Environmental Assessment for
Crosslinked Polyacrylic Acid Sodium Salt

1. **Date:** December 29th, 2005

2. **Name of notifier:** BASF Aktiengesellschaft

3. **Address:** 67056 Ludwigshafen, Germany

4. **Description of proposed action:**

a. Requested action:

The USFDA has previously approved the use of a grafted copolymer of cross-linked sodium polyacrylate with polyvinyl alcohol (CAS # 166164-74-5) for use as a fluid absorbent in food contact material in poultry (21C.F.R. 177.121 l), red meat (FCN #42) and cubed tomatoes, fresh-cut fruits, vegetables, whole berries, and fresh or frozen fish fillets (FCN #283). Very recently the USFDA has approved the use of a crosslinked polyacrylic acid sodium salt polymer CAS # 9003-04-7), which due to the crosslinking shows improved properties (FCN 427).
BASF Aktiengesellschaft, Germany and its subsidiary BASF Corporation., USA, have developed a similar crosslinked polyacrylic acid sodium salt polymer (CAS# 9003-04-7) consisting of a primary and a secondary crosslinker. The resulting superabsorber has a high absorbing capacity and low level of low molecular weight species.
They are expected to compete with absorbent pads containing the previously approved products under FCN 427.

b. Need for action:

Food products sold in grocery stores, supermarkets etc. are usually displayed and sold in packages.The package is most often composed of a supporting tray that is overwrapped by a transparent plastic film, or by a transparent plastic bag. These packages allow the consumer to inspect the product and, at the same time, protect the food from external contamination.

Some food types, such as meat, poultry, fresh-cut fruit and vegetables, and fish, are typically washed before packaging. Fluids from washing, as well as fluids discharged from the food products themselves, can accumulate inside the package. The accumulated fluids can support the rapid growth of microorganisms which could cause food to spoil. Moreover, fluid within the food packages often creates an unsightly appearance and may lower the product's appeal to the consumer. Cellulose pads are typically used to absorb excess fluid in food packages, but their absorption capacity is very limited. To improve absorption capacity, and specifically the retention capacity of liquid under an external pressure, an absorbent core made of special polymers, the so called "superabsorber," can be added to the pads.

Due to their structure, these polymers have the ability to absorb excess liquid into the polymer matrix by swelling, even against external pressure. The retention capability of the polymer prevents the squeezing out of liquid and minimizes food contamination by stagnant liquids. Thus, is intended to be used as an absorbent agent to improve the absorption capacity, and specifically the retention capacity, of composite structures for food packaging applications.

c. Location of use:

The crosslinked polyacrylic acid sodium salt will be used to manufacture absorbent pads in plants that manufacture food packaging or components of food packaging.

The crosslinked polyacrylic acid sodium salt will be used as absorbent medium in packaging of all types of solid food containing high amount of liquids, such as fresh meat, poultry, fresh cut vegetables, fresh or frozen fish or other.

d. Location of disposal:

Disposal of absorbent pads containing the crosslinked polyacrylic acid sodium salt is expected to occur nationwide with the whole packaging ultimately being disposed in municipal solid waste or landfills or burned, which is the same as for disposal of any other food contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of superabsorber pads containing crosslinked polyacrylic acid sodium salt.

5. Identification of Substance that is the Subject of the Proposed Action:

Generic information regarding the chemical identity of the crosslinked polyacrylic acid sodium salt is provided below. A complete description of the physical and chemical properties are confidential and are not for public disclosure. This information is provided in Chapter II-A of this Notification.

a. Complete nomenclature

The indirect food additive consists of a crosslinked polyacrylic acid, sodium salt .

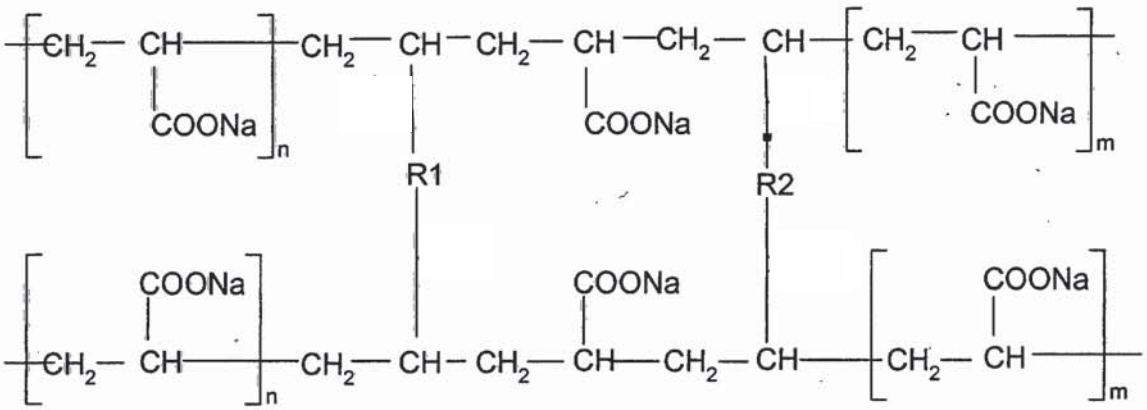
Chemical Abstracts name: 2-Propenoic acid, homopolymer, sodium salt

