

Petitioner:

STOCKHAUSEN, INC.

2401 Doyle Street
Greensboro, North Carolina 27406

ENVIRONMENTAL ASSESSMENT

FOR

FAVOR-PAC[®]

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**A superabsorbent polymer (SAP) for use as
an absorptive medium in absorbent pads
employed in the packaging of poultry (e.g., chicken)
which is either refrigerated or frozen until used**

Amendment of Food Additive Petition 2B4323

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1. **DATE:** February 3, 1997
2. **NAME OF PETITIONER:** Stockhausen, Inc.
3. **ADDRESS:** 2401 Doyle Street
Greensboro, North Carolina 27406

4. ***DESCRIPTION OF PROPOSED ACTION***

A. Requested Approval

Stockhausen requests that the food additive regulations be amended to permit the use of a grafted copolymer of cross-linked polyacrylic acid sodium salt polymer with polyvinyl alcohol (FAVOR® PAC) as an absorptive medium in absorbent pads employed in the packaging of poultry (e.g. chicken) which is either refrigerated or frozen until used.

B. Need for the 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.

Some food types, such as meat, poultry, 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, 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

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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, FAVOR® PAC 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 Production

The production site for FAVOR® PAC is located in Greensboro, North Carolina, where Stockhausen, Inc. is based. The Stockhausen Greensboro, North Carolina plant is located within the city limits approximately one mile south of the downtown business district. Stockhausen is part of an industrial park located on the east side of Elm and Eugene Streets. Other uses in the industrial park include warehouses, textile facilities, and meat packagers. Residential and commercial shopping areas are located in the vicinity of the industrial park.

D. Locations Where Product Will Be Assembled, Used and Disposed

(1) Assembly

Following production, FAVOR® PAC will be assembled into food packaging pads by pad manufacturers in the United States, Australia, Europe and other countries.

(2) Use

Primary users of FAVOR® PAC include chicken processing firms in the United States. Approximately 80 percent of the chickens processed by the companies below are placed in packages that contain cellulose or fluff PULP absorption pads. The number of pads currently used per year by each chicken processor are estimated as follows:

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COMPANY	PADS/WEEK	PADS/YEAR
Tyson	38,000,000	1,989,000,000
ConAgra	16,800,000	874,000,000
Gold Kist	14,600,000	757,000,000
Perdue	11,200,000	582,000,000
Pilgrim's Pride	9,600,000	499,000,000
Continental Grain	6,200,000	324,000,000
Hudson Food	6,100,000	316,000,000
Foster Farm	5,100,000	266,000,000
Seaboard Farm	4,600,000	241,000,000

(3) Disposal

After use, the absorption pads containing FAVOR® PAC will be disposed of in household waste, following the common routes of disposal, such as incineration, composting, and landfill, similar to those utilized for disposable diapers and other personal care articles. Disposal requirements would be no different than that presently employed for absorbent pads in food packaging, although total volume of disposal could be reduced due to the enhanced performance of the new superabsorbent product.

E. Brief Description of Environments That May be Affected During Production, Use, and Disposal

A brief description of the environments that may be affected during production, use, and disposal is provided below. A more detailed description is provided in Section 6, below.

1. Production

Air: During production exhaust gases are emitted to the atmosphere after they have been cleaned in an air scrubber. The air scrubbers remove over 98 percent of the acrylic acid, the main component of FAVOR® PAC. Stockhausen holds and complies with all required federal, state, and local air permits.

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Water: Wastewater from the air scrubbers contains acrylic acid and particulates which form suspended and dissolved organic matter. The acrylic acid is neutralized with sodium hydroxide and then

discharged to local wastewater treatment plants where it is treated by the municipal treatment plant. Stockhausen is in compliance with all required federal, state, and local wastewater permits.

Soil/Groundwater: Direct emissions to soil or groundwater do not occur because production wastes are incinerated and/or landfilled in State- and EPA-approved industrial landfills designed to prevent leaching into surface and/or groundwater.

2. Use

Users of FAVOR® PAC will dispose of it by common routes of disposal, such as incineration, composting, and landfills. Therefore, environments potentially affected by use are the same as those potentially affected by disposal. However, because FAVOR® PAC is encased within a pad structure, the matrix of the absorbent environmental exposure during use is essentially absent.

3. Disposal

Landfill is the primary route of disposal in the United States. Environments potentially affected by disposal would be watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from landfills and incineration sites.

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5. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE THE SUBJECT OF THE PROPOSED ACTION

Generic information regarding the chemical identity of FAVOR® PAC is provided below. A complete description of the physical and chemical properties of FAVOR® PAC are confidential and are not for public disclosure. This information was provided in Chapter III of Stockhausen's amended petition and is attached to this environmental assessment in *Attachment A*.

A. Chemical Name

The indirect food additive consists of:

a grafted copolymer of crosslinked polyacrylic acid sodium salt polymer with polyvinyl alcohol.

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

2-Propenoic acid, polymers with N,N-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft.

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 FAVOR® PAC.

The indirect food additive is manufactured in a formulation known as FAVOR® PAC 100.

