

*Small
Booklet*

SOME PROBABLE QUESTIONS ON 3M FLUORO-CHEMICALS WITH SUGGESTED ANSWERS

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A. ORGANIC FLUORINE IN HUMAN BLOOD

A-1. What is "organic" fluorine in blood?

Fluorine in blood exists in two forms. One form is inorganic fluoride ion. The other form of fluorine is non-ionic in nature and is covalently bound in an organic molecule.

A-2. What is the normal level of organic F in blood?

Reported range is 0.01 to 0.1 ppm.

A-3. What is an elevated level of organic F in blood?

It is not easy to define precisely an "elevated" level. We have adopted 1.0 ppm as an elevated level.

A-4. What fluorochemicals have so far been detected in blood?

Perfluorooctane sulfonic acid, Perfluorohexane sulfonic acid, Perfluorooctanoic acid.

A-5. Do you believe other fluorochemicals could be present in blood?

Yes, such fluorochemicals could be derived not only from exposure to synthetic/industrial fluorochemicals (manufactured by several companies) but also from natural sources particularly through the food chain.

Dichapetalem cymosum (Gifblaar), a plant indigenous to South Africa, produces or biosynthesizes fluoroacetic acid, so also do two legumes growing in Australia, Acacia georginae and Bastrolobium grandiflorum and another plant from South America, Palicourea marcgravii (rat weed). More recently, certain long chain fatty acids containing an -fluoro substituents such as 18-Fluoro-cis-, 9-octadecenoic acid (fluoro oleic acid), 16-fluoro palmitic, 6-fluoro capric acid, and 14-fluoro myristic acid have been identified in plant sources.

Further salad and forage crops, soybean, crested wheat grass, when exposed to high levels of inorganic fluoride in field and laboratory studies, were reported to biosynthesize fluoroacetate and fluorocitrate.

A-6. What relationship do the known fluorochemicals in blood have to the product exposed to or used by the individuals?

In our experience, at 3M plants, fluorochemicals in the blood of workers are related to the fluorochemicals they are exposed to - mostly FC-143 in Chemolite workers and mostly FC-95 in Decatur workers.

A-7. Do other companies' employees have fluorochemicals in their blood? If so are they 3M fluorochemicals or some other company's fluorochemicals?

We believe that every one has some amount of organic fluorine in his/her blood, but the fluorochemical is not necessarily of industrial origin.

We do not know whether employees of other companies have industrial fluorochemicals in their blood. There are no published reports. To the best of our knowledge, 3M is the first to publish such results on FC levels in blood of the employees. We believe there may be some instances of occurrence of FCs in the blood of employees of other companies also.

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A-8. What work have other fluorochemical companies done? What are their findings?

As yet, there is no published information about what other companies have done.

A-9. If 3M fluorochemicals are structurally unique, might the problem involve only 3M fluorochemicals?

We do not know.

A-10. Is there any reason to believe that anyone else's fluorochemicals (i.e., other than 3M's) can be found in blood?

We do not know for sure, but may be.

A-11. Do other companies make fluorochemicals structurally similar to 3M fluorochemicals?

That might be the case, but ----

A-12. How long do fluorochemicals stay in a person's blood?

We have definite information on perfluorooctanoic acid. It may stay for years and excrete slowly. We do not know for certain about other fluorochemicals.

A-13. Does organic fluorine concentrate in any part of the body other than blood? If so, what does it mean?

Blood is the only human tissue/organ studied thus far.

A-14. What is the relationship of fluorochemicals in blood to fluorochemical-containing blood substitutes?

There is some similarity. Both are perfluoro compounds.

B. 3M INDUSTRIAL HYGIENE PROGRAM

B-1. Has 3M told its affected employees what the level of organic F is in their blood? If not, why not?

Yes. They were all informed. Further the results of laboratory tests and physical examinations which formed a part of special health screening program were always sent to a physician of their choice.

B-2. How do the employees feel about having elevated levels of organic F in blood?

