

BFGoodrich

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

May 19, 1992

Gary Strassell
The Shepherd Color Company
4539 Dues Drive
P.O. Box 465627
Cincinnati, OH 45246

RE: Blue No. 1 (CAS. No. 1345-16-0)

Dear Mr.

The Sheph
(our Code
productic

I have en
"Form B"
of receipt

Per Diana 9/10/92
NSF has received
all the necessary
forms for the application
Next step is in NSF
hands to determine what
tests are needed + an audit
of plant (Polyvinyl) info
provided will be done.

Goodrich with Blue No. 1
gradient in the

Review Submission (TDRS)
to NSF within 30 days

rian
ecialist
Program
(NSF)

-0140

If you need assistance in completing the form, call the
assistance hotline (1-800-252-6000) A.M. to 4:00 P.M.
EST) which is available except answer supplier's

9/25
Diana needs add
data from Polyvinyl
She will contact
John Beck at Polyvinyl
216-447-6000
Submitted
87004-133
Beck
applies
the recipe
(NSF)
(313) 769-8111
21545024
Diana
Jida
9/25
NSF
has
paid
8733
87004-133
Beck
applies
the recipe
(NSF)
(313) 769-8111
21545024

CND/jp

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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.

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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 (PMI). 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)

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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.

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