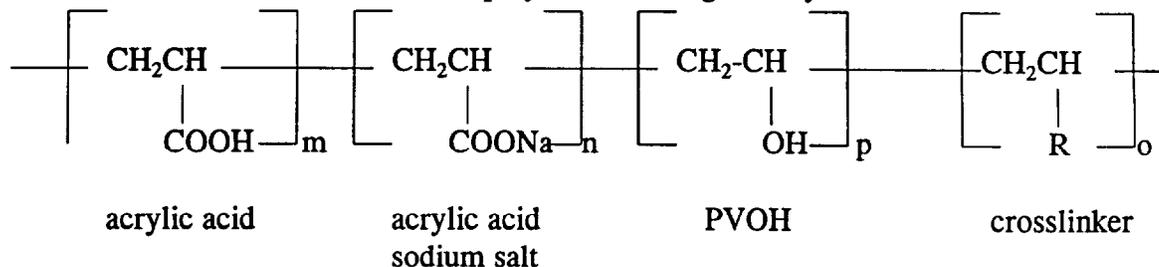
C. Chemical Abstracts Service (CAS) Registry Number

The *Chemical Abstracts Service* registry number for the indirect food additive is 166164-74-5.

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D. Structural Formula

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



R: crosslinking agent

E. Molecular Weight

Current technology available for molecular weight determinations is insufficient for molecular weight analysis of FAVOR® PAC superabsorbent products. Typical molecular weight determinations require sample preparation procedures that provide a homogeneous (dissolved) solution of the compound. FAVOR® PAC 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 FAVOR® PAC particle represents essentially only one molecule with an extremely large molecular weight. Therefore, FAVOR® PAC polymer products can be safely said to exceed ten (10) million Daltons.

F. Physical Description

FAVOR® PAC is a white granulate with residual amounts of moisture [2.2 - 4.9 % (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 FAVOR® PAC is 5.8 - 6.0.

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G. Impurities

Impurities that may occur in the final product include (1) the residual monomer and crosslinker, (2) the by-products formed by side reactions of catalysts, (3) polymerized water soluble components, and (4) heavy metals.

Residual monomer and crosslinker: During the manufacturing process residual amounts of free acrylic acid are routinely measured in accordance with standardized methods. Residual crosslinker is measured periodically. The mean values (x) of the free acrylic acid and crosslinker are presented in *Attachment A*.

By-products formed by side reactions of catalysts: Due to extreme temperatures used in the manufacture of FAVOR® PAC, impurities resulting from by-products formed in side reactions of the catalysts are unlikely. Where methods exist to measure the possible by-products that may be formed from the side reactions, no values above the limits of detection have been measured.

Polymerized Water Soluble Components: Polymerized acrylic acid up to molecular weights of 10^6 are soluble in watery solvents and can therefore be extracted from the crosslinked insoluble polymer. The amount of soluble components ranges from 3 to 5 percent by weight, depending on the modification and specific test method used.

Heavy Metals: Stockhausen has evaluated FAVOR® PAC for the presence of heavy metals. Only one element, Iron, has been measured above the limits of detection. Its occurrence is due to impurities contained in the raw materials, as well as the manufacturing process.

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6. ***INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT***

A. Overview

A description of the environments that may be affected during production, use, and disposal is provided in Section 4 above. Figure EA-1 outlines the routes by which substances may enter the environment during production, transport and storage, use, and disposal of FAVOR® PAC.

B. Production Sites

FAVOR® PAC will be produced at the Greensboro, North Carolina, plant site of Stockhausen, Inc. Based on Stockhausen's experience with the production of superabsorbent polymers for the hygiene industry, the potential for substances to be introduced into the environment is minimal. However, potential routes by which substances may enter the environment are described below.

1. Air Emissions during production

At the Greensboro, North Carolina facility air emissions are primarily water, in the form of steam, from the polymer drying process. Emissions of acrylic acid, a major component in the manufacture of FAVOR® PAC, are controlled by air scrubber devices with a design removal efficiency of over 98 percent. Emissions of acrylic acid to the environment are 0.058 lb./1,000 lb. of SAP, which are below Stockhausen's permit limits. Moreover, acrylic acid has a short atmospheric half life and is easily destroyed in the atmosphere due to reactions with photochemically produced hydroxyl radicals and ozone.

2. Incineration

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Solid waste produced during production is incinerated in the local municipal incinerator along with typical household waste. There are no combustible products contained in FAVOR® PAC. Therefore, disposal of

FAVOR® PAC via incineration is not expected to affect incineration operations or the composition of exhaust gases.

3. *Emissions to Waste Water and Wastewater Treatment*

Waste water from the emissions control devices (air scrubbers) contains suspended and dissolved organic matter. The waste water is piped directly to the local municipal waste water treatment plants in Greensboro, North Carolina.

FAVOR® PAC will not interfere with wastewater treatment plant operations. Chemically, FAVOR® PAC is similar to well-known compounds like the polycarboxylates (used as co-builders in detergents for phosphate and phosphate substitution) and anionic flocculants which are widely used in solid/liquid separation processes like biosludge treatment. *See Attachment B.* Further, FAVOR® PAC will not affect microbial growth in wastewater treatment processes because it is not toxic to either bacteria or ciliates.

