

3M Response to the Call for evidence supporting an analysis of restriction options for PFAS

For 5.1.1c

IV. Information on institute/organisation/person & Data protection rights

Data subject rights: Access, rectification, erasure, blocking, right of revocation

By participating in this survey, personal data may be processed in terms of the General Data Protection Regulation (GDPR) of the European Union. "Personal data" is any piece of information that allows a natural person to be identified directly or indirectly, for example a name or a personified e-mail address. "Processing" may mean, for example, the collection, recording and storing of these data.

PERMISSION FOR INFORMATION PURPOSES: I agree to the personal data I provide in the present survey, including my name and my e-mail address, to be collected, processed and stored for potential follow-up questions regarding this survey by the service provider of Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), namely Webropol Deutschland GmbH, and to these being subsequently stored in the database of the Federal Chemicals Office. *

☒ Yes ☐ No

The following information marked with * on institute/organisation/person are mandatory fields.

Information on institute/organisation/person

Name*	5.1.2e	
Surname*		
Name of institute/organisation *	3M Company	
E-Mail*	5.1.2e	@mmm.com

Can we contact you with follow-up questions? *

☒ Yes ☐ No

Are you interested in attending a meeting on specific uses of PFAS, mixtures and articles containing PFAS?

☒ Yes ☐ No

Note on Confidentiality of information and data

I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc.). The competent authorities for REACH will not be held liable for any damages caused.

☒ Yes

I understand that it is my responsibility to mark confidential data and attachments as confidential. *

☒ Yes

1. Please choose one of the following options. Do you have information on **PFAS**, PFAS-containing mixtures and articles or **alternatives** being able to replace PFAS.

☒ PFAS, PFAS-containing mixtures and/or articles

☐ alternatives i.e. other substances, non-chemical or functional replacement

PART I – PFAS & PFAS Containing Mixtures and Articles

V. Questions - Section A -PFAS and PFAS-containing mixtures and articles

2. Please define your role(s) with regard to PFAS and/or PFAS-containing mixtures and articles (see above for definitions of different roles). Please choose according to your primary role but multiple roles can be indicated. (please see Supplementary document for further explanation) *

☒ Manufacturer of PFAS and/or PFAS-containing mixtures

☒ Manufacturer of PFAS-containing articles

☒ Importer of PFAS and/or PFAS-containing mixtures

☒ Importer of PFAS-containing articles

☐ Distributor of PFAS and/or PFAS-containing mixtures

☐ Distributor of PFAS-containing articles

☒ Downstream User of PFAS and/or PFAS-containing mixtures

☒ Downstream User of PFAS-containing articles

☐ Other (e.g. NGOs, Scientists)

V. Questions - Section A -PFAS and PFAS-containing mixtures and articles

Information on substance identity and quantities *

- ☒ I have information
☐ I have no information

3. Please fill in following information for PFAS and/or PFAS contained in mixtures and/or articles:

- chemical names, trade names, CAS and EC numbers:

5.1.1c

5.1.1c

V. Questions - Section A - PFAS and PFAS-containing mixtures and articles

Information on hazards *

- ☐ I have information
☒ I have no information

V. Questions - Section A - PFAS and PFAS-containing mixtures and articles

Information on uses *

- ☒ I have information
☐ I have no information

7. Which are the area(s) of use and application of your PFAS and/or PFAS containing mixtures and/or articles.

- ☐ Textiles, leather and apparel, and textile related products
☐ Cosmetic products
☐ Food contact materials and non-stick kitchenware
☐ Paper and packaging
☐ Firefighting foams
☐ Household articles/Consumer mixtures (e.g. non-sticking coating, impregnation agents, polishes etc.)
☒ **Construction products (e.g. surface treatments (paints, coatings))**
☐ Lubricants and greases

☐ Chrome plating (including mist suppressing agents)

☐ Semiconductors

☐ Ski waxes

☒ **Medical devices and applications**

☐ Applications of PFAS within oil, gas and mining (apart from firefighting foam)

☐ F-gases e.g. (PFC, HFC, HCFC, HFE, HFO) in air-conditioning, heat-pump equipment, aerosol cans, foams etc.

☐ Uses of C1 perfluorinated carboxylic and sulfonic acids (trifluoroacetic acid (TFA) or trifluoromethanesulfonic acid (triflic acid, TfOH))

☒ **Transportation (automotive, aviation etc.) other than listed above (e.g.greases)**

☐ Photographic surface layers

☐ Other

8. If possible, please assign or estimate annual quantities of your PFAS and/or PFAS containing mixture and/or article to the individual uses. If possible, **list products in the relevant application area that contain your PFAS** and provide information or an estimate on quantities (i.e. concentrations or applied amount per cm²).

