

**ENVIRONMENTAL ASSESSMENT
FOR [REDACTED] [REDACTED]**

1. **Date:** April 15, 2004
2. **Name of notifier:** Stockhausen, Inc.
3. **Address:** 2401 Doyle Street
Greensboro, North Carolina 27406
4. **Description of the 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 (21 C.F.R. 177.1211), red meat (FCN #42) and cubed tomatoes, fresh-cut fruits and vegetables, whole berries, and fresh or frozen fish fillets (FCN #183). Advances in manufacturing technologies have allowed Stockhausen to develop a more efficient and complete polymerization process that results in significantly reduced amounts of low molecular weight (LMW) extractives available for migration to food. This "new generation" of [REDACTED] consists of a crosslinked polyacrylic acid sodium salt polymer (CAS #9003-04-7) and is produced in three formulations depending upon the crosslinker used. The formulations are

[REDACTED], or collectively the [REDACTED]. In this Food Contact Notification, Stockhausen submits the [REDACTED] Series for use as an absorbent medium in food contact materials used in the packaging of poultry, red meat, cubed tomatoes, fresh-cut fruits and vegetables, fresh whole berries, and fresh and frozen fish.

The [REDACTED] [REDACTED] is expected to replace the approved [REDACTED] for all intended uses. [REDACTED] Series is manufactured, used, and disposed of in exactly the same manner as the approved [REDACTED].

b. **Need for action:** Food products sold in grocery stores, supermarkets and similar stores 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.

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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. As much as 3 ounces of fluid can accumulate in the package from the time the food is packaged until it is consumed. 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 meat, poultry, fruit, vegetable, and fish 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 "superabsorbents," 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, [redacted] 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 [redacted] [redacted] will be used to manufacture absorbent pads in plants that manufacture food packaging or components of food packaging. The absorbent pads will be employed in the packaging of poultry, red meat, cubed tomatoes, fresh-cut fruit and vegetables, fresh whole berries, and fresh or frozen fish fillets in food processing and packaging facilities.
- d. **Location of disposal:** Disposal of absorbent pads containing the [redacted] [redacted] is expected to occur nationwide with the [redacted] [redacted] ultimately being disposed in municipal solid waste landfills or burned as a result of the disposal of the absorbent pads.

5. **Identification of substances that are the subject of the proposed action:**

Generic information regarding the chemical identity of the [redacted] [redacted] is provided below. A complete description of the physical and chemical properties of [redacted] [redacted] are confidential and are not for public disclosure. This information is provided in Chapter III of the FCN.

a. **Chemical Name**

The indirect food additive consists of:

a crosslinked polyacrylic acid sodium salt polymer

The *Chemical Abstracts* name for the indirect food additive is:

2-Propionic acid, homopolymer, sodium salt.

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b. **Common or Trade Names**

The common name for the indirect food additive is "superabsorbent polymer" or "SAP." The trade name for the indirect food additive is

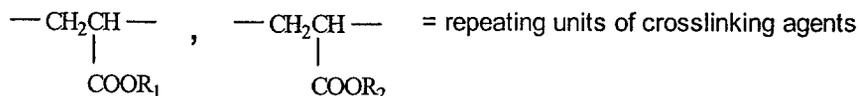
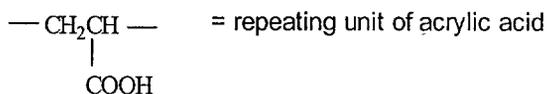
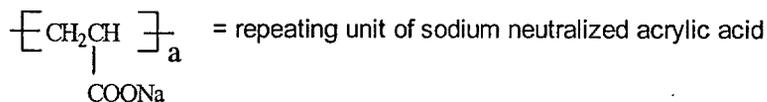
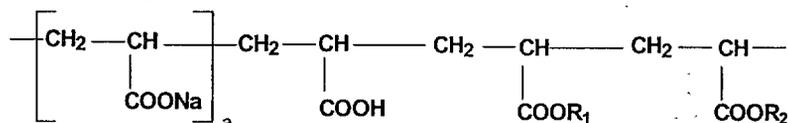
The indirect food additive is manufactured in three formulations known as

c. **Chemical Abstracts Service (CAS) Registry Number**

The *Chemical Abstracts Service* registry number for the indirect food additive is 9003-04-7.