We are unable to speak for them, but we have discussed the subject with many of them. They are, of course, interested and some are concerned and we share that concern with them. We have made a concerted effort to keep the employees informed by the use of videotapes, crew meetings and health evaluations.

- B-3. How many employees have elevated levels of organic F in blood? How high are the levels elevated?

Sampling is not yet complete. We anticipate elevation in those employees involved with manufacturing and laboratory use of these materials. I would estimate that at Chemolite we are talking about 200 or 300 people.

- B-4. Have the F levels in blood of employees dropped with decrease in exposure levels?

In some instances, yes. Removal from exposure seems to result in a decline. We are unable to speak of a direct relationship yet.

- B-5. What about the employee's wives and children getting exposure to fluorochemical dust carried home by the employees?

We have no data, but it may be possible. With the current protectional clothing and with reasonable personal hygiene (like after-work showers), this should be minimal.

- B-6. How soon can you arrange testing the blood of family members, if the employee so wishes?

Only if there is a good reason for doing it.

- B-7. Is there a 3M guideline for exposure to fluorochemicals? What is the recommended safe exposure level?

3M guidelines are no more than 0.1 mg/m^3 in air and no skin contact. It generally takes good engineering controls to obtain these objectives. These are 3M general guidelines, and not based on toxicological or any other data.

- B-8. What steps is 3M practicing to minimize or eliminate exposure of the employees to fluorochemicals?

- a. Further engineering for complete enclosure of all chemical processes.
- b. Personal protective clothing and respirator until the complete implementation of the new engineering steps.
- c. Good personal hygiene, e.g., promptly washing off spills or contamination, showers at the end of work shift.

- B-9. What steps is 3M recommending to the customers to reduce exposure of customers' employees to fluorochemicals?

Recommendations are contained on the Material Safety Data Sheets, furnished with the product.

- B-10. Has the company been implementing its own recommendations in a satisfactory manner?

Yes, progress is being made.

- B-11. What is the risk of a new employee coming to work in a fluorochemical area of having an elevated blood level of organic F, since the present implementation of 3M recommendations?

There is a small risk. The risk is less now than before. We have taken precautions to minimize exposure for all employees. This includes proper handling procedures and a continuous tightening of industrial hygiene controls.

- B-12. Have we tested the fluorochemical levels in the blood of any new employees since the stricter exposure limits have been set?

We wish to obtain such information, but most of our workers (including our "new"* employees) have some time or other worked in fluorochemical production areas.

*Worked some years ago at Chemolite Plant, were laid off for some time and were reemployed recently by 3M.

- B-13. Does exposure to fluorochemicals worsen the health status of employees who are already in a less than good health (i.e., asthma, heart condition, drinkers/smokers, frequent head aches, etc.)?

We have allowed such persons to work in fluorochemical areas. We do not know of any health effect on our employees that would require work restrictions related to the "less than good health" situations. We have been unable to identify any illness, disease or adverse effect that could be associated with the levels of fluorochemicals that we encountered among our employees. Further epidemiology study at Chemolite has revealed no unfavorable trends.

- B-14. If fluorochemicals pose a possible health hazard, why don't we stop manufacturing fluorochemicals?

When the presence of organic fluorine in blood was recognized for the first time, the manufacture of fluorochemicals was already approximately 25-30 years old. We were unaware of any health problems at the plant where the fluorochemicals have been produced for all these 30 years. We have not been able to identify any adverse health related problems associated with the presence of fluorochemicals in blood. As with most substances, we feel that they can be handled with proper industrial hygiene controls.

C. PRODUCT INFORMATION

- C-1. What 3M products contain perfluorooctanoic acid or its salts?

This is proprietary information. The answer depends on the person seeking the information and 3M's relationship with the person.

- C-2. What 3M products contain fluorine?

A relatively small percent (less than 1%). We cannot tell which ones (proprietary information).

- C-3. Can you provide a list of all 3M fluorochemical products which we should be concerned about?

The answer is to be tailored to the "need to know". We provide toxicity data on most of our products (MSDS).

- C-4. Can you list the products for which there should be no concern?

