BFGoodrich

The BFGoodrich Company
Geon Vinyl Division
6100 Oak Tree Boulevard
Cleveland, Ohio 44131
216-447-6000

June 2, 1992

Ms. Cindy Tchilinguirian
Additives Toxicology Group
NSF International (NSF)
3475 Plymouth Rd.
P.O. Box 130140
Ann Arbor, MI 48113-0140

Dear Ms. Tchilinguirian:

I am enclosing a completed TDRS - Section B form for Geon 110X388.

The composition of Geon 110X388 is confidential to BFGoodrich and therefore subject to the generic secrecy agreement signed by BFGoodrich and the National Sanitation International, October 24, 1979.

Sincerely,

THE BFGOODRICH COMPANY
GEON VINYL DIVISION

Connie N. Dillon

Connie N. Dillon
Regulatory and Data System Specialist

CND/jp

Attachments

cc: Joe Kelley/Doug Wetzig

2156001

BFG15178

Initial if NSF
Std. 60/61-Listed

NSF USE ONLY [ ]
Document Control Code: PL00950-001
Supplier Co. No. I0810
Accepted By _____

TOXICOLOGY DATA REVIEW SUBMISSION - FORM B
NSF *International* (NSF)
STANDARD 60/61: DRINKING WATER SYSTEM COMPONENTS
(CONFIDENTIAL INFORMATION)

FOR ASSISTANCE: 1-800-252-6010
From 9am to 4pm Eastern Time

TO BE COMPLETED BY INGREDIENT SUPPLIER, unless the ingredient is currently Certified under NSF Standard 60 or 61 or has preliminary acceptance by NSF. (See Instructions Before Completing). Please return form within 30 days or call for assistance.

I. IDENTIFICATION INFORMATION

Company name B.F. GOODRICH
Address Geon Vinyl Division
6100 Oak Tree Blvd.
Cleveland, OH 44131

Company contact J. C. Kelley
Telephone Number (216) 447-6567
FAX Number (216) 447-6262

Plant name _____
Address _____

Plant contact _____
Telephone Number ( ) _____
FAX Number ( ) _____

1. Name of chemical or material (use acceptable chemical nomenclature) _____

2. Trade Designation 110 X 388
Please specify other names under which you market this product _____

3. Structural formula, if applicable (Note: $C_7H_{12}O_4$ is NOT structural)

4. Chemical Abstracts Services (CAS) number (if applicable) _____

FORMULATION INFORMATION

Analysis of the applicant's product will be conducted to identify potential contaminants to drinking water. The analytical tests selected will be determined in part from the information provided below. List ALL components of the formulation and related information as follows:

- In column (1) place an I, R, or P corresponding to Ingredient (basic chemical constituents), Reactant (catalysts, initiators, etc.), or Processing aid (mold releases, suspension solvents, filtering aids, cutting fluids, etc.)
- In columns (2) and (3) provide the chemical name and CAS number respectively of each entry placed in column (1).
- In column (4) include the parts by weight (%) of each component and the acceptable tolerances, e.g., 38% +/ - 1%.
- In columns (5) and (6), for each chemical identified, list the Trade Name and respective supplier. It is IMPORTANT that you identify EVERY supplier of the chemical used at your facility.
- Attach analytical methods for determining the level of each chemical, if available.

If this is a multi-part system, (e.g., epoxy coatings) the formulation for each part must have its components shown individually.
PLEASE NOTE: The applicant will avoid delays in the application process if the information is accurate and complete. Please attach additional sheets if necessary.

I,R,P (1)	Chemical Description (2)	CAS No. (3)	Parts by Weight (% or ppm) (4)	Trade Name (5)	Supplier (6)
I	PVC Resin	9002-86-2	> 99 %	Geon 110X388	BFGoodrich

III. PRODUCTION AND CHEMICAL INFORMATION

1. Is the product X manufactured or ___ mined?

   a. If mined, is it purified? YES___ NO___
   If YES, how?_____
   Is it ground or mixed to a homogeneous mixture YES___ NO___

   b. If manufactured or synthesized, provide the following:
   Please provide separate attachments as necessary.
   Manufactured:
   1. Process description Polymerized
   2. Literature and/or patent reference for synthesis method_____