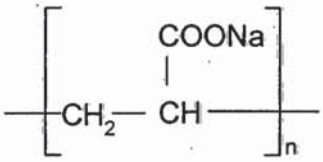
Chemical Abstracts number: 9003-04-7

Common name: Superabosrber

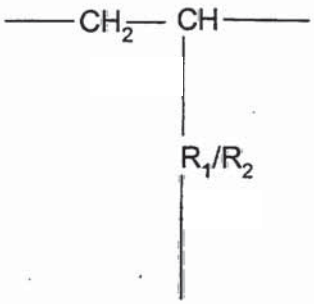
Tradename of BASF: Luquasorb® FP800

b. Structural Formula:





= repeating unit of acrylic acid neutralized



= repeating unit of crosslinker R1 or R2

c. Molecular weight

The superabsorber is a crosslinked polyacrylic acid, sodium salt. At it is crosslinked, the molecular weight is theoretically infinite.

d. Physical description

The crosslinked polyacrylic acid sodium salt is a white, non-volatile, hygroscopic powder with a density about 0,8 g/l., which is insoluble in water. Upon addition of aqueous fluids it starts to swell yielding a gel. Uptake of aqueous fluid is in the range of 200 –300 g per g of crosslinked polyacrylic acid sodium salt. The pH is 5,9-6,1.

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture:

Under 21 CFR § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as the result of the manufacture of crosslinked polyacrylic acid sodium salt. Consequently, information on the manufacturing site and compliance with relevant emission requirements is not provided here.

b. Introductions of substances into the environment as a result of use:

No environmental release is expected upon the use of the subject polymer because it is completely incorporated into absorbent pads and essentially all of it is expected to remain with these materials throughout the use of the pads in the manufacture of food packaging and through use by consumer.

c. Introduction of substances into the environment as a result of disposal:

Landfills:

Disposal by the ultimate consumer of food-contact materials produced by the subject polymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. Only extremely small amounts, if any, of superabsorper polymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact films, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material.

Combustion:

The crosslinked polyacrylic acid sodium salt consist of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers. Due to the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, the combustion products from incinerating of the crosslinked polyacrylic acid sodium salt will not cause a violation of applicable emissions regulations.

7. Fate of emitted Substances in the Environment

No significant effect on the concentrations of any exposures to any substances in the atmosphere are anticipated due to the proposed use of crosslinked polyacrylic acid sodium salt. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact films manufactured with these polymers. The products of complete combustion of the polymer would be carbon dioxide and water, along with small amounts of [redacted]; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications. No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon its disposal in landfills due to the extremely low levels of migration of polymer components. Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject crosslinked polyacrylic acid sodium salts. In particular, the extremely low levels of migration of components of the polymer, even assuming 100% migration, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact films are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of crosslinked polyacrylate sodium salt the manufacture as superabsorber in absorbent pads in food packaging.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the subject polymers consist of extremely small quantities of combustion products and extractables. None of the potential migrating components of the polymers present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of films containing the copolymers. In addition, the use and disposal of the polymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. part 60 that pertain to municipal solid waste combustors and part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of crosslinked polyacrylic acid sodium salts involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymers in superabsorbent pads is expected to be an alternative to those approved by FCN 427. Therefore there is essentially no effect on the use of natural resources and energy. Moreover, like the FCS of FCN 427, the crosslinked polyacrylic acid sodium salt described here is intended for the same use as another additive already in use (i.e., fluff pulp), and therefore will not materially change the potential use of the packaging material to which it is added. Cellulose Fluff (wood pulp) is used in food packaging. The crosslinked polyacrylic acid sodium salt is intended as an adjunct to or replacement for the fluff.

Superabsorbent pads containing crosslinked polyacrylic acid sodium salt are expected to be disposed of according to the same patterns when they are used in place of the currently used pads with or without superabsorbent materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of superabsorbent pads containing the subject polymers. This is primarily due to the minute levels of leaching of potential migrants from the packaging, the insignificant impact on environmental concentrations of combustion products of the polymers, and the close similarity of the subject polymers to the materials they are intended to replace. Thus, the use of the polymers as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject polymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the crosslinked polyacrylic acid sodium salt for use in absorbent pads, the fact that the polymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact films, and the absence of any significant environmental impact which would result from their use, the clearance of the use of crosslinked polyacrylic acid sodium salt as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

Dr. Martin Klatt, Head of Product Safety and Regulatory Affairs; PhD in Chemistry, BASF AG, KS/KS – E100, D-67056 Ludwigshafen,
Dr. Ruth Zschiesche, Manager Product Safety and Regulatory Affairs, PhD in Chemistry, BASF AG, KS/KS – E100, D-67056 Ludwigshafen

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date:

Signature:

Dr. Martin Klatt
KS/KS Head of Product Safety and Regulatory Affairs