4. *Emissions to Surface Water*

FAVOR® PAC binds to biosludge or associates with the biosludge fraction in the wastewater treatment process. The concentration of FAVOR® PAC in biosludge is estimated to be approximately 1.8 kg of polymer per ton of dry biosludge. If FAVOR® PAC were assumed not to absorb to biosludge, a predicted environmental concentration of approximately 1 µg of suspended and dissolved organic matter (polymer) per liter of river water can be derived. *See Attachment C.*

5. *Emissions to Soil*

Biosludge generated from wastewater treatment at the municipal treatment plant may be used on soil. Assuming that 5 tons of biosludge were spread on 10,000m² of soil over a three year period, the predicted concentration of FAVOR® PAC in the soil would be 18 mg of polymer per kg soil. However, all biosludge generated at the Greensboro municipal wastewater

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treatment plant is incinerated. Therefore, no emissions to soil in connection with the production of FAVOR® PAC in Greensboro are expected.

6. *Emissions of By-Products Theoretically Formed in the Production Process*

As discussed in Section 5(G) above, theoretically by-products may be formed in the side reactions of the catalysts used in the polymerization process. Because of the extreme temperatures under which polymerization occurs such by-products have not been measured. Moreover, should these by-products form, emissions would be controlled by Stockhausen's emissions control devices. Therefore, these by-products will not be introduced into the environment.

C. *Transport and Storage*

Environmental exposure during transport and storage of FAVOR® PAC is not expected because the FAVOR® PAC granules are packaged and shipped in moisture-proof containers. Further, FAVOR® PAC does not dissolve when it comes into contact with water.

D. *Use*

It is highly unlikely that users of FAVOR® PAC will come into direct contact with the polymer. Moreover, toxicological testing conducted on the polymer shows FAVOR® PAC to be nontoxic. See Indirect Food Additive Petition 2B4323, Chapter VI.

E. *Municipal Solid Waste*

1. *Landfilling*

Migration of the soluble components under worst-case conditions with respect to a realistic landfill situation are estimated to be very low. Studies reveal only 3 - 5 percent by weight of the soluble components of FAVOR® PAC is extracted. Studies also show that 20 percent of the soluble components of

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FAVOR® PAC are degraded to carbon dioxide within 39 weeks. *See Attachment V.* Recent work also suggests that superabsorbents may be able to be biodegraded in the presence of white-rot fungi. *See Attachment W.*

Further calculations are difficult to make because data about the typical amount of leachates out of a landfill and their subsequent dispersion into ground and/or surface waters are not available.

2. *Incineration*

There are no combustible products contained in FAVOR® PAC. Therefore, disposal of FAVOR® PAC via incineration is not expected to affect incineration operations or the composition of exhaust gases.

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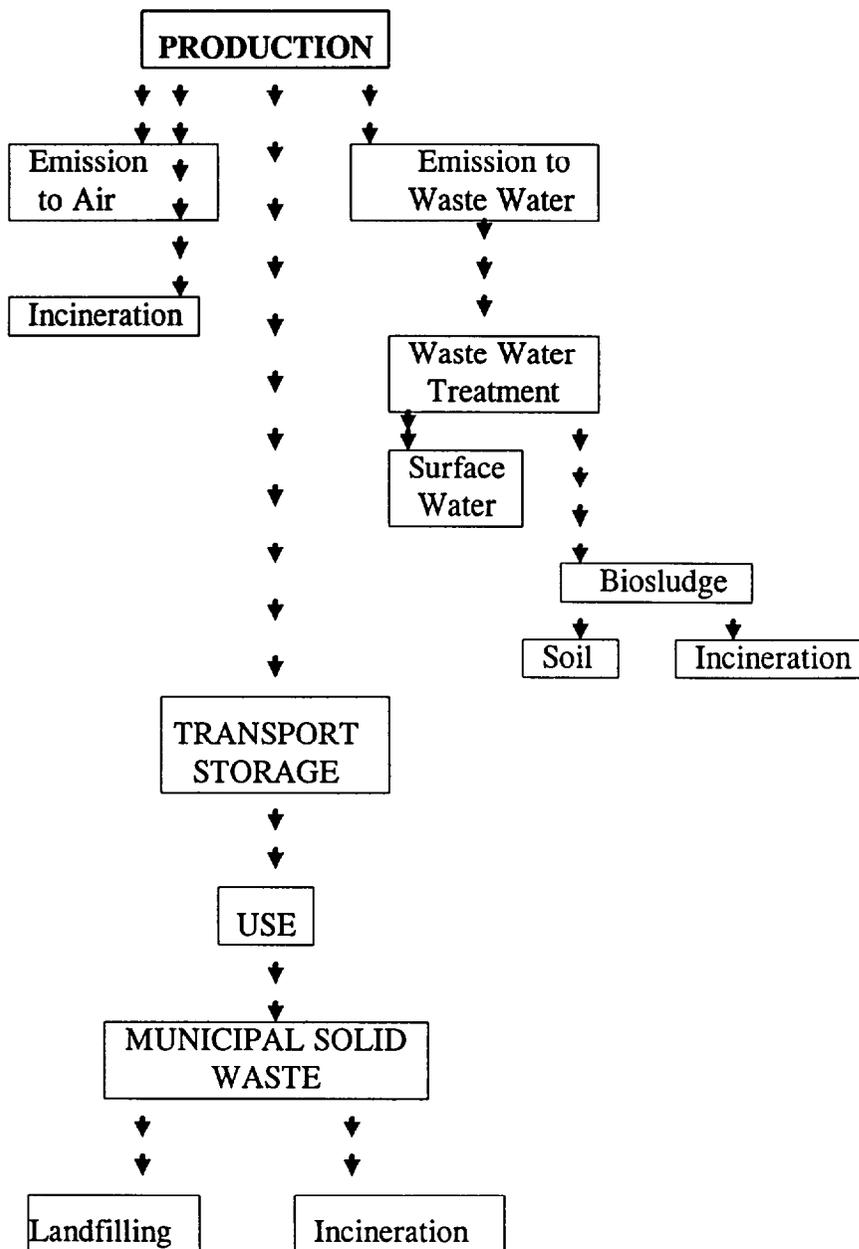