   Synthesized:
   1. Recognized name of synthesis:_____
   2. Literature and/or patent reference for synthesis method:_____
   3. Purification procedure_____
   4. Provide the analytical procedure for the analysis of your product. Provide either a literature reference or a written procedure_____
   5. Molecular weight (molecular weight distribution for polymers) IV = 1.14
   6. Itemize the reaction products of initiators, stabilizers, and catalysts used in the manufacture or synthesis of your product.

   c. ___ Product is handled/bagged by a single use (dedicated) system.
   ___ Product is handled/bagged by a multiple use (non-dedicated) system.
   If multiple products are handled, show other products handled by the system:

2. What is the specified purity range (if applicable)? _____

3. Itemize below, known or suspected impurities in the product including, but not limited to, unreacted starting materials, by-products, low molecular weight polymers, etc. If available, provide literature reference(s) or written procedure(s) for the identification of impurities in your product and starting materials.

Chemical Name	CAS #	Analytical Method

IV. MIGRATION/EXTRACTION INFORMATION

1. If the product is not intended to be dissolved in water, has the solubility of the product been determined?
   ___ YES ___ NO ___ NOT APPLICABLE

   If yes, what is the solubility? _____ @ _____ Temperature and _____ pH

2. Have tests been run on your product to examine migration/extraction of a MATERIAL(s) or IMPURITY(s) from your product into water? ___ YES ___ NO

   If yes, please append the complete report(s) for every component or impurity studied.

V. HEALTH EFFECTS

An extraction test of the applicant's product will be conducted to identify potential contaminants to the drinking water. Laboratory values of contaminant concentrations will be normalized to "at-the-tap" values. Those contaminants for which the Environmental Protection Agency has not established a Maximum Contaminant Level (MCL) may require additional toxicity testing according to the guidelines of NSF Standard 61, Appendix A. Information you provide (as attachments to this form) regarding your knowledge of specific toxicology studies will expedite the applicant's Certification and may alleviate the need for additional toxicity testing.

1. Toxicology Studies: As an attachment to this form, please provide a detailed listing of all known toxicology studies (acute, subchronic, chronic, mutagenicity, teratogenicity, reproductive, carcinogenicity, epidemiology, etc.) relevant to your product, materials, ingredients, and/or impurities. For each reference include:
   a. Name of specific material, ingredient, or impurity addressed by the study.
   b. Type of study (Ames, Sister Chromatid Exchange, etc.).
   c. Complete reference: (author[s], title, source, volume, pages, year).
   d. Summary of study results (include all treatment-related effects; provide your opinion, with justification, for any results you feel should be discounted; attach complete reports, if desired).

   ___ (Check if no knowledge of toxicity data exists within your company.)

2. If any product, material, ingredient, or impurity potentially contributed to the drinking water by your product should, in your opinion, either be exempt from toxicology evaluation (non-migratory, no-residual, etc.) or should be evaluated in light of previous regulatory clearance (21 CFR, EPA National Primary Drinking Water Regulations, etc.), please complete below:

Product, material, ingredient, or impurity	Complete Reference	*Justification* (provide documentation) or opinion

3. A toxicology literature search provided by your company may expedite the toxicology review and minimize costs to the applicant for obtaining toxicology data. For each literature search appended to this form, itemize as described below:

Database	_____	_____	_____
File #	_____	_____	_____
Keywords	_____	_____	_____
Date	_____	_____	_____

___ (Check if no literature search has been, or will be, conducted by your Company.)

VI. ATTACHMENTS AND SIGNATURE

List Attachments to this form _____ No. of pages _____

_____ _____

_____ _____

I hereby certify that the information provided is accurate and complete, and that I, and the Company I represent, know of no reason the product described herein should not be used in the Applicant's product which is used in contact with drinking water.

X Signature Connie N. Dillon Date 06/02/92

Typed or printed name Connie N. Dillon

Position/Title Regulatory and Data System Specialist

Company The BFGoodrich Company

Phone 216/447-7831 Telex _____ FAX 216/447-6459

The following authorization is OPTIONAL. It in no way authorizes NSF to share the information with other Applicants. Authorized NSF staff ONLY will be allowed access to this information. By completing this authorization, this Form B may be used to support the referenced ingredient/material/product as part of another applicant's package.