Medical/Healthcare applications:

- Skin Staples
- Oral Health Care Products
- Equipment for detection of food pathogens
- Chemical Indicators for sterility of medical devices

Construction and Industrial applications:

- Cyanoacrylate adhesives for industrial or occupational use

Automotive applications:

- Automotive adhesive products

Transport infrastructure applications

- Pavement marking films
- Traffic sign films

Commercial (signage) applications:

- Digital print films, including graphic films

V. Questions - Section A - PFAS and PFAS-containing mixtures and articles

Information on functionality and final mixtures/articles *

☒ I have information

☐ I have no information

27. Please describe the technical function of the PFAS, also with regard to the presence of PFAS in mixtures.

5.1.1c-enabled fluorosurfactants are used in the processing of various products used in high-performance applications in construction, healthcare, automotive, transport infrastructure, industrial and commercial applications. The purpose of a surfactant is to reduce the surface tension of a mixture in which it is dissolved to aid in manufacturing certain products at large scale. One of the major usages is the even dispersion of small particles onto or into a product. For example, reflective beads in road signage and abrasive granules in specific abrasive products leverage this material. The fluorosurfactant is used because no alternate chemistry has been identified that enables the performance needed in these applications. Fluorosurfactants can lower the surface tension to a value half of what is attainable by using hydrocarbon surfactants. Further, fluorosurfactants are more stable and fit for harsh conditions than hydrocarbon surfactants due to the stability of the carbon-fluorine bond. The primary uses covered in this questionnaire are in pavement markings and traffic signs, graphic reflective films, abrasive products, adhesives and multiple healthcare applications.

Pavement markings and traffic signs:

In pavement markings and reflective sheeting usages the purpose of using a 5.1.1c-enabled surfactant is as a bead treatment, which embeds the reflective beads to an optimum level into uncured or dried polymeric coatings. Without the 5.1.1c surfactant treatment, beads sink too far into the coatings. Beads are used to retroreflect light from vehicles at night and are used in a variety of different pavement marking and reflective sheeting products sold by 3M and others.

5.1.1c-enabled surfactant is used also in inks used to image the reflective sheeting used for traffic signs. The levels of the 5.1.1c-enabled surfactant used products are very low in the screen print inks. They are there to allow the ink to flow into a coating and to repel dirt.

Additionally, 5.1.1c films are used for anti-graffiti properties. The films are sold with an adhesive coating and used as overlaminates on 3M's reflective signs (so they can be cleaned and graffiti removed).

Graphic Films:

5.1.1c-enabled surfactants are used to treat the reflective beads in the product to align to the right location in the film to give specific retroreflective properties. No current replacement is known at this time.

Adhesives:

5.1.1c-enabled surfactants are used as a material in a variety of high-performance applications in the automotive industry. An example are certain automotive adhesive products.

5.1.1c-enabled surfactant is used in a very high viscosity

5.1.1c

adhesive. This type of adhesive is designed to give exceptional performance on difficult-to-bond plastic and rubber substrates. Superior performance is achieved on materials such as heavily plasticized PVC, EPDM, ABS, Nylon, Santoprene, and Viton.

It is also used in a surface-insensitive cyanoacrylate with high viscosity 5.1.1c that has gap filling capability. Its gel formulation is suitable for bonding poorly mating components, for porous substrates (e.g. china, ceramics), and rough, porous, contaminated, and acidic substrates including wood, cardboard, veneer, fabric, cork, and leather. It can be used on vertical surfaces as it will not drip or slump.

The fluorosurfactant helps in the application of the adhesive to bonding surfaces and improves its gap filling ability. It also contributes to the ability of the adhesive to be used on contaminated surfaces.

Healthcare products:

Skin staples are used to approximate skin for surgical or other acute wounds to ensure proper healing. 5.1.1c-enabled surfactant is used as a protective coating for these surgical staples.

3M produces various products to improve and maintain oral health. 5.1.1c-enabled surfactant is used in some applications to improve oral health. The use of 5.1.1c-enabled surfactant in oral health applications is critical for product performance and to ensure the safe and effective clinical use of the product.

3M produces testing equipment which allows for the detection of potentially harmful food pathogens. 5.1.1c-enabled surfactant is used to improve the functionality of the testing equipment.