d. **Structural Formula**

The chemical formula of the polymer form is generally as follows:



e. **Molecular Weight**

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Current technology available for molecular weight determinations is insufficient for molecular weight analysis of superabsorbent products. Typical molecular weight determinations require sample preparation procedures that provide a homogeneous (dissolved) solution of the compound. products are highly crosslinked polymers with a three dimensional network that is not soluble in any known solvent. Due to the crosslinking network, the determination of the exact molecular weight is not possible with today's available technology. Each separate particle represents essentially only

one molecule with an extremely large molecular weight. Therefore, the molecular weight can be very large.

f. Physical Description

The [] [] is a white granulate with residual amounts of moisture [2.2 - 2.5 % (w/w)]. Upon addition of aqueous fluid it starts to swell, yielding a gel-like suspension. Uptake of aqueous fluid is in the range of approximately 70 - 200 grams of fluid per gram of polymer, depending upon the fluid. The pH of [] is 5.6 - 6.3.

g. Impurities

[]

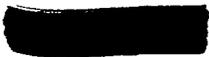
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6. **Introduction of substances into the environment:**

a. **Introduction of substances into the environment as a result of manufacture:** There are no extraordinary circumstances pertaining to the manufacture of [redacted]

b. **Introduction of substances into the environment as a result of use:** Little or no introduction of the SAP into the environment will result from its use 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 consumers.

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

(i) **Landfills:** Only very low levels of the [redacted] [redacted] will leach from the food packaging materials in landfills. Moreover, even if a very small amount of the food contact substance migrates from the food packaging materials in landfills, only extremely low quantities will enter the environment. This finding is based on the Environmental Protection Agency (EPA) regulations governing municipal solid waste landfills. In addition, introducing these substances into the environment will not threaten a violation of the EPA regulations in 40 C.F.R. part 258 that pertain to landfills.

(ii) **Combustion:** The [redacted] is composed predominately of carbon, hydrogen, and oxygen elements commonly found in municipal solid waste. The complete combustion of the [redacted] in a properly functioning incinerator will produce only carbon dioxide and water. Since the market volume of the [redacted] [redacted] is a small fraction of the municipal solid waste generated and disposed in the United States, adding it to waste that is burned will not alter significantly the emissions from the municipal waste combustors. 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 the [redacted] [redacted] will not cause a violation of applicable emissions laws and regulations.

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7. Fate of Emitted Substances in the Environment

The superabsorbent polymer [] can enter the environment in three different forms: as a granulate, as a gel, and after extraction in a watery environment, as soluble components. There is no significant environmental exposure from the granulate. When the dry granulate are exposed to aqueous fluids a gelled material will result due to the uptake of the fluid by the granulate. This might be the relevant physical form after use of [] as an absorbent medium in absorbent pads for food packaging.

In soil and possibly in landfills the gel slowly undergoes irreversible shrinkage. Polyacrylate polymers function in an anionic exchange capacity where the sodium ion is replaced predominantly by calcium and magnesium ions and other multivalent cations. A slow but constant degradation has to be anticipated. A solubilization will take place over time and under the influence of physical and biological impacts.

When excess water is added to the polymer soluble components can migrate out of the polymer matrix. The soluble components are biodegradable.

A. Degradation by physical and chemical processes

Stability data of [] under UV-light and heavy metal exposure has been generated by means of viscosity measurements and gel permeation chromatography, to determine shifts in molecular weight distribution. It was observed that UV-light is able to effect the cross linked gel and its water extracts in a way that the molecules disintegrate, i.e. viscosity of the gels is reduced sharply. Concomitantly, the amount of water extractables increases drastically, and the molecular weight distribution of the water extractables fraction is shifted from high to low molecular weight species. The same pattern of disintegration/degradation takes place with heavy metal cations like iron or copper.

