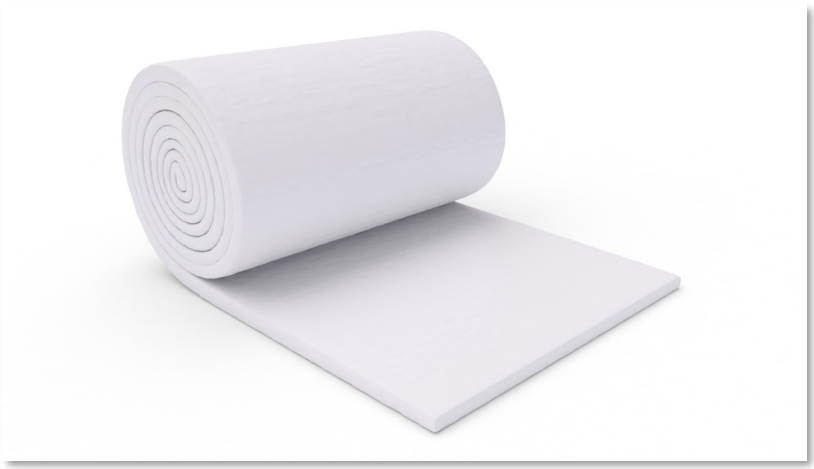
Low Biopersistent Fibre

Testing and Classification



Superwool® Low Biopersistent FIbre

- **Superwool Plus**
- **Superwool HT**
- **Superwool Prime**
- **Superwool XTRA**

Testing and Classification of Superwool Prime Fibres