Figure EA-1

Routes By Which Substances May Enter the Environment During Production, Transport and Storage, use, and disposal of FAVOR® PAC

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F. Applicable Requirements and Permits

1. Air Regulations

The Greensboro, North Carolina facility is regulated pursuant to North Carolina Air Pollution Control Laws, N.C. Gen. Stat. §§ 143-215.105 *et seq.*, and North Carolina Air Pollution Control Regulations, N.C. Admin. Code, Subchapter 2D - Air Pollution Control Requirements and Subchapter 2H - Permits. The industry emission standard for acrylic acid is 0.05 mg/m³.

2. Occupational Regulations

The Occupational Safety and Health Act sets the following exposure limits (*See* 29 C.F.R. § 1910.1):

Acrylic acid	10 ppm
Total Particulates:	15 mg/m ³
Respirable Particulates	5 mg/m ³

3. Surface Water Regulations

Discharge to Greensboro's municipal waste water treatment plant is regulated by City of Greensboro ordinance in conjunction with the City's Department of Utilities Wastewater Division-Industrial Waste Section.

Stormwater runoff is regulated by the State of North Carolina pursuant to N.C. Gen. Stat. § 143-215.1.

4. Permits

Stockhausen's Greensboro, North Carolina facility holds the following permits:

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Air Emissions:

Permit No. 4535R12, expiration date August 31, 2000.

Substance	Permit Limits
Acrylic acid	2.006 lbs/hr
Ethylene carbonate	1.124 lbs/hr
Particulates	3.194 lbs/hr
Volatile organics	18.974 lbs/hr

Wastewater:

Permit No. P021, expiration date, August 31, 1998

Substance	Permit Limits
Biological Oxygen Demand	200 mg/L
Temperature	less than 35°C
Total Suspended Solids	200 mg/L
pH	5.0 to 12.00
Flow	200,000 g/day
Cadmium	0 .0015 lbs/day
Chromium	0.025 lbs/day
Copper	0.031 lbs/day
Nickel	0.011 lbs/day
Silver	0.0025 lbs/day
Lead	0.8056 lbs/day
Zinc	3.0474 lbs/day

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Stormwater: Permit No. 000010, expiration date August 31, 1999

Substance	Permit Limits
pH	6.0 to 9.0
Oil and Grease	< 30 mg/L
Lead, total recoverable	< 0.033 mg/L
Total Suspended Solids	< 100 mg/L
Detergents (MBAS)	< 0.50 mg/L

5. Statement of Compliance

Stockhausen, Inc., certifies that its Greensboro, North Carolina facility exercises air, wastewater and occupational safety control in accordance with all applicable federal, state and local requirements.

G. Effect Approval of Proposed Action Will Have Upon Compliance With Emissions Requirements at Both Production Sites

The approval of the food additive FAVOR® PAC will not burden compliance with current emission requirements at the Greensboro, North Carolina plant. FAVOR® PAC is already produced for export to Australia and the polymer contained in FAVOR® PAC is also produced for non-food contact products (e.g. diapers, incontinence pads, and feminine hygiene products).

H. Estimated Production Quantities of FAVOR® PAC

The amount of FAVOR® PAC employed by manufacturers in an absorbent pad will be driven by two factors: (1) the minimum performance of the pad (i.e. fluid absorption and retention; and (2) the market price of FAVOR® PAC versus fluff pulp. Therefore, it is difficult to devise precise estimates of production quantities of FAVOR® PAC estimates of absorbent pads containing FAVOR® PAC that will be produced. Stockhausen will only

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produce quantities of FAVOR® PAC for which there is market demand. However, assuming 0.8 grams of FAVOR® PAC per absorbent pad, Stockhausen estimates the following production quantities of both FAVOR® PAC and absorbent pads over a 5-year period:

FAVOR® PAC:

first year	500 metric tons
second year	1,500 metric tons
third year	3,000 metric tons
fourth year	5,000 metric tons
fifth year	10,000 metric tons

Absorbent Pads:

first year	625,000,000 pads
second year	1,800,000,000 pads
third year	3,750,000,000 pads
fourth year	6,250,000,000 pads
fifth year	12,000,000,000 pads

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7. ***FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT***

The super absorbent polymer FAVOR® PAC can enter the environment in three different forms: as a granulate, as a gel, and after extraction in a watery environment, as soluble components.