B. Biodegradation in aquatic systems

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The water-soluble fraction of [] was tested for biodegradability according to the carbon dioxide evolution test (OECD Guideline 301 B). In the case of 10 mg test substance/liter, 4 % of the theoretical CO₂ (ThCO₂) was generated by the test substance within 28 days. Twenty mg of the test substance/liter generated 0% ThCO₂ within 28 days (calculated from the organic carbon content of the test substance and the measured CO₂ generation). Based on measured dissolved organic carbon (DOC) the test material was degraded to 18 % and 11 % with 10 mg and 20 mg test substance, respectively. These data show that the water-soluble fraction of [] may be regarded as "poorly biodegradable". *Ready Biodegradability (modified Sturm Test) of Water*

soluble Fraction of [] Batelle Europe (1992). (See Attachment A).

Further tests for ready biodegradability and inherent biodegradability have been performed. The overall evaluation of these degradation studies shows that extracts of [] have a very slow biodegradation rate (<30 %) in aqueous systems within 28 days. The elimination rate in inherent test is up to 90%.

C. Biodegradation in soil systems

a. Biodegradation of soluble fractions in soil

The metabolism of the aqueous soluble fraction of [] in soil was monitored under aerobic conditions. Radiolabelled [] was incubated with intact soil for 78 weeks. The rate of mineralization was monitored by quantifying the amount of ^{14}C - CO_2 produced and the amount of radioactivity extractable as well as non-extractable from the soil was determined. Within the first few days an increase in the CO_2 -evolution and a decrease in the extractable fraction was determined. A slow but steady increase of the mineralization rate was observed leading to a cumulative mineralization rate of 21 % after 1.5 years. The amount of non-extractable radioactivity was high during the whole time period indicating a high adsorption capacity of [] to soil. *The metabolism of the aqueous soluble fraction of [] in soil under aerobic conditions (1994). (See Attachment B).*

b. Biodegradation by fungi in liquid cultures

The degradation of [] by white-rot fungi, ubiquitous organisms which are capable of degrading the most recalcitrant biopolymer, lignin, was investigated. Liquid cultures of *Phanerochaete chrysosporium* were incubated with radiolabelled [] as a gel under nutrient limited conditions and the rate of mineralization was monitored by quantification of the amount of ^{14}C - CO_2 produced. The insoluble polymer was depolymerised within 3 weeks to water-soluble products by an extra cellular enzymatic degradation system. The polymer degradation products were neither toxic to the fungus nor to other organisms as shown in toxicological tests with bacteria, algae, ciliates and daphnia. Over longer time periods up to 70 % of the water-soluble metabolites were incorporated in the fungal mycelial mat. Mineralization by the fungus occurred throughout the time course and although the overall amount of polymer mineralized was low, the results suggest that almost the entire polymer was degraded to fungal metabolites. *Cellobiose dehydrogenase-dependent biodegradation of polyacrylate polymers by Phanerochaete chrysosporium (2000). (See Attachment C)*

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c. Biodegradation in soil by microorganisms

The synergistic effect of soil bacteria and white-rot fungi on the biodegradation of the non-soluble fraction of [redacted] in soil was investigated. The soil microcosms were prepared by mixing soil with radiolabelled [redacted] and with sawdust inoculated with the fungus *Phanerochaete chrysosporium*. Control microcosms with either sterile soil but with fungus or with intact soil but uninoculated sawdust were prepared as well. Microcosms were maintained at 37 °C for 76 days and mineralization rates were determined by the amount of $^{14}\text{CO}_2$ produced. Mineralization was low in microcosms with soil bacteria but without the fungus (0.27 %) or with fungi but without soil bacteria (0.76 %). The highest mineralization was observed in microcosms containing soil bacteria and fungi accounting for 0.95 % in 76 days. Solubilization of the polymer was only evident in microcosms that contained visible fungal growth. The results indicate that fungi initiate conversion and degradation processes, leading to an increase of the polymer fraction which can be mineralized by soil microorganisms. *Biodegradation of superabsorbent polymers in soil (2000)*. (See Attachment D)

d. Biodegradation in compost

[redacted] was studied in a controlled composting biodegradation test. It is an optimized simulation of an intensive aerobic composting process where the biodegradability of a test substance under dry aerobic conditions is determined. The inoculum consisting of stabilized and mature compost was mixed with 10 % (w/w) [redacted] and incubated for 45 days at temperatures following a realistic composting temperature profile. Biodegradation was calculated by the percentage of solid carbon of the test compound which has been converted to carbon dioxide. Under the described test conditions [redacted] was degraded to 14 %. *Aerobic biodegradation under controlled composting conditions (1992)*. (See Attachment E)