Chemical indicators are vital to ensure the sterility of various medical devices and are used to confirm the efficacy of sterilization cycles based on ink color changes following effective sterilization processing. 5.1.1c-enabled surfactant is used in the identification inks for these chemical indicators.

For all the healthcare applications mentioned above, 5.1.1c surfactants are critical for product performance and to ensure the safe and effective clinical use of the product.

28. Please specify the final mixtures/articles (with industrial, professional and consumer relevance) resulting from the use(s) of your PFAS. Please indicate whether your substance(s) is/are a component(s) of mixtures and/or articles. List the nature of these articles/mixtures as precisely as possible.

All applications are sold to industrial or professional users. The products are labeled for industrial or occupational use only and are not intended nor labeled for consumer use.

The final products in most cases are articles that use these fluorosurfactants as a processing aid in manufacturing. The one exception is in healthcare for dental impressions. In the applications for dental impression materials and fillers, PFAS is a substance incorporated into products classified as mixtures.

29. Please give information for every mixture/article you are producing/using on the tonnage of PFAS you are producing/using per year.

We would need more time to reproduce this data for all our products in response to this call for evidence.

30. To whom do you supply the PFAS and mixtures/articles containing PFAS you manufacture/import?

3M pavement markings are used by companies in charge of public or private roads, normally contracted by the Ministry of Transport in each country. The ink users are also industrial players, normally sign fabricators.

3M graphic films are sold to installers and applied to vehicles (cars, boats, trucks, etc) and non-regulated signage.

3M automotive adhesive products are supplied to Automotive OEMs and Tier Suppliers. The 5.1.1c surfactants are used as a process aide to manufacture these articles. We manufacture these articles in EU and import them into EU from other locations.

3M 5.1.1c adhesives in question are sold for industrial or occupational use mainly through distribution channels. The products are not labeled nor marketed for consumer use.

3M healthcare products are supplied to health care providers, health care distributors, consumers/patients, and other health care/medical device companies.

31. If possible, indicate the concentration (or concentration range) of PFAS or application levels (i.e. in mg per m²) for the PFAS and/or PFAS in your articles/mixtures, including polymers, and uses. Are they impurities, residues or intended additives?

We would need more time to reproduce this data for all our products in response to this call for evidence.

32. Which minimum concentration of PFAS alone or in your mixtures including polymers is feasible using the best available technique?

We would need more time to reproduce this data for all our products in response to this call for evidence.

33. Is the concentration mentioned in question 32 necessary for the performance of your substance, mixture, polymer? What is the minimum concentration of PFAS, mixtures including polymers that is necessary to maintain its function?

We would need more time to reproduce this data for all our products in response to this call for evidence.

40. Would it be possible for the use referred to in Question 7, listing the applicable use areas), to substitute this use with a different technical solution without environmental emissions?

There is no substitution in the applicable use areas as marked in Question 7 with equally high performing, technically and economically feasible products without environmental emissions from an overall life cycle assessment point of view. The strong C-F bond in the substance is key to get the required high performance and durability of the products in the various use areas. Any non C-F substance is expected to perform less and a detailed and comprehensive life cycle assessment would still need to evaluate the potential impact on the environment. Many of these high performing and highly durable products, used in a critical environment from a health and safety point of view, have to be externally certified, which means that any different product developed, if at all possible for the reasons mentioned above, would need to go through a lengthy certification process.

Questions 41-48

Please see the answer to question #40.

PART II – SPECIFIC USES

V. Questions - Section A - Specific Uses: Medical devices

10. What specific function do PFAS fulfil?

5.1.1c-enabled fluorosurfactants are used in the processing of various products used in high-performance applications in healthcare. The fluorosurfactant is used because no alternate chemistry has been identified that enables the performance needed in these applications.

1. Skin staples are used to approximate skin for surgical or other acute wounds to ensure proper healing. PFAS is used as a protective coating for these surgical staples.
3. 3M produces various products to improve and maintain oral health. PFAS is used in some applications to improve oral health. The use of PFAS in oral health applications is critical for product performance and to ensure the safe and effective clinical use of the product. 3M produces testing equipment which allows for the detection of potentially harmful food pathogens. 5.1.1c-enabled surfactant is used to improve the functionality of the testing equipment.
4. Chemical indicators are vital to ensure the sterility of various medical devices and are used to confirm the efficacy of sterilization cycles based on ink color changes following effective sterilization processing. PFAS is used in the identification ink for these chemical indicators.