A. *The Granulate*

There is no significant environmental exposure from the granulate.

B. *The Gel*

When the dry granulate are exposed to aqueous fluids a gelled material will result due to uptake of the fluid by the granulate.

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. Exchange of ions leads to a sharp reduction of the water retention capacity and hence the potential of any water soluble components to leach out of the polymer matrix.

The gel itself appears to be stable against microbial attack. UV-light and some heavy metals, such as iron, appear to be able to destroy the gel, disintegrating it into soluble components. The practical relevance of these mechanisms for soil is still not clear.

C. *Soluble Components*

When excess water is added to the polymer soluble components can migrate out of the polymer matrix. Preliminary data indicate that biological degradation of the water soluble components is possible. *See Attachment D.*

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Suspended polymer and soluble components of SAP were tested with respect to their behavior in waste water plants (*See Attachment E*). It was found that 97% of the polymer was retained in the solids and effluent releases were only minimal. This indicates that the elimination rate due to precipitation and adsorption is very high.

Furthermore, behavior of soluble components of SAP in sand with respect to migration and adsorption was examined (*See Attachment F*). Some migration dependent upon molecular weight was indeed observed, but most of the polymer was retained in the sand.

Additional data about desorption, absorption and migration in soil will be available in the future, due to an ongoing study program involving radiolabelled superabsorbent polymer. This study will give a very clear picture of the actual behavior of all aspects of SAP in the ecosystem.

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8. ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

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 FAVOR® PAC.

B. Water Ecosystems

No adverse effects to water organisms are expected under realistic environmental exposure conditions. Tests performed to evaluate FAVOR® PAC's 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 determine the water extracted components of the carbon content (referred to as "mg C/l").

1. *Effects on Growth of Water Organisms*

- a. Chronic effects to the growth behavior and propagation of the microorganism *Pseudomonas putida* were determined with a watery extract of FAVOR® PAC. 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 Favor PAC 990 on Pseudomonas putida*, Laboratory for Toxicology and Ecology, Stockhausen (1991). *See Attachment G.*
- b. Growth behavior of the single cellular algae *Scenedesmus subspicatus* was determined with a watery extract of FAVOR® PAC. Inhibition of growth was observed at all concentrations

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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 Favor PAC 990 on Scenedesmus subspicatus*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment H.

- c. Cells of the ciliate *Tetrahymena pyriformis* were incubated for 48 hours with a watery extract of FAVOR® PAC. 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. *Chronic Ciliate Toxicity of Favor PAC 990 on Tetrahymena pyriformis*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment I.

2. Cytotoxic Effects

- a. Cytotoxic effects and inhibition of reproduction of the water polyp *Hydra littoralis* were determined by exposure to a watery extract of FAVOR® PAC 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

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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 Favor PAC 990 on Hydra litoralis*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment J.

The observed inhibition of reproduction is thought to be of minor practical importance when realistic environmental exposure conditions are taken into consideration. Laboratory for Toxicology and Ecology, Stockhausen (1991).

- b. Acute effects on the immobilization of the daphnids *Daphnia magna* were determined with a watery extract of FAVOR® PAC. 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 Favor PAC 990 on Daphnia magna*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment K.
- c. Adverse chronic effects on the reproduction of the daphnids *Daphnia magna* were determined with watery extracts of FAVOR® PAC. 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. *Daphnia Reproduction Test of Favor PAC 990 on Daphnia magna*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment L. Therefore, FAVOR®

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PAC will have no critical deleterious effects on the swimming ability and no negative influence on the reproduction rate of daphnids under relevant environmental exposure conditions.

3. *Acute Effects to 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 FAVOR® PAC 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 Favor PAC 990 on Leuciscus idus (golden orf)*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment M.
- 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 Favor PAC 990 on Brachydanio rerio (Zebra fish)*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment N.

4. *Chronic Effects to Fish*

- a. Golden orfs: *Leuciscus idus* were exposed to water extracts of FAVOR® PAC over 14 days. None of the concentrations to which the fish were exposed caused death or toxic symptoms. The LC₅₀ value for chronic exposure is 300 mg C/l which equals 4.98 g polymer/l. *Chronic Fish Toxicity of Favor PAC 990 on*

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Leuciscus idus (golden orf), Laboratory for Toxicology and Ecology, Stockhausen (1992). See Attachment X.

- b. Zebra fish: *Brachydanio rerio* (zebra fish) were exposed to watery extracts of FAVOR® PAC 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. *Chronic Fish Toxicity of Favor PAC 990 on Brachydanio rerio (Zebra fish)*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment O.

Therefore, FAVOR® PAC has to be regarded as essentially non-toxic to fish.

5. *Effects on Germination and Development*

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 FAVOR® PAC. 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. *Cress Germination Test of Favor PAC 990 on Lepidium sativum*, Laboratory for Toxicology and Ecology, Stockhausen (1991). See Attachment P.

The observed slight phytotoxic effect is thought to be due to suffocation of the plants and to be of no practical importance, when realistic environmental exposure conditions are taken into consideration.