D. Distribution in soil systems

The adsorption and desorption capacity of aqueous soluble fraction of radiolabelled [redacted] in four different soil types was investigated. The Freundlich adsorption coefficient was 35.16 for sand, 141.25 for sandy loam, 168.66 for silty clay loam, and 289.07 for clay loam. The magnitude of the Freundlich *adsorption* coefficient indicates that [redacted] has a high capacity to adsorb to soil. *Adsorption/desorption of aqueous soluble fraction of [redacted] in soil (1992)*. (See Attachment F).

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The soil leaching characteristics of aqueous extractable components of [redacted] in four different soil types were determined. Leaching was in the order sand > sandy loam > silty clay loam > clay loam with corresponding distribution coefficient (Kd) 88, 582, 988 and 1199 respectively. The distribution coefficient for each of the soil types indicated that the potential for leaching is very low and is obviously restricted to the very low molecular weight oligomeric species of the water extracts. *Investigation of soil leaching characteristics of the aqueous extractable components of [redacted] (1993). (See Attachment G).*

Conclusions regarding Environmental Fate

Physical and chemical effects can depolymerise cross-linked polyacrylates.

Polyacrylates are not readily biodegradable but are expected to be eliminated in wastewater treatment plants.

Soil microorganisms are in principle capable of degrading [redacted] [redacted]. The synergistically cooperation of white-rot fungi and soil bacteria will lead to the degradation of the polymer with time. Taking into account all investigations with respect to biodegradability research has shown that [redacted] does not constitute a persistent polymer, but is susceptible to natural, fungal degradative processes known to occur in the environment. After solubilization, degradation and mineralization the constituents of the polymer are integrated into the natural carbon cycle.

This is in accordance with published conclusions of Cutie & Gonsior (1997). (See Attachment H).

8. Environmental effects of released substances

The following environmental and ecotoxicity studies have been conducted on [redacted]

a. Air

Air emissions are controlled by air scrubber devices that have a design removal rate of over 98 percent. Therefore, substances are not released to air during the manufacture of [redacted]

b. Aquatic Ecosystems

No adverse effects to water organisms are expected under realistic environmental exposure conditions. Tests performed to evaluate [redacted] effects on water organisms are described below. It is important to note that water extracts can only be tested technically, as there is no specific analytical means to

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determine the water extracted components of the carbon content (referred to as "mg C/l").

For evaluation of the toxicity test results, the generic communication criteria for ecotoxicity from Hamilton et. al (1997) are used. (See Attachment I).

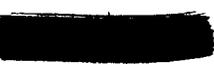
1. Microorganisms and Algae

- a. Chronic effects to the growth behavior and propagation of the microorganism *Pseudomonas putida* were determined with a watery extract of [redacted]. No inhibitory effects of growth behavior of the bacteria were observed; i.e., cytotoxic, cytostatic or biocidal effects are not to be expected. The EC₅₀ value for half maximum propagation is higher than the highest concentration tested, i.e., 698 mg C/l which equals 6 g polymer/l. Therefore, no critical effects to bacteria are expected under relevant disposal conditions. *Chronic Bacterial Toxicity of [redacted] on Pseudomonas putida*, (1991). (See Attachment J).
- b. Growth behavior of the single cellular algae *Scenedesmus subspicatus* was determined with a watery extract of [redacted]. Inhibition of growth was observed at all concentrations tested. The EC₅₀ value which defines half maximum growth is approximately 50 mg C/l which equals 0.5 g polymer/l.

The observed moderate toxicity is thought to be of minor practical importance under realistic environmental exposure conditions. *Chronic Algae Toxicity of [redacted] on Scenedesmus subspicatus* (1992). (See Attachment K).