Proper handling is the key. Such information is provided with the product literature.

C-5. I am with OSHA. I read about your fluorochemicals in blood studies in a recent issue of AIHA Journal. I recently inspected a carpet mill where they spray FC-XXX. I am making a return visit to do some air monitoring and I would like to know the full composition of FC-XXX including residual monomers. Can you please provide me the information?
Perfluorooctanoic acid is not used in carpet treatment.

C-6. Two days ago I had someone come in and SCOTCHGARD my carpet. My one year old child played on the wet carpet. The next day he did not feel well and I took him to our doctor. The doctor wanted to know what was in the product. The carpet cleaning company said that something called Butyl Cellosolve was present, but had no further information. Can you call the doctor and provide him with the necessary information?
Yes.

D. CUSTOMER SERVICE (QUESTIONS FROM OUR CUSTOMERS)

D-1. Will the use of 3M fluorochemicals result in elevation of organic fluorine in blood of our employees?

We do not know. It depends on which fluorochemical it is and the degree of employee exposure to it.

D-2. Is it safe for our employees to work with fluorochemicals? Is there any danger from inhaling spray or fumes, having skin contact (SCOTCHGARD, SCOTCHBAN, FLUORINERTS, LIGHT WATER). Please answer for each one of the products.

Yes, with proper handling procedures (MSDS) and industrial hygiene control. Although we have not identified any associated adverse health effects due to exposure to our fluorochemicals, we have continued to lower substantially the potential for exposure. The fluorochemicals can be handled safely. In any chemical industry, general good practices should include avoidance of skin contact, ingestion or inhalation. Questions on toxicology specific to any of 3M products could be addressed to our Toxicology services in the 3M Medical Department.

D-3. What are the maximum permissible (non-hazardous) levels in air of each of the fluorochemicals supplied to us?

Such established threshold limit values (TLVS) or OSHA standards for any of our fluorochemicals, have not been defined. 3M has established arbitrarily a 0.1 mg/m^3 limit in air and no skin contact for certain of its materials in 3M plants. With the exception of the FLUORAD Surfactants, most of the other materials these limits apply to are primarily in-house intermediates. Our recommendation of 0.1 mg/m^3 limit is not based on toxicological effects, but it is a rather conservative low level minimal exposure.

D-4. What personal safety precautions do you recommend (respirator type, glove material, clothing material) for our employees? Do you recommend any extra precautions?

These would be highly dependent on the specific material and the mode of use. For the dry surfactants, personal protection precautions should include:

- a. Dust-respirator, 3M 9900
 - b. Impervious gloves. These must be worn and maintained so that dust does not collect inside the glove; otherwise skin contact would be possible.
 - c. Impervious clothing. Disposable impervious clothing such as Tyvels should be suitable.
 - d. Rubber or plastic coats to keep the material from contaminating the shoes.
 - e. Effective local exhaust ventilation to capture and remove air borne contaminants.
 - f. Enclosed handling system at all possible process steps.
 - g. Implementation of good personal hygiene habits - prompt washing of contaminated skin areas, washing of hands, arms and face before eating, drinking or smoking; showering at the end of the work shift.
- D-5. What control measures to reduce the ambient fluorochemical level would you recommend, which is appropriate to our use and application? (1000 lbs/month inerts evaporated into the atmosphere in a company manufacturing electronic components.)
- See answers to question D-4, particularly recommendations e. and f.
- D-6. Should we have our employees' blood tested?
- We have no basis for making any such recommendation.
- D-7. How do we monitor the fluorochemical levels in air and in blood of our employees? Is 3M going to help us?
- 3M could provide the knowhow (analytical techniques). The extent of 3M help is to be decided on individual basis.
- D-8. What precautions should we convey to our customers using SCOTCHGARD treated carpet/fabric/garments?
- None.
- D-9. Rat studies indicate compounds are more toxic in males. Should I preferentially restrict males to fluorochemical exposure?
- This observation pertains to only one fluorochemical and one species and does not extend to other fluorochemicals or other species, including primates. There is not the right-type of information to take the above measures stated in the question.
- D-10. We have women working in our production area. Do fluorochemicals have any effects on reproduction (teratogenic or fetotoxic effects)?
- Not to the best of our knowledge. Further studies are in progress.
- D-11. Are there any other special effects of fluorochemicals on women?
- No, not to the best of our knowledge.
- D-12. My union says that they want physical examinations. Do you think that such examinations are necessary?
- We have not identified any health hazards in our employees.