I give NSF permission to use the information contained in this TDRS Form B as a basis for reviewing/accepting other products which use the referenced ingredient/material/product covered by this form.

Optional Authorization _____

WHERE TO MAIL? Insert the completed form in an envelope marked "CONFIDENTIAL BUSINESS INFORMATION," seal in an outer envelope, and return to:

VIA U.S. MAIL:

Additives Toxicology Group
NSF *International* (NSF)
PO Box 130140
Ann Arbor, MI 48113-0140

VIA COURIER SERVICE:

Additives Toxicology Group
NSF *International* (NSF)
3475 Plymouth Road
Ann Arbor, MI 48105

Permission to Use TDRS Form Information For Multiple Applicants

To be completed when a TDRS form for a particular product has previously been submitted to NSF *International* (NSF) and that information is authorized for use with other applicant(s).

Dear NSF:

Our company, _____, previously submitted a TDRS form for our product _____ under the Document Control Code (found in the upper right hand corner of the original submission): _____.

Permission for NSF to use the above-referenced TDRS form, accompanying information, and appended toxicology data is now given for the following applicant(s) to the NSF's Drinking Water Additives Program.

_____All applicants

_____Only the following company

Company Name: _____

Document Control Code (found in the upper right hand corner of the requested submission): _____

I understand that the files will remain confidential and closed to all, but NSF authorized personnel, according to NSF Confidential Information Security Procedures.

Name_____

Signature*_____

Company (Ingredient Supplier)_____

Telephone Number _____Date_____

***Signature must be notarized:**

Subscribed and sworn to before me this _____ day of _____, 19____.

_____
Notary Public

My Commission Expires:_____

cav/a:/OPT61.PM3

GENERAL INSTRUCTIONS FOR COMPLETING TDRS FORMS A & B

Applicants seeking Certification under NSF Standards 60/61 will have their evaluations expedited if the information in the TDRS-A form is complete, accurate, and promptly returned. Likewise, the Ingredient Supplier (TDRS-B Form) can expedite the process for the Applicant by promptly returning the forms with complete and accurate information.

SECTION V - HEALTH EFFECTS:

Any toxicology, mutagenicity, teratology, or supporting research reports known to the Applicant or the Suppliers should be identified. Submission of such reports may shorten the overall time needed to complete NSF's toxicology evaluation and may reduce required extraction testing, thereby reducing the amount of the NSF testing and toxicology review fees. Literature references are sufficient when the information is available in scientific journals. Summaries of studies completed within your organization or, by contract laboratories, should be appended directly to the Form. Detailed data may be required at a later date. NSF strongly encourages the Applicant and its suppliers to collaborate in the review and submission of supporting toxicology data.

Toxicology information from the US Food and Drug Administration (21 CFR), US Environmental Protection Agency (Drinking Water Regulations), World Health Organization, etc. will be used in support of product applications. However, consideration will be given to the basis of regulatory approval (usage, restrictions, current literature, and state of the science). If the supplier asserts that any product, ingredient, impurity, or other chemical introduced into drinking water as a result of product use should be exempt from toxicology review and evaluation, justification must be provided. (For example, a detailed justification report would need to be appended where the applicant or supplier claims that no residual is found under potable water use conditions, an ingredient is non-migratory, etc.) Reports justifying an exemption must be appended to this application.

DEFINITIONS - TDRS FORMS A AND B:

Applicant: A corporation, company, or individual that manufactures, mines, blends, assembles, packages, repackages, or otherwise produces a direct or indirect additive product or material to drinking water for which a Listing is sought.

Material Supplier (Form A): A corporation, company, or individual (possibly the Applicant) which manufactures a material used in the final production of the Applicant's product.

Ingredient Supplier (Form B): A corporation, company, or individual that provides an ingredient used by the Component Supplier to produce its material.

Component: A sub-unit or part of the Applicant's product; e.g., a valve, a valve stem, a tank liner, a pump, a filter, etc.

Material: A homogeneous and defined formulation of ingredients composing a component in the Applicant's product; e.g., PVC in a plastic pipe, a rubber gasket in a valve, activated carbon in a filter, brass in a valve body, etc.