- c. Cells of the ciliate *Tetrahymena pyriformis* were incubated for 48 hours with a watery extract of [redacted]. At low concentrations of 30 - 60 mg C/l, no negative effects on growth behavior were observed; higher concentrations of 250 - 500 mg C/l led to a reduction in the growth rate but no biocidal effects to the point that the cells were killed. The EC₅₀ value for half maximum cell propagation is greater than the highest concentration tested, i.e., 500 mg C/l which equals 6 g polymer/l. The no observed effect concentration (NOEC) is 60 mg C/l, corresponding to 0.34 g [redacted]. *Chronic Ciliate Toxicity of [redacted] on Tetrahymena pyriformis* (1991). (See Attachment L).
- d. Cytotoxic effects and inhibition of reproduction of the water polyp *Hydra littoralis* were determined by exposure to a watery extract of

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[redacted] for 14 days. At concentrations of 12.5 - 50 mg C/l, no cytotoxic effects were observed, but reproduction rates were reduced; higher concentrations of 100 - 200 mg C/l led to cytotoxic symptoms and a greater reduction in reproduction. The reproduction rate in comparison to the control was reduced in each concentration tested. The EC₅ value, defined as the concentration of the test substance which restricts the reproduction rate to about 5%, is between 10 and 15 mg C/l which equals 0.18 - 0.26 g polymer/l. Correspondingly, the EC₅₀ value, defined as a reduction of reproduction to about 50%, is between 70 and 78 mg C/l, which equals 1.23 - 1.37 g polymer/l. *Hydra Reproduction Test of [redacted] on Hydra litoralis* (1991). (See Attachment M).

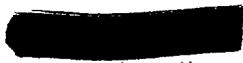
With respect to acute and chronic effects to microorganisms and algae extracts of [redacted] are of low concern.

2. Daphnia

- a. Acute effects on the immobilization of the daphnids *Daphnia magna* were determined with a watery extract of [redacted]. At low concentrations of 12.5 - 150 mg C/l, none of the daphnids were affected. The EC₅₀ value after 48 hours is approximately 175 mg C/l which equals 3 g polymer/l. *Acute Daphnia Toxicity of [redacted] [redacted] on Daphnia magn*, (1991). (See Attachment N).
- b. Adverse chronic effects on the reproduction of the daphnids *Daphnia magna* were determined with watery extracts of [redacted]. At concentrations of 25 mg C/l, a small increase of the reproduction rate could be determined; higher concentrations of 75 - 100 mg C/l led to a reduced reproduction rate and an increase in the number of very small and dead neonates. The EC₅₀ value, defined as that concentration which reduces the reproduction rate by 50% over a time period of 21 days, is approximately 160 mg C/l which equals to 3.2 g polymer/l. The EC₀ was at 50 mg C/l, which equals 1 g polymer. *Daphnia Reproduction Test of [redacted] on Daphnia magna* (1991). (See Attachment O).

With respect to acute and chronic effects to daphnia extracts of [redacted] [redacted] are of low concern.

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3. Fish

To determine acute lethal effects to fish, the cold water species *Leuciscus idus* (golden orf) and the warm water species *Brachydanio rerio* (zebra fish) were exposed to watery extracts of [] for 96 hours.