For all the applications mentioned above, PFAS is critical for product performance and to ensure the safe and effective clinical use of the product.

11. In what types of medical devices are they used?

Skin Staples

Oral Health Care Products

Equipment for detection of food pathogens

Chemical Indicators for sterility of medical devices

12. What PFAS-substances or PFAS-groups are used?

As mentioned above, 3M uses PFAS and similarly related fluorocarbons in the production of skin staples, oral health care products, equipment for detection of food pathogens and chemical indicators for sterility of medical devices. Most of those products are using 5.1.1c-enabled fluorosurfactants.

13. Please give information for every medical device you are producing/using on the tonnage of PFAS you are producing/using per year.

We would need more time to reproduce this data for all our products in response to this call for evidence.

14. Please indicate the concentration (or concentration range) of PFAS(s) in your medical devices and applications.

We would need more time to reproduce this data for all our products in response to this call for evidence.

15. Please indicate the technical function of the PFAS(s) in the products.

1. Skin staples are used to approximate skin for surgical or other acute wounds to ensure proper healing. PFAS is used as a protective coating for these surgical staples.
2. 3M produces various products to improve and maintain oral health. PFAS is used in some applications to improve oral health. The use of PFAS in oral health applications is critical for product performance and to ensure the safe and effective clinical use of the product.
3. 3M produces testing equipment which allows for the detection of potentially harmful food pathogens. 5.1.1c-enabled surfactant is used to improve the functionality of the testing equipment.
4. Chemical indicators are vital to ensure the sterility of various medical devices and are used to confirm the efficacy of sterilization cycles based on ink color changes following effective sterilization processing. PFAS is used in the identification inks for these chemical indicators.

For all the applications mentioned above, PFAS is critical for product performance and to ensure the safe and effective clinical use of the product.

16. Please also specify potential PFAS-impurities, residues or intended additives and indicate their possible concentrations or concentration ranges.

Not applicable.

17. Would you be able to phase out PFAS or pledged to phase out PFAS soon from all your products?

PFAS is a critical component used in the production of skin staples, oral health care products, equipment for detection of food pathogens and chemical indicators for sterility of medical devices. PFAS enables proper functionality and ensuring the safe use of the product. Removal or phasing out PFAS from these applications would most likely have significant implications on functionality and potential safe use of the product, requiring clinical practice change and increasing risk of complications.

18. If you use alternative substances, do you have any information on their risk profiles?

No alternative substances are being used. See answer to Question 17.

19. Please specify any information you have on reformulation costs.

Generally, costs associated with reformulation of health care products and medical devices is high due to re-registration requirements and activities needed to qualify the alternative formulation. As substitution would require feasibility studies, R&D efforts, processability and validation in production, plus clinical studies followed by (re)registration of the medical device according to medical device legislation, it could take several years to implement potential alternatives.

20. Please specify any information you have on impact on exports.

No specific information.

V. Questions - Section A - Specific Uses: Construction Products

10. What specific function do PFAS fulfil in construction products?

5.1.1c-enabled fluorosurfactants are used in the processing of various products used in high-performance applications in industrial applications and construction. The fluorosurfactant is used because no alternate chemistry has been identified that enables the performance needed in these applications.

Adhesives

5.1.1c-enabled surfactant is used in a very high viscosity 5.1.1c adhesive. This type of adhesive is designed to give exceptional performance on difficult-to-bond plastic and rubber substrates. Superior performance is achieved on materials such as heavily plasticized PVC, EPDM, ABS, Nylon, Santoprene, and Viton.

It is also used in a surface-insensitive cyanoacrylate with high viscosity 5.1.1c that has gap filling capability. Its gel formulation is suitable for bonding poorly mating components, for porous substrates (e.g. china, ceramics), and rough, porous, contaminated, and acidic substrates including wood, cardboard, veneer, fabric, cork, and leather. It can be used on vertical surfaces as it will not drip or slump.

The fluorosurfactant helps in the application of the adhesive to bonding surfaces and improves its gap filling ability. It also contributes to the ability of the adhesive to be used on contaminated surfaces.

11. In what types of construction products are they used?

5.1.1c-enabled surfactant is used in a very high viscosity 5.1.1c adhesive. This type of adhesive is designed to give exceptional performance on difficult-to-bond plastic and rubber substrates. Superior performance is achieved on materials such as heavily plasticized PVC, EPDM, ABS, Nylon, Santoprene, and Viton.