Product: For the purpose of completing the TDRS-A and -B Forms, the subject of the form (i.e., the chemical, material for which the form is requested) will be considered the "product."

Ingredient: As used in Forms A and B, a constituent used in the production of the "product" for which the form has been requested.

Impurity: A chemical or substance present in the product which contributes neither to the manufacturing process, nor to the function of the "product."

By-Product: A chemical produced during the manufacturing process which is not part of the original starting materials and which is not the major or intended final "product."

Reactant: A chemical used in the manufacturing process of the Applicant Product, or a substance that enters into, and/or is altered in the course of a chemical reaction.

Direct Additives: Contaminants added to water in the production of drinking water.

Contaminant: Any physical, chemical, biological, or radiological substance or matter in water.

GENERAL INFORMATION - FORMS A & B

WHO IS NSF? NSF *International* (NSF) is an independent, not-for-profit organization of scientists, engineers, technicians, educators, and analysts. It is a trusted neutral agency, serving government, industry, and consumers in achieving solutions to problems relating to public health and the environment since 1944. The mission of NSF is to provide clients and the general public with objective, high quality, timely, third-party services at acceptable cost. Services include development of consensus standards, voluntary product testing and certification with policies and practices which protect the integrity of registered Marks, education and training, and research and demonstration, all relating to public health and the environmental sciences.

WHAT IS THE DRINKING WATER ADDITIVES PROGRAM? ANSI/NSF Standard 60 (Drinking Water Treatment Chemicals - Health Effects) and ANSI/NSF Standard 61 (Drinking Water System Components - Health Effects) are voluntary consensus standards developed by regulators, industry, and product users and specifiers under the guidance of NSF and its consensus standards process. Standard 61 addresses two aspects: (1) Do contaminants leach or migrate from the material into the drinking water; and (2) If so, is the level of migration acceptable from a public health viewpoint? Standard 60 addresses direct treatment chemicals and their contaminants and if the levels of these chemicals are acceptable from a public health viewpoint. NSF's Drinking Water Additives program is a third-party Certification which includes auditing, sampling, testing, toxicology review, and evaluation relating to the potential health effects of drinking water products/materials, in accordance with the criteria established in Standards 60/61.

HOW DOES THE PROCESS WORK? The first step toward Certification under NSF Standard 61 requires the Applicant to complete a Product/Materials Information Form (P/MI). After the form is reviewed by NSF, the Applicant is provided with one Toxicology Data Review Submission Form A (TDRS-A), for each material determined to be in contact with drinking water. The Applicant must either complete this form (if the Applicant manufactures the material) OR, forward the form to the appropriate Material Supplier (if the Applicant merely assembles or repackages the material).

The first step towards Certification under NSF Standard 60 requires the Applicant to complete a Toxicology Data Submission-Form A (TDRS-A).

As the TDRS-A forms are received at NSF, a toxicologist will identify ingredients in the material which require additional information. A TDRS-B form will then be prepared for each ingredient and forwarded to the Material Supplier who, in turn, forwards the forms to the appropriate Ingredient Suppliers for completion. Once all of the TDRS forms have been returned, a Formulation Review is conducted by authorized NSF chemists and toxicologists to determine which analytical tests are necessary to evaluate the Applicant's product. During the selection of the testing protocol for potential contaminants, consideration is given to the degree of toxicological concern as well as the economic and practical limitations of the analytical tests within the constraints of the Standard.

Measured contaminant concentrations are normalized to reflect the levels anticipated "at the tap." Regulated contaminants (those which have a Maximum Contaminant Level set by the USEPA) do not require further toxicology evaluation. However, establishing Maximum Allowable Levels for nonregulated contaminants will require additional toxicology review data, either from new toxicology studies initiated at the time of the testing or previously completed and defensible studies. Should additional toxicology data be necessary, NSF toxicologists will work with the Applicant to determine whether or not previous studies or literature sources fulfill the requirements of Standards 60/61.

CONFIDENTIALITY: Only personnel authorized by NSF shall be allowed to review form A and B Applicant and Supplier information, which shall be secured according to NSF Confidential Information Security Procedures. Proprietary information will not be revealed or provided to Applicants or their Suppliers or third parties unless there is prior notarized written approval. However, the sharing of toxicological information between companies is encouraged where such sharing may expedite product certification.