- a. Golden orfs: At concentrations of 40 - 160 mg C/l, no deaths were observed, while 30% of the fish exposed to 320 mg C/l died. The LC₅₀ value, which defines the median lethal concentration after 96 hours, is greater than 320 mg/l, which equals 5.5 g polymer/l, for golden orfs. *Acute Fish Toxicity of [] on Leuciscus idus (golden orf)* (1991). (See Attachment P).
- b. Zebra fish: At concentrations of 40 - 160 mg C/l, no deaths were observed, while 90% of the fish exposed to 320 mg C/l died. The LC₅₀ value for zebra fish, which defines the median lethal concentration after 96 hours, is approximately 250 mg/l, which equals 4.3 g polymer/l. *Acute Fish Toxicity of [] on Brachydanio rerio (Zebra fish)* (1991). (See Attachment Q).
- c. Golden orfs: *Leuciscus idus* were exposed to water extracts of [] over 14 days. None of the concentrations to which the fish were exposed caused death or toxic symptoms. The LC₅₀ and NOEC value for prolonged exposure is 300 mg C/l which equals 4.98 g polymer/l. *Prolonged Fish Toxicity of [] on Leuciscus idus (golden orf)*, (1992). (See Attachment R).
- d. Zebra fish: *Brachydanio rerio* (zebra fish) were exposed to watery extracts of [] over a time period of 28 days. No deaths were observed at levels up to 150 mg C/l which equals 2.5 g polymer/l. The LC₅₀ value for the prolonged toxicity test with zebra fish is 250 mg C/l, which equals 4 g polymer/l. *The NOEC is 150 mg C/l, which equals 2.5 g polymer Prolonged Fish Toxicity of [] on Brachydanio rerio (Zebra fish)* (1991). (See Attachment S).

With respect to acute and chronic effects to fish extracts of [] [] are of low concern.

c. Terrestrial Ecosystems

Testing of [] in soil was executed with the polymer in a gelled state. The following tests were performed:

1. Soil Organisms

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The percentage mortality of the earthworm *Eisenia foetida* exposed to [] over a time period of 14 days was determined. The test soil was mixed with 200 g of [] per 10 kg of dry soil. Percentage mortality was 31% after 14 days and, therefore, the LC₅₀ value for half maximum mortality is greater than 20 g/kg. Taking realistic exposure conditions into account, [] is regarded to be non-toxic to earthworms. [] *Determination of Acute Toxicity to Earthworms (Limit Test)* (1990). (See Attachment T).

With respect to acute effects to soil organisms [] is of low concern.

2. Plants

- a Adverse effects on germination and development of germs of the cress *Lepidium sativum* in water were determined after 5 days in a watery extract and in the gelled form of []. At low concentrations of 50 - 100 mg C/l, which equals 0.75 - 1.5 g polymer/l, no negative effect on the root length, the dry weight or the bonity of the seedlings was observed; concentrations of 200 - 500 mg C/l of the extract and 10 g/l of the gel led to inhibition of root growth and weight development. The EC₅₀ value, defined as the concentration of the test substance which reduces the growth of the germinating plants by 50%, is 145 mg C/l which equals 2.2 g polymer/l. *Cross Germination Test of [] on Lepidium sativu*, (1991). (See Attachment U).
- b Phytotoxic effects of [] upon the emergence and growth of seedlings of *Triticum aestivum* (winter wheat) and *Phaseolus aureus* (mung bean) in soil were determined by mixing the test substance with the soil. Target concentrations were 0, 5.0, 10.0 and 20.0 g/kg⁻¹. After 14 days, no phytotoxic effects were observed in the winter wheat, including death of seedlings due to rotting and failure of cotyledons to open. Root growth was stunted at the highest test concentrations; the LC₅₀ value for emergence was greater than 20 g/kg⁻¹; the EC₅₀ for growth rate based on weight at termination was 8.80 g/kg⁻¹. **001629**

In mung beans, the LC₅₀ value for emergence is 9.2 g/kg⁻¹; the EC₅₀ for growth rate based on weight at termination was 11.85 g/kg⁻¹. Phytotoxic effects on mung beans include the death of seedlings due to rotting and failure of cotyledons to open. This is thought to be due to physical effects by creating a very moist environment around the roots, leading to rotting of the mung bean seedlings. [] [] *Terrestrial plants, growth test* (1990). (See Attachment V).

- c. Phytotoxic effects of [] on the emergence and growth of seedlings of the following plants were determined with application rates of 0, 0.2, 2.0 and 20.0 g/kg soil:

Phaseolus aureus (mung bean), *Lactuca sativa* (lettuce), *Lepidium sativum* (cress), *Lycopersicon esculentum* (tomato) and *Cucumis sativus* (cucumber).