- D-13. What should we do if one of our workers has a high organic fluorine level in his blood?

We have found no reason to remove the person from his job. Our recommendation would be "reduce exposure" (thoroughly review the process and engineering controls, procedures, work habits and personal protective equipment used).

- D-14. Do you think that your products - SCOTCHGARD, SCOTCHBAN, AFFF and FLUORINERTS - would continue to be available? Or, are you planning to discontinue their production.

The products will continue to be available. We see no need for discontinuing any of our products.

- D-15. Do you have analytical methods so that we can sample and evaluate exposure levels in our operating areas?

Yes, we have some analytical methods, two of which have been published. We will try to supply the methods.

- D-16. Are you going to develop analytical methods for other fluorochemicals?

Yes, method development is an ongoing program in our laboratories.

E. PUBLIC HEALTH ISSUES

- E-1. Does the presence of fluorochemicals in blood involve the general public
Organic fluorine was found for the first time in the blood of the general public. While part of it could be from natural sources (see A-4), a portion of it could be from synthetic fluorochemicals. Guy and Taves suggested the presence of perfluorooctanoic acid in a pooled sample of blood from the general public. It could have been present in the blood of just one person or few persons or more. It is difficult to say how many may have fluorochemicals of industrial origin in their blood. Keeping in mind the possibility that some of the organic fluorine in blood could be derived from natural sources (i.e., non-industrial fluorochemicals we have obtained and analyzed blood from people in China far removed from any industrial exposure. The blood for these persons also contained trace of organic fluorine. So it would seem safe to say organic fluorine could be present in the blood of all general public. How much of it is from natural sources and how much from exposure to industrial fluorochemicals not easy to determine, because of the smallness of the amount present and the difficulties in characterizing such small trace amounts.

- E-2. What is the relationship between blood fluorochemical levels in the general public and the products used?

We don't know. Because of the low levels of organic fluorine in the blood of the general public it is not possible to characterize or identify the fluorochemical so present. A great deal of progress in analytical methods is required before data necessary to answer this question can be collected.

- E-3. Have studies relating to the general public been planned?
Yes, we are primarily developing analytical methodology required to undertake such studies.
- E-4. What are the exposure levels of people residing near 3M fluorochemical plants?
We do not know.
- E-5. Is there any danger associated with handling, wearing, sitting on or crawling on fabrics/carpets treated with SCOTCHGARD?
Consumers do not face any health threat, on the basis of information known at this time.
- E-6. I am a physician. I have a patient in our emergency ward who had just swallowed LIGHT WATER FC-XXX Concentrate. Should I induce vomiting?
No.
- E-7. My two year old son was in the room when I used 3 cans of SCOTCHGARD aerosol to spray my couch. I heard about fluorochemicals in blood and in your product. Must I be concerned that my child may now have fluorochemicals in his blood? What should I do?
Should not be concerned.

F. HEALTH EFFECTS

- F-1. Does the presence of fluorochemicals in blood cause cancer?
There is no such evidence. An extensive epidemiology study was carried out, which involved all past employees at one of our large chemical plants covering approximately 30 years. There were no increased deaths in any disease category (including cancer) among the workers engaged in fluorochemical production over the death rates in a control population. Additionally 3M has tested specific fluorochemicals for mutagenicity and recombinogenic effects. The results were negative, suggesting that 3M fluorochemicals have no carcinogenic potential.
- F-2. What tests has 3M conducted to determine whether fluorochemicals may cause cancer?
a. Ames Salmonella typhimurium assay for mutagenicity. 5 strains of S. typhimurium were used in these tests.
b. Yeast, Saccharomyces cerevisiae recombinant bioassay.
- F-3. Have you conducted lifetime feeding studies in animals to determine if fluorochemicals can cause cancer? If so what are the results? If you have not, why not?
We are considering such studies. We would rather depend on information on humans than on observations on experimental animals. Our epidemiological studies on our plant workers has not revealed any information pointing the direction of cancer potential of our fluorochemicals.