WHERE TO SEND THIS FORM: Insert the completed form in an envelope marked "CONFIDENTIAL BUSINESS INFORMATION," seal in an outer envelope, and return to:

VIA US MAIL:

Additives Toxicology Group
NSF *International*
PO Box 130140
Ann Arbor, MI 48113-0140 USA

VIA COURIER SERVICE

Additives Toxicology Group
NSF *International*
3475 Plymouth Road
Ann Arbor, MI 48105 USA

(Over for General Instructions -TDRS Forms A and B)

60009 2/

Date_____

_____
Ingredient Supplier's Representative

_____
Company Name

_____
Address

Applicant's Product:_____

As a material supplier for NSF *International* (NSF) Certification under ANSI/NSF Standard 61 (Drinking Water Additives program), information is required from each of our Ingredient Suppliers regarding ingredients used in our products. Please complete the attached Toxicology Data Review Submission form (TDRS-B) for your product and mail it to NSF within 30 working days. All information supplied to NSF by you will be held in strict confidence. Only NSF authorized personnel will have access to this information. The completeness and timeliness of your response is important to expediting our application.

If previously you submitted a TDRS form for this product on behalf of another manufacturer, please do not complete the TDRS form again. Instead, authorize NSF's use of your original TDRS form in support of our product by completing the last page of the attached form only.

If assistance is needed in completing the TDRS-B form, please do not hesitate to call the NSF Ingredient Supplier Hotline (800/252-6010) which has been established to answer ingredient supplier questions. If you act solely as a distributor for this ingredient, please forward this correspondence immediately to the manufacturer(s) that supplies your organization.

I would like to thank you in advance for your assistance in expediting our application. Your cooperation is appreciated.

Sincerely,

_____
Material Supplier Representative

_____
Company

IMPORTANT: PLEASE DO NOT PHOTOCOPY THE ENCLOSED TDRS FORM B FOR USE WITH OTHER INGREDIENTS: The Document Control Code(s) are product Specific.

4sbd52add.txt

21560010

BFG15187

P001R71 BF GOODRICH COMPANY MESSAGE SERVICE 13:00:43
FROM: P103R360 TO: CLEVMAIN DOCUMENT: 010014 46 LINES 06/01/92

ROUTE TO: DILLON, CONNIE N

****
* GEON VINYL TECHNICAL DOCUMENT *
****

R103360 G E O N V I N Y L RECIPE 06/01/92 12:00:41

GEON RESIN 110X388 LOC: 12 DEPT: 5668 ISSUE: S92
COMMODITY NO.: 00110 388 0000 EFFECTIVE DATE: 01/01/92
SBC NBR: 1112 DELETE FLAG: NO
LAB REF: CMPR:
BASED ON:
APPLICATION:

PARTS	INGREDIENTS			SEQ	LOC	PERCENT
101.52000	968	000039	6611	010		99.766
.07850	953	709160	ALCOTEX 72.5%	020		.077
.01710	957	00W013	PVA, 88%	030		.017
.00714	953	00G127	METHOCEL F50	040		.007
.10200	953	00G052	PEROXYESTER	050		.100
.03300	911	00A028	DTAHQ DISPERSION	060		.032
101.75774				TOTAL		100.000

TYPE SAMPLE:
ISSUED:
MARKETING APPROVAL:

Meets GMP's per Ed Fratellone
Prior Sanction

21560011

I N T E R O F F I C E M E M O R A N D U M

Date: 29-May-1992 01:54pm EDT
From: JEF
JEF@ALTC@MRGATE@CLE
Dept:
Tel No:

TO: DILLON, CONNIE@A1

Subject: RE: GEON 110x388

CONNIE,

GEON 110X388 DOES MEET THE GOOD MANUFACTURING PRACTICE SPECIFICATIONS: MAXIMUM VOLATILITY OF 3.0% (1 HOUR AT 105 DEG C) AND AN INHERENT VISCOSITY OF NOT LESS THAN 0.35 BY ASTM D-1243-79. IV = 1,14

ED FATTLAR

21560012

BFG15189