Germination was not effected in lettuce, tomato and cucumber up to the highest concentration and for mung bean and cress in the LC₅₀ values for emergence is 9.2 and 4.1 g/kg, respectively. Growth rate of the seedlings was reduced in all species and the EC₅₀ values for half maximum growth rate varies between 10.1 and 0.22 g/kg. Test material was observed to adhere to the roots as jelly-like particles at 2.0 and 20.0 g/kg concentration. The observed phytotoxic effects on the seedlings may be due to different sensitivity of the species to the very moist environment around the roots and are thought to be of minor practical importance when realistic environmental exposure conditions are taken into consideration. [] *Terrestrial plants, growth test* (1991). (See Attachment W).

With respect to acute and chronic effects to plants [] is of low concern.

3. Birds

Acute toxicity of [] to the bird *Colinus virginianus* (bobwhite quail) was determined by administering a single oral application of [] and observing the birds for 14 days. As no deaths or adverse clinical effects were observed at a dose level of 2,000 mg/kg body weight the LD₅₀ value for half maximum lethality is greater than 2,000 mg/kg. [] - *An Investigation of the Acute Toxicity of a Superabsorbent Polymer to Bobwhite Quail* (1990). (See Attachment X).

9. Use of resources and energy

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The [] [] is expected to replace previously approved [] for all uses. Therefore, there is essentially no effect on the use of natural resources and energy. Moreover, like [], the [] [] 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 [] superabsorbent polymer is intended as an adjunct to or replacement for the fluff.

10. Mitigation measures

Mitigation measures are not required because of [redacted] negligible impact on the environment. Therefore, a discussion of mitigation measures is not required.

11. Alternatives to the proposed action

Based on available data, [redacted] has no significant environmental impacts. Therefore, a discussion of alternatives to the proposed action is not required.

12. List of preparers

Dr. Bernd Diener, Manager of the Laboratory for Toxicology and Ecology, Stockhausen GmbH & Co. KG, Degussa Services Krefeld, Stockhausen GmbH & Co. KG, Bäkerpfad 25, 47805 Krefeld, Germany. Biology and social science; University of Kassel, Germany, Biology; University of Mainz, Germany, Civilian service in an environmental protection center in the Wadden Sea; Hallig Langene, Germany, Diploma thesis in biology / toxicology; Institute for Toxicology, University of Mainz, Dissertation in natural science / toxicology; Institute for Toxicology, University of Mainz, Fachtoxikologe DGPT / Eurotox Registered Toxicologist.

Sigrid Hey, Study Director For Toxicology And Plant Physiology In the Laboratory for Toxicology and Ecology, Stockhausen GmbH & Co. KG, Krefeld, Germany, Biology; University of Düsseldorf, Germany, Toxicology training to become a Eurotox Registered Toxicologist.

Seungoo Kang, Research Scientist, Stockhausen, Inc., Greensboro, North Carolina, Ph.D. in Chemistry. Korea Advanced Institute of Science and Technology (KAIST), Seoul, Korea.

Jane Mills Davis, Consultant, Stockhausen, Inc., Greensboro, North Carolina; Bachelor of Science in Chemistry.

The FDA was consulted regarding the proper format of the EA.

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13. Certification

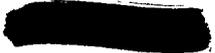
The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Stockhausen, Inc.

DATE: April 15, 2004

SIGNATURE: 

John McLeod
Title: Sales Manager
Technical Superabsorbant

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14. References

Cameron M.D., Post Z.D., Stahl S.D., Haselbach J. & Aust S.D. (2000): *Cellobiose dehydrogenase-dependent biodegradation of polyacrylate polymers by Phanerochaete chrysosporium*. *Environ. Sci. & Pollut. Res.* 7 (3) pp 130-134. (See Attachment C).

Cutie, S.S. and Gonsior, S.J., Polyacrylate Superabsorbents (1997), in *Ecological Assessment of Polymers, Strategies for Product Stewardship and Regulatory Programs*. Ed. Hamilton J.D & Sutcliffe R. Van Nostrand Reinhold, New York. (See Attachment H).

Hamilton, J.D, Vasconcellos S.R & Keener E.L (1997). Introduction, in *Ecological Assessment of Polymers, Strategies for Product Stewardship and Regulatory Programs*. Ed. Hamilton J.D & Sutcliffe R. Van Nostrand Reinhold, New York. (See Attachment I).