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As can be seen from the data (a summarized compilation is enclosed in *Attachment Q*, the extracts of the FAVOR® PAC are essentially non-toxic if the calculated PEC value for surface water is taken into consideration. The safety factor is at least in the order of 2×10^5 to 5×10^6 if the appropriate no observed effect levels/concentrations (NOEL/C) of *Attachment Q* are used for calculation.

C. Terrestrial Ecosystems

Testing of the FAVOR® PAC in soil was executed with the polymer in a gelled state. The following tests were performed:

1. Soil

The percentage mortality of the earthworm *Eisenia foetida* exposed to FAVOR® PAC over a time period of 14 days was determined. The test soil was mixed with 200 g of FAVOR® PAC 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, FAVOR® PAC is regarded to be non-toxic to earthworms. *Favor PAC 990 Determination of Acute Toxicity to Earthworms (Limit Test)* (1990). See *Attachment R*.

2. Birds

Acute toxicity of FAVOR® PAC to the bird *Colinus virginianus* (bobwhite quail) was determined by administering a single oral application of FAVOR® PAC 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. *Favor PAC 990 - An Investigation of the*

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*Acute Toxicity of a Superabsorbent Polymer to Bobwhite Quail (1990).
See Attachment S*

Therefore, no critical effects to birds are expected under relevant waste conditions.

3. *Plants*

- a. Phytotoxic effects of FAVOR® PAC 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. 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.

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. *Phytotoxic Effects of a Cross-Linked Homopolyacrylate (1991). See Attachment T.*

Therefore, under appropriate use conditions no critical deleterious effects are expected.

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- b. Phytotoxic effects of FAVOR® PAC 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. *See Attachment U.*

Taking into consideration the PEC estimated above, either no safety factors can be calculated because of any lack of toxicity for bacteria and quails or calculation is not possible because of unrealistic exposure conditions.

9. USE OF RESOURCES AND ENERGY

Precise data regarding the sue of resources and energy related to FAVOR® PAC are not available. FAVOR® PAC, however, is not required if the proposed food additive 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

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material to which it is added. Cellulose Fluff (wood pulp) is presently used in food packaging. The FAVOR® PAC superabsorbent polymer is intended as an adjunct to or replacement for the fluff.

The use of the superabsorbent FAVOR® PAC significantly improves absorbent pad performance in that higher amounts of fluid even under high pressure are taken up by the SAP reinforced pads as compared to conventional types. Due to the enhanced absorption and retention of the new structure, fewer pads will be necessary per package of poultry, meat, or fish. This means that the total volume of disposed soaker pads could be reduced by the introduction of the new food additive FAVOR® PAC.

10. MITIGATION MEASURES

Mitigation measures are not required because of FAVOR® PAC's negligible impact on the environment. Therefore, a discussion of mitigation measures is not required.

11. ALTERNATIVES TO THE PROPOSED ACTION

Based on available data, FAVOR® PAC has no significant environmental impacts. Therefore, a discussion of alternatives to the proposed action is not required.

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12. LIST OF PREPARERS

Jane Elisabeth Mills, Senior Applications Chemist, Stockhausen, Inc., Greensboro, North Carolina; Bachelor of Science in Chemistry.

Dr. rer. nat. Joachim Haselbach, biochemist and toxicologist, Chemische Fabrik Stockhausen GmbH, Krefeld, Germany, diploma in Biochemistry, Ph.D. in Molecular Toxicology; Board Certified Toxicologist of German Society of Pharmacology and Toxicology (DGPT).

Sigrid Hey, Zoologist; diploma in Biology, Chemische Fabrik Stockhausen GmbH, Krefeld, Germany.

Richard Pelt, Manager, Environmental & Safety, Stockhausen, Inc. Greensboro, North Carolina; Bachelor of Science in Chemistry.

Richard J. Scovic, Manager-Absorbent Polymers & Textile Auxiliaries Division, Stockhausen, Inc., Greensboro, North Carolina; Bachelor of Science in Mechanical Engineering.

W. David Carter, Sales Manager Absorbent Polymers Emerging Technologies, Stockhausen, Inc., Greensboro, North Carolina, Bachelor of Science in Chemistry.

13. CERTIFICATION

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm responsible for the preparation of the environmental assessment.

DATE: February 3, 1997

SIGNATURE:



W. David Carter
Title: Sales Manager
Absorbent Polymers
Emerging Technologies
Stockhausen, Inc.

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14. ATTACHMENTS

- A. Chemical Identity of FAVOR® PAC (No Public Disclosure)
- B. H.J. Opgenorth, L. Umweltuerträglichkeit von Polycarboxylaten, 24 Tenside Surfactants Detergents, 366 (1987) with English translations
- C. Estimation of Predicted Environmental Concentration (PEC)
- D. Aerobic biodegradation Under Controlled Composting Conditions (1992)
- E. Martin, J. Et al, Carbon-14 Tracer Study of Polyacrylate Polymer in a Waste Plant, 41 *Appl. Radiat. Isot.* 1165 (1989)
- F. Martin, J. Et al. Environmental Behavior of ¹⁴C-Tagged Polyacrylate Polymer: Column Studies of Flow and Retardation in Sand, 7 *Nuclear and Chemical Waste Management* 265 (1987)
- G. Chronic Bacterial Toxicity of FAVOR® SAB 990 on *Pseudomonas putida*
- H. Chronic Algae Toxicity of FAVOR® PAC 990 *Scenedesmus subspicatus*
- I. Chronic Ciliate Toxicity of FAVOR® SAB 990 on *Tetrahymena pyriformis*
- J. Hydra Reproduction Test of FAVOR® SAB 990 on *Hydra littoralis*
- K. Acute Daphnia Toxicity of FAVOR® SAB 990 on *Daphnia magna*
- L. Daphnia Reproduction Test of FAVOR® SAB 990 on *Daphnia magna*
- M. Acute Fish Toxicity of FAVOR® SAB 990 on *Leuciscus idus*
- N. Acute Fish Toxicity of FAVOR® SAB 990 on *Brachydanio rerio*
- O. Chronic Fish Toxicity of FAVOR® SAB 990 on *Brachydanio rerio*
- P. Cross Germination Test of FAVOR® SAB 990 on *Lepidium sativum*
- Q. Summary of Ecotoxicity Data of FAVOR® PAC
- R. FAVOR® SAB 990 Determination of Acute Toxicity to Earthworms
- S. An Investigation of the Acute Toxicity of a Superabsorbent Polymer to Bobwhite Quail
- T. Phototoxic Effects of FAVOR® PAC on Winter Wheat and Mung Bean
- U. Phototoxic Effects of FAVOR® PAC on Mung Bean, Lettuce, Cress, Tomatoes, and Cucumber
- V. The Metabolism of the Aqueous Soluble Fraction of [¹⁴C]-FAVOR® SAB 990 in Soil Under Aerobic Conditions
- W. Degradation of Crosslinked Acrylic Polymers by White-Rot Fungi
- X. Chronic Fish Toxicity of FAVOR® SAB 990 on *Leuciscus idus*

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Attachments A and C are not included because they contain confidential information.

Attachments B, E, and F are not included because they are copyrighted publications, which are publicly available.

Attachments G through P and R through X are not included in order to limit the length of the environmental assessment. The information they contain is summarized adequately in the environmental assessment and in attachment Q.

ATTACHMENT D

**AEROBIC BIODEGRADATION UNDER CONTROLLED
COMPOSTING CONDITIONS (1992)**

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FINAL REPORT
 AEROBIC BIODEGRADATION UNDER
 CONTROLLED COMPOSTING CONDITIONS

OF

Test substances

W-42068










STUDY SH-1-3141

STOCKHAUSEN G.m.b.H.
 Bäkerpfad, 25
 Postfach 570
 D-4150 Krefeld 1
 Germany

Author: Bruno DEWILDE
 Date : June 30, 1992

Tel : 49/2151/3381 (Mrs. Sigrid HEY)

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VI. INTRODUCTION - PRINCIPLE OF TEST METHOD

The controlled composting biodegradation test 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 consists of stabilized and mature compost derived from the organic fraction of municipal solid waste (MSW). The test substance is mixed with the inoculum and introduced into a static reactor vessel where it is intensively composted under optimal oxygen, temperature and moisture conditions.

During the aerobic biodegradation of organic materials, a mixture of gases, principally carbon dioxide and water, are the final decomposition products while part of the organic material will be assimilated for cell growth. The carbon dioxide production is continuously monitored and integrated to determine the carbon dioxide production rate and the cumulative carbon dioxide production.

After determining the carbon content of the test compound, the percentage of biodegradation can be calculated as the percentage of solid carbon of the test compound which has been converted to gaseous, mineral C under the form of CO_2 . Also the kinetics of the biodegradation can be established.

The test method is identical to the method which has been proposed to the ASTM Subcommittee D 20.96 on Degradable Plastics under the name of "Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials under Controlled Composting Conditions".

Study on the
'Ready Biodegradability'(modified Sturm Test) of
Water soluble Fraction of Favor^(R) SAB

according to OECD-Test Guideline 301 B
and to the 6th Amendment of the
Council Directive 67/548/EEC

Final Report for
Inveresk Research International,
Scotland

Study-No.: BE-E-27-91-04-STT-01

prepared by

Dr. H. Lebertz

Date: February 10th, 1992

Battelle Europe
Battelle-Institut e.V.
Am Römerhof 35
6000 Frankfurt a.M. 90

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2. SUMMARY

The water soluble fraction of "Favor^(R) SAB" was tested for biodegradability according to 'modified Sturm-Test'(OECD Guideline 301 B). Calculated from the organic carbon content of the test substance and the measured CO₂ generation 4 % of the theoretical CO₂ (ThCO₂) has been generated by the test substance within 28 d in the case of the 10 mg test substance/L - culture. 0 % of the theoretical CO₂ (ThCO₂) has been generated by the test substance within 28 d in the case of the 20 mg test substance/ L - culture. Based on the control of the DOC performed at t₀ and at the end of the test the test material was degraded to 18 % within the 10 mg/L test solution and to 11 % within the 20 mg/L test solution. From these data obtained the water soluble fraction of "Favor^(R) SAB" may be regarded as "poorly biodegradable".