- F-4. Can any of the following ill effects be caused by fluorochemicals?
a. blood disease, b. impotency, c. birth defects, d. chromosome damage,
e. reproductive effects, f. immunoresponsive effects.
- No, not to our knowledge.

G. TOXICOLOGY STUDIES

- G-1. Have you studied the toxicological effects via inhalation route?
Some acute inhalation studies have been carried out on some of our fluorochemicals.
- G-2. The 28-day mice and rat studies were conducted at Industrial Bio-Test L. Have you validated these studies?
Yes, the results are consistent with the 90-day study results (GLP, no).

H. ENVIRONMENTAL ISSUES

- H-1. I have heard that fluorochemicals are persistent. Does this mean that they are like PCBs and DDT?

The answer is "NO". PCBs and DDT are environmentally hazardous, because they combine 3 characteristics - (1) they are persistent, (2) they are concentrated in the living organisms and (3) they cause serious toxic effects. As a general rule, highly fluorinated organic compounds, particularly those with completely fluorinated portions are persistent. Like DDT and PCBs these molecules, or at least their highly fluorinated portions, will persist unchanged for long times under typical environmental conditions, but persistence alone does not mean that a compound is an environmental hazard. If a compound is hazardous, the chemical has also to cause some adverse effects. Persistence, however, is a reason to carefully study fluorinated products to demonstrate that they are unlikely to cause undesirable effects at anticipated environmental concentrations. 3M has and is continuing to conduct such studies on their fluorochemical compounds. To date, no evidence exists that a 3M fluorochemical presents an unreasonable environmental risk.

- H-2. Do fluorochemicals bioconcentrate?

Not all fluorochemicals bioconcentrate. Laboratory studies using fish have shown that some lipophilic fluorochemicals do concentrate from water in fish. The mechanism appears to be simple partition of these lipophilic compounds into the fatty tissues of the fish. Compounds with high octanol-water partition coefficients are most likely to bioconcentrate in this manner. The 3M fluorochemical having the highest octanol-water partition coefficient studied to date was found to concentrate in 14 days to levels about 200 and 300 times the concentration in water in the case of Channel Cat Fish and Bluegill Sunfish. On return to fluorochemical free water, approximately 95% of this compound was cleared from the storage tissues. In spite of such a degree of bioconcentration, none of the 3M fluorochemicals were found to exert any toxic effects on fish, fish eggs or fish fry (exposed to saturated solutions of the fluorochemicals). In addition, low production levels make high environmental concentrations unlikely. Thus, although some fluorochemicals bioconcentrate, the data we have indicate that these fluorochemicals do not present any unreasonable environmental risk.

- H-3. Are there any special concerns about disposing of process wastes. What procedures do you recommend for waste disposal?

Fluorochemical waste disposal does present some concerns. Waterborne process wastes are likely to resist biodegradation, but since it is impractical to remove them from dilute water solutions, 3M normally recommends discharging these solutions to waste water treatment systems. Fluorochemicals so disposed may be removed to some extent by being adsorbed in the sewage sludge, particularly if they have low water solubility. But, water soluble fluorochemicals may pass through the treatment system undegraded. For most fluorochemicals, such a passage is of negligible concern because of their low toxicity. Large discharge of moderately toxic or foam producing fluorochemical products, however, may require monitoring (metering) to avoid adverse effects on both the treatment system and the receiving aquatic environment.

Solid fluorochemical wastes may be either landfilled or incinerated. 3M recommends burying most solid fluorochemicals in a chemical waste landfill. Although many fluorochemicals are nontoxic and it appears that they could be safely buried in a general sanitary landfill, because of their persistence, 3M chooses to err on the side of caution. Burying in a chemical waste landfill will prevent problems due to as yet unknown adverse effects.

