

SC Johnson Letter

July 21, 2004

Mr. Jim Wallace
S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403-2236

Dear Mr. Wallace:

This is in response to your letter of April 14, 2004 requesting that the Agency provide guidance regarding claims that can be made for control of biofilm for products intended for use in the residential setting. Your letter raises several questions regarding biofilm. I will answer the questions in the order they are raised in your letter.

Does any label claim referencing biofilm in a residential setting constitute a pesticidal claim requiring registration under FIFRA?

Biofilm is considered to be a pest by the Agency. Therefore, any claim to prevent, destroy, repel or mitigate biofilm is a pesticide claim which requires registration under FIFRA.

Would such a claim as "cleans biofilm stains" be construed as a pesticidal claim since elimination of the stain would require elimination of the biofilm itself?

Historically, the Agency has not considered a claim to clean stains to be a pesticide claim. However, in the case of biofilm the Agency believes that a cleaning claim such as "cleans biofilm stains" is a pesticide claim. The reason being that you are unlikely find a biofilm stain without the biofilm also being present. Thus, in the case of biofilm you would be removing the stain as well as the biofilm.

Since slime is a form of biofilm, should registrants be required to support claims to control slime with biofilm data?

Industrial biofilms have been classified as slimes for regulatory purposes. There are numerous products registered as slimicides that are used in the industrial/commercial setting. Since the environment in which they exist usually

does not result in purposeful human exposure, the Agency does not typically require efficacy data to be submitted to support such claims. The Agency has made a distinction regarding the term "slime or slimicide" and strived to limit its use to products that are used exclusively in the industrial/commercial setting. Products that are limited in that manner do not have to submit efficacy data, although the data are expected to be maintained in the company files. The Agency considers the use of the term "slime" to be inappropriate for a consumer product. The term to be used on consumer product labeling is "biofilm". The Agency will not accept the term "slime" on consumer product labels.

Would any claim to "penetrate" or "cut through" bacterial layers/biofilm/slime, even used to support a cleaning claim, require approval in conjunction with registration due to the fact that "penetration" would essentially be another way of claiming mitigation of the biofilm?

Any claim to penetrate or cut through bacterial layers/biofilm/slime is a pesticide claim and requires the product to be registered.

If you have any questions regarding this letter I can be reached at 703-308-8087.

Sincerely,

/s/

Dennis H. Edwards, Jr., Chief
Regulatory Management Branch 1
Antimicrobials Division (7510C)