3. Principle of the Test

The test substance and polyvalent inoculum (sewage microorganisms from a sewage plant working with predominantly domestic sewage) were incubated at 21 to 22 °C. CO₂ released from the test material was trapped as BaCO₃ using a trap system described in the indicated guideline and the protocol (see 10. Amendments). The degradation was followed by CO₂ analysis. After reference to blank control, the total amount of CO₂ produced by the test substance was determined for the test period and calculated as a percentage of the total CO₂ that the test substance, based on its carbon content, could have theoretically produced (%TCO₂). Additionally DOC (Dissolved Organic Carbon) was measured at t₀ and at the end of the test for control purpose.

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ATTACHMENT Q

SUMMARY OF ECOTOXICITY DATA OF FAVOR® PAC

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SUMMARY OF ECOTOXICITY DATA OF FAVOR SAB

Chronic Bacterial Toxicity
(Pseudomonas putida) Test Concentration :
0.7 - 700 mg C/l (0.006-6 g polymer/l)
EC₅₀ : > 700 mg C/l
MIC : > 700 mg C/l

Chronic Algae Toxicity
(Scenedesmus subspicatus) Test Concentration :
20 - 80 mg C/l (0.2-0.8 g polymer/l)
EC₅₀ : 50 mg C/l (0.5 g polymer/l)
NOEC : < 20 mg C/l (< 0.2 g polymer/l)

Chronic Ciliate Toxicity
(Tetrahymena pyriformis) Test Concentration :
30 - 500 mg C/l (0,35-6 g polymer/l)
EC₅₀ : > 500 mg C/l (> 6 g polymer/l)
NOEC : 60 mg C/l (0.7 g polymer/l)

Hydra Reproduction Test
(Hydra littoralis) Test Concentration :
12.5 - 200 mg C/l (0.2-3.5 g polymer/l)
EC₅₀ : 75 mg C/l (1.3 g polymer/l)
EC₅ : 10-15 mg C/l (~0.2 g polymer/l)

Acute Daphnia Toxicity
(Daphnia magna) Test Concentration :
12.5 - 250 mg C/l (0.2-4.5 g polymer/l)
EC₅₀ : 175 mg C/l (3 g polymer/l)
NOEC : 150 mg C/l (2.4 g polymer/l)

Daphnia Reproduction Test
(Daphnia magna) Test Concentration :
25 - 100 mg C/l (0.5-2 g polymer/l)
EC₅₀ : 160 mg C/l (3.2 g polymer/l)
NOEC : 50 mg C/l (1 g polymer/l)



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Acute Fish Toxicity
(Brachydario rerio; zebra fish)
(Leuciscus idus; golden orf)

Test Concentration :
40 - 320 mg C/l (0.7-5.5 g polymer/l)
LC₅₀ : 250 mg C/l (4 g polymer/l)
NOEC : 160 mg C/l (2.8 g polymer/l)

Chronic Fish Toxicity
(Brachydario rerio; zebra fish)

Test Concentration :
37.5 - 300 mg C/l (0.6-5 g polymer/l)
LC₅₀ : 250 mg C/l (4 g polymer/l)
NOEC : 150 mg C/l (2.5 g polymer/l)

Acute Toxicity to Earthworms
(Eisenia foetida)

Test Concentration : 20 g/kg soil
mortality : 31 % (14 d)
LD₅₀ : > 20 g/kg

Acute Toxicity to Birds
(Colinus virginianus; quail)

Test Concentration : 2000 mg/kg
no mortality
LD₅₀ : > 2000 mg/kg

Cress Germination Test
(Lepidium sativum)

Test Concentration :
50 - 500 mg C/l (0.8-8 g polymer/l)
LC₅₀ : 145 mg C/l (2 g polymer/l)
NOEC : 100 mg C/l (1.6 g polymer/l)

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Terrestrial Plants Growth Test Test Concentration : 5 - 20 g/kg soil
 (Triticum aestivum; wheat) LC50 Emergence : > 20 g/kg
 EC50 Growth : 8.8 g/kg
 NOEC : < 5 g/kg

(Phaseolus aureus; mung bean) Test Concentration : 5 - 20 g/kg soil
 LC50 Emergence : 9.2 g/kg
 EC50 Growth : 11.8 g/kg
 NOEC : < 5 g/kg

(Lactuca sativa; lettuce) Test Concentration : 0.2 - 20 g/kg soil
 LC50 Emergence : > 20 g/kg
 EC50 Growth : 7.2 g/kg
 NOEC : 0.2 g/kg

(Trepidium sativum; cress) Test Concentration : 0.2 - 20 g/kg soil
 LC50 Emergence : 4.1 g/kg
 EC50 Growth : 2 g/kg < EC50 > 20 g/kg
 NOEC : 2 g/kg

(Lycopersicon esculentum; tomato) Test Concentration : 0.2 - 20 g/kg soil
 LC50 Emergence : > 20 g/kg
 EC50 Growth : 1.6 g/kg
 NOEC : 2 g/kg

(Cucumis sativus; cucumber) Test Concentration : 0.2 - 20 g/kg soil
 LC50 Emergence : > 20 g/kg
 EC50 Growth : 0.2 g/kg
 NOEC : 0.2 g/kg

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