It is also used in a surface-insensitive cyanoacrylate with high viscosity 5.1.1c that has gap filling capability. Its gel formulation is suitable for bonding poorly mating components, for porous substrates (e.g. china, ceramics), and rough, porous, contaminated, and acidic substrates including wood, cardboard, veneer, fabric, cork, and leather. It can be used on vertical surfaces as it will not drip or slump.

The fluorosurfactant helps in the application of the adhesive to bonding surfaces and improves its gap filling ability. It also contributes to the ability of the adhesive to be used on contaminated surfaces.

12. What PFAS-substances or PFAS-groups are used?

5.1.1c

13. Please give information for every construction product you are producing/using on the tonnage of PFAS you are producing/using per year.

We would need more time to reproduce this data for all our products in response to this call for evidence.

14. Please indicate the concentration (or concentration range) of the PFAS(s) in your construction products and uses. Please also indicate the technical function of the PFAS(s) in the products.

We would need more time to reproduce this data for all our products in response to this call for evidence.

15. Please also specify potential PFAS-impurities, residues or intended additives and indicate their possible concentrations or concentration ranges.

We would need more time to reproduce this data for all our products in response to this call for evidence.

16. Please specify any robust data you might have on reduced service life when only water-repellent properties are available (but no grease-, stain-repellence) for coated construction products

No information.

17. If you use alternative substances, do you have any information on their risk profiles?

No alternate chemistry has been identified that enables the release of the liner.

18. Please specify any information you have on reformulation costs

We would need more time to reproduce this data for all our products in response to this call for evidence.

PART III – ADDITIONAL INFORMATION

Transportation Infrastructure / Signage Information

5.1.1c-enabled fluorosurfactants are used in the processing of various products used in high-performance applications in transportation and signage. The fluorosurfactant is used because no alternate chemistry has been identified that enables the performance needed in these applications.

In pavement markings and reflective sheeting usages the purpose of using a 5.1.1c-enabled surfactant is as a bead treatment, which embeds the reflective beads to an optimum level into uncured or dried polymeric coatings. Without the 5.1.1c surfactant treatment, beads sink too far into the coatings. Beads are used to retroreflect light from vehicles at night and are used in a variety of different pavement marking and reflective sheeting products sold by 3M and others.

5.1.1c-enabled surfactant is used also in inks used to image the reflective sheeting used for traffic signs. The levels of the 5.1.1c-enabled surfactant used products are very low in the screen print inks. They are there to allow the ink to flow into a coating and to repel dirt.

Pavement Marking Tapes, Reflective Sheetings and Screen Printing Inks are the backbone of the 3M's traffic safety product portfolio. These products help bring critical, decision making information to motorists and pedestrians at dawn, dusk, and nighttime, so that families can return safely to their homes. There are numerous studies that support the usage of our materials in this capacity.

3M Pavement Marking Tapes are more durable, requiring less restriping than less durable liquid pavement marking systems. These tapes also offer higher levels of retro reflectivity, meaning the lanes can be seen further away allowing for more preview time for the drivers.¹ Higher reflectivity values have been found to reduce crashes² and better accommodate the needs of older drivers.³

In the signing market the number of annual road traffic deaths has reached 1.35 million, road traffic injuries are now the 8th leading cause of death for all people and the leading cause of death for children and young adults aged 5 - 29 years.⁴ Reflective sheetings, including beaded reflective sheetings, are important tools in addressing these concerns. 3M Reflective Sheeting is an example of this product offering. The entire family of 3M's reflective traffic sheetings can be imaged with our screen printing inks which are formulated to be transparent and durable. These imaged signs impart the messaging needed for critical decision making for both drivers and pedestrians.

All of the above mentioned products (pavement marking tapes, reflective sheetings, and screen printing inks) rely on durability and reflectivity as key attributes, both of which are enabled by the use of the PFAS-treatment in the beads or as an additive in the inks.

¹ Enhanced Night Visibility Series, Volume VIII: Phase II—Study 6: Detection of Pavement Markings During Nighttime Driving in Clear Weather, FHWA-HRT-04-139.

² Nighttime Safety and Pavement Marking Retroreflectivity on Two-Lane Highways: Revisted with North Carolina Data, Carlson Avelar, Park, Kang, Texas Transportation Institute.

³ Enhanced Night Visibility Series, Volume VIII: Phase II—Study 6: Detection of Pavement Markings During Nighttime Driving in Clear Weather, FHWA- HRT-04-139.

⁴ Global Status Report on Road Safety 2018, World Health Organization.