

Project Title: CMR Self Classification

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Final Report prepared by: Ramboll US Consulting, Inc.
Global Product Safety and Stewardship practice

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This provides a technical assessment of available Annex VII and VIII toxicological data and associated hazard classification recommendation under the EU REACH/CLP regulation for 3M(TM) Novec(TM) 4710 Insulating Gas, as well as a recommendation for future testing proposals should the Annex VIII 100 tpa tonnage band be exceeded.

Ramboll's Global Product Safety and Stewardship practice was engaged to provide an objective third party assessment of 3M(TM) Novec(TM) 4710 Insulating Gas, a new mono-constituent substance heptafluoroisobutyronitrile¹ – (CAS# 42532-60-5) / (EC# 806-451-7). The primary use of this substance is as an environmentally improved (lower greenhouse gas potential) alternative for SF₆, which serves as an insulator in electrical power distribution equipment in industrial settings. Importantly, as a Non-Phase-In substance imported from the USA, 3M has already fulfilled its REACH registration obligation and registered Novec 4710 gas to cover the 1-10 tpa/Annex VII in 2014. Further, they have conducted additional testing to fulfill the 10-100 tpa/Annex VIII requirements, with the intention to update the REACH registration by the end of 2020, and these data are summarized herein.

The focus of Ramboll's assessment is on the potential for any carcinogenic, mutagenic or reproductive toxicity (CMR) classification and, in anticipation of exceeding 100 tpa in future years, what, if any, further Annex IX studies should be proposed or waived.

Key Findings

1. Based on the available data, no self-classification for the CMR hazard categories is currently warranted or anticipated in the future.
2. Should Annex IX (>100 tpa) or Annex X (> 1000 tpa) tonnages be reached in the future, there is an opportunity to waive some of the higher tier mammalian studies, based on Ramboll's current understanding of the substance's use, the available toxicity data, and the specific rules for adaptation from the standard information requirements under REACH contained in Column 2 of Annex IX and X.

¹ IUPAC Name: 2,3,3,3-tetrafluoro-2-(trifluoromethyl)propanenitrile

Ramboll recommendation for further testing

At this time, Ramboll does not recommend any additional testing beyond the testing requirements already being fulfilled by 3M under Annex VIII for the 10 – 100 tonnage band.

Should the tonnage exceed 100 tpa, the following test proposals would likely need to be submitted for 3M(TM) Novec(TM) 4710 Insulating Gas according to Annex IX of REACH:

- Sub-chronic toxicity study (90-day), one species, rodent, male and female, inhalation
- Pre-natal developmental toxicity study, one species, inhalation

Based on the information, Ramboll believes that the following Annex IX and Annex X studies could likely be waived

- Extended One-Generation Reproductive Toxicity Study – propose to waive based on the use Novec 4710 gas does not lead to significant exposure of consumers or professionals.
- Carcinogenicity study – propose to waive as Novec 4710 gas does not have a widespread dispersive use or evidence of frequent or long-term human exposure.