Incineration of fluorochemical waste requires special care because their combustion products include corrosive and toxic materials such as hydrofluoric acid (HF) and perfluoroisobutylene. Exposure to these combustion products can cause toxic effects to people, animals or vegetation. Being very reactive, they could also speed the deterioration of the incineration equipment. For this reason, incineration of fluorochemical wastes should be avoided except when special facilities designed to handle safely halogenated chemical wastes are available.

- H-4. Do fluorochemicals cause ozone depletion?

Unlike the fully halogenated chloro-fluoroalkanes such as F-11 (CCl_3F), F-12 (CCl_2F_2) and F-113 ($\text{C}_2\text{Cl}_3\text{F}_3$), 3M perfluorochemicals do not contain chlorine. Chlorine, not fluorine, is the element involved in ozone depletion reactions in the stratosphere. Although some of 3M volatile fluorochemicals may be stable enough to reach the stratosphere, they will not contribute to ozone depletion by the known chemical mechanisms of ozone depletion.

J. REGULATORY ISSUES

- J-1. If you have known about the condition of elevated plasma organic F levels in your employees four years ago, why have you not notified the government during that time?

We gathered data; we have no legal obligation; there were no untoward health effects.

When we first learned about the elevated plasma levels, the number of people examined were few, the analytical methods were more involved and time consuming. The total information was meager. There were no health problems. At this point, primarily 3M had the responsibility to generate more data and to investigate the significance of the findings. Toxicology studies in experimental animals were undertaken. An independent epidemiology study was instituted. Results of these studies have been submitted for publication and in the meantime also discussed with representatives of government agencies - OSHA.

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- J-2. Prior to the publication, has 3M informed the Government (EPA, OSHA, NIOSH, CPSC, FDA, etc.) about the fluorochemical contamination in blood of the general public?
- Such findings were already published in scientific journals by the investigators themselves. The information is a matter of public record.
- J-3. What was the reaction or comment of the Government on the occurrence of fluorochemicals in the blood of your employees or the general public?
- As a representative of OSHA, Dr. Vincent F. Garry, Director, Environmental Pathology Laboratory, University of Minnesota had been in contact with us. He was acquainted with our findings and he made the following comments on long-term human effects. "Indicated in your recent clinical study, there are a number of workers with elevated total fluoride levels with no perceivable noxious health effects. The epidemiologic evidence seems to confirm this notion. In the body of the data it is noted that cardiovascular problems are well below expected." Dr. Garry suggests that we should explore the role of fluorochemicals in minimizing platelet aggregation, etc. "...In a clinical pharmacological sense, then, they could be of some therapeutic value".
- J-4. Are the fluorochemical levels in blood currently regulated by any government agency?
- No.
- J-5. Have you any other information that you have not published? If so, what information do you have? When do you publish such information?
- We will publish when we have enough information to justify publication.
- J-6. Will you give additional unpublished information in your possession to any government agency, if so requested?
- Yes, to an appropriate agency.
- J-7. We have been using paper treated with fluorochemicals in direct contact application for food packaging for ten years. I am surprised that an FDA approval was obtained on a product that shows the "effects" on human blood described in your recent publication. Are these findings going to affect the FDA approval?
- The publication does not deal with the fluorochemical you now use to treat the food packaging wrapper. The chemical in question is only an "indirect" food additive. This fluorochemical is absorbed very little, even if it is extracted from the wrapper into the food. The information published has no bearing on the FDA approval.
- J-8. Did 3M file any information on fluorochemicals under EPA-TSCA 8 (e)?
- No, it was not found to be necessary on the basis of inhouse evaluation of the various criteria for reporting under EPA-TSCA 8 (e).

K. LEGAL ISSUES

K-1. What liability is 3M willing to accept for any ill effect that we, the customers, determine now or in the future?

K-2. Does 3M face any law suits as a result of causing elevated levels of fluorine in anybody's blood.