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15. Attachments

A	<i>Ready Biodegradability (modified Sturm Test) of Water soluble Fraction of [redacted]</i> Batelle Europe (1992) Report BE-E-27-91-04-STT-01.
B	<i>The metabolism of the aqueous soluble fraction of [redacted] in soil under aerobic conditions.</i> Inveresk Research International (1994) Report 8826.
C	Cameron M.D., Post Z.D., Stahl S.D., Haselbach J. & Aust S.D. (2000): <i>Cellobiose dehydrogenase-dependent biodegradation of polyacrylate polymers by Phanerochaete chrysosporium.</i> <i>Environ. Sci. & Pollut. Res.</i> 7 (3) pp 130-134.
D	Stahl S.D., Cameron M.D., Haselbach J. & Aust S.D. (2000): <i>Biodegradation of superabsorbent polymers in soil.</i> <i>Environ. Sci. & Pollut. Res.</i> 7 (2) pp 83-88.
E	<i>Aerobic biodegradation under controlled composting conditions.</i> Organic Waste Systems N.V. (1992) Report SH-1-3141.
F	<i>Adsorption/desorption of aqueous soluble fraction of [redacted] in soil.</i> Inveresk Research International (1992) Report 8826.
G	<i>Investigation of soil leaching characteristics of the aqueous extractable components of [redacted].</i> Inveresk Research International (1993) Report 9403.
H	Cutie, S.S. and Gonsior, S.J., <i>Polyacrylate Superabsorbents</i> (1997), in <i>Ecological Assessment of Polymers, Strategies for Product Stewardship and Regulatory Programs.</i> Ed. Hamilton J.D & Sutcliffe R. Van Nostrand Reinhold, New York.
I	Hamilton, J.D, Vasconcellos S.R & Keener E.L (1997). Introduction, in <i>Ecological Assessment of Polymers, Strategies for Product Stewardship and Regulatory Programs.</i> Ed. Hamilton J.D & Sutcliffe R. Van Nostrand Reinhold, New York.
J	<i>Chronic Bacterial Toxicity of [redacted] on Pseudomonas putida,</i> (1991).
K	<i>Chronic Algae Toxicity of [redacted] on Scenedesmus subspicatus</i> (1992).
L	<i>Chronic Ciliate Toxicity of [redacted] on Tetrahymena pyriformis,</i> Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 453/90
M	<i>Hydra Reproduction Test of [redacted] on Hydra litoralis,</i> Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 438/90
N	<i>Acute Daphnia Toxicity of [redacted] on Daphnia magna,</i> Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 312a/90
O	<i>Daphnia Reproduction Test of [redacted] on Daphnia magna,</i> Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 170/91

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P	<i>Acute Fish Toxicity of [redacted] on Leuciscus idus (golden orf), Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 712/90</i>
Q	<i>Acute Fish Toxicity of [redacted] on Brachydanio rerio (Zebra fish), Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 713/90.</i>
R	<i>Prolonged Fish Toxicity of [redacted] on Leuciscus idus (golden orf), Laboratory for Toxicology and Ecology, Stockhausen (1992) Report 267/91.</i>
S	<i>Prolonged Fish Toxicity of [redacted] on Brachydanio rerio (Zebra fish), Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 10/91..</i>
T	<i>[redacted] Determination of Acute Toxicity to Earthworms (Limit Test), Inveresk Research International (1990) Report 6644</i>
U	<i>Cross Germination Test of [redacted] on Lapidium sativum, Laboratory for Toxicology and Ecology, Stockhausen (1991) Report 22/91.</i>
V	<i>[redacted] Terrestrial plants, growth test, Inveresk Research International (1990) Report 6691</i>
W	<i>[redacted] Terrestrial plants, growth test, Inveresk Research International (1991) Report 6903</i>
X	<i>[redacted] - An Investigation of the Acute Toxicity of a Superabsorbent Polymer to Bobwhite Quail, Inveresk Research International (1990) Report 7449.</i>

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