.

Count on Niacet

Reliable
We keep our promises and do our utmost to solve everyday problems. We adapt to our customers’ changing needs and stand behind what we promise.

Cooperative
We put time and effort into understanding our partners’ world. For us, an assignment always begins with listening and progresses with the sharing of our expertise and experience. By working together in this way, we are able to achieve our customers’ objectives.

Responsible
We constantly seek out ways to improve the safety of our products and processes. We want to play a positive role in social development and are doing our best to protect the environment. Doing our part in being a good corporate citizen goes hand-in-hand with good business practice.

Proactive
We work to improve our customers’ business. By anticipating future needs, we are able to plan and develop new applications, better ways of working, and products that help our customers realize their own goals.
Main Applications

1. Diabetes Treatment

Diabetes is one of the most common non-infectious diseases; it develops when the pancreas produces little or no insulin (type 1), or when the body cannot effectively use the insulin it produces (type 2). Diabetes is considered one of the leading causes of death in most developed countries, and is growing into an epidemic in many developing and newly industrialized nations.

Niacet acetates, mainly sodium acetate but also ammonium acetate, potassium acetate, and zinc acetate are used in the production of insulin. Additionally, as a constituent in insulin products, sodium acetate acts as an oxidative fuel preventing the body from producing anti-bodies during insulin injection.

2. End Stage Renal Disease (ESRD)

One of the most common complications of diabetes is End Stage Renal Disease (ESRD). People whose kidneys no longer function properly need to undergo hemodialysis or peritoneal dialysis for as long as they live, or until they receive a kidney transplant. Dialysis fluid (dialysate) consists of purified water in which various substances are dissolved. Dialysate regulates the electrolyte and acid-base balance of the dialysis patient and removes waste metabolic products from the body.

Niacet acetates, such as sodium acetate, sodium diacetate, magnesium acetate and potassium acetate, play an important role as a buffer regulating the pH level of the dialysis solution. Sodium acetate also enables the liver to produce sodium bicarbonate, which is needed in order to prevent the blood from acidifying.

Sodium acetate is mostly used in solutions. Sodium diacetate is used in dry concentrates and gives better results in the dialysate due to the higher acidity/lower pH. It also prevents the precipitation of calcium carbonate on artificial kidneys.

Sodium diacetate offers clinics the benefit of dissolving the dry mix locally, instead of having to store a liquid product. Sodium diacetate is also used in other applications where it is advantageous to use a solid source of free acetic acid, e.g. for safer handling and reduced transportation costs.
Main Applications

3. Hyperphosphatemia

Since the kidneys of End Stage Renal Disease (ESRD) patients are no longer able to filter out the phosphates present in every day food, 60% of these patients suffer from hyperphosphatemia (elevated blood phosphate levels). Added to this, dialysis doesn’t fully remove all phosphate from the body.

Niacet’s **calcium acetate** is an Active Pharmaceutical Ingredient in so-called phosphate binders, which are used to reduce the absorption of phosphate into the human body. Calcium acetate combines with the phosphates present in most foods and drinks, and forms insoluble calcium phosphate complexes that are eliminated from the body. This reduces phosphate absorption by the body and lowers the phosphate levels of the blood. Our calcium acetate is FDA listed (DMF #18997).

Other Applications

Niacet acetates are also used in various applications such as in the production of penicillin, antibiotics, hormones, enzymes and oral cleansers.

One of the most commonly known antibiotics is penicillin. Penicillin is a natural substance produced by the micro-organism *Penicillium chrysogenum*, which is related to the green mold commonly found on fruit or jam. Our acetates like ammonium acetate and potassium acetate are used in the penicillin production process.

In many applications **ammonium acetate** can be used as a buffer in the separation of different compounds in liquids. For example in the separation of hormones from human urine.

In the application of oral cleansers **zinc acetate** is not only applied to combat oral malodor. It is also an effective component for slowing down the formation of dental plaque, which is the microbial film on teeth.

**Sodium phenoxy acetate** (SPA) is most commonly used in the fermentation of Penicillin V. Patent literature also refers to the usage of SPA in esters of cortical hormones.
Focus on quality

Niacet’s pharmaceutical grade products are subject to stringent quality control to ensure very high purity, and fulfill all the required specifications of various pharmacopoeias. We are continuously developing our processes and strive to provide our customers with consistent and top quality products.

### Niacet’s product range for the pharmaceutical industry

<table>
<thead>
<tr>
<th>Product</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium acetate</td>
<td>Crystal 97%</td>
</tr>
<tr>
<td></td>
<td>Crystal 98%</td>
</tr>
<tr>
<td></td>
<td>57.5% solution</td>
</tr>
<tr>
<td></td>
<td>50% solution</td>
</tr>
<tr>
<td>Sodium diacetate</td>
<td>Crystal</td>
</tr>
<tr>
<td>Magnesium acetate</td>
<td>Tetrahydrate Crystal</td>
</tr>
<tr>
<td>Zinc acetate</td>
<td>Dihydrate Crystal</td>
</tr>
<tr>
<td>Sodium acetate</td>
<td>Trihydrate Crystal</td>
</tr>
<tr>
<td></td>
<td>Anhydrous Agglomerate</td>
</tr>
<tr>
<td></td>
<td>Anhydrous Powder</td>
</tr>
<tr>
<td>Calcium acetate</td>
<td>Agglomerate Powder</td>
</tr>
<tr>
<td>Potassium acetate</td>
<td>Agglomerate</td>
</tr>
<tr>
<td></td>
<td>70% solution</td>
</tr>
<tr>
<td>Sodium phenoxy acetate (SPA)</td>
<td>Powder</td>
</tr>
</tbody>
</table>

Niacet is a leading producer of organic salts, including propionates and acetates, serving the Food and Pharmaceutical industries. With two longstanding and fully automated manufacturing sites, located in Niagara Falls, NY USA, and Tiel, The Netherlands, Niacet offers world-class quality products to a global market.

www.niacet.com

Niacet makes this information available as an accommodation to its customers and it is intended to be solely a guide in customer’s evaluation of the products. You must test our products, to determine if they are suitable for your intended uses and applications, as well as from the health, safety and environmental standpoint. You must also instruct your employees, agents, contractors, customers or any third party which may be exposed to the products about all applicable precautions. All information and technical assistance is given without warranty or guarantee and is subject to change without notice. You assume full liability and responsibility for compliance with all information and precautions, and with all laws, statutes, ordinances and regulations of any governmental authority applicable to the processing, transportation, delivery, unloading, discharge, storage, handling, sale and use of each product. Nothing herein shall be construed as a recommendation to use any product in conflict with patents covering any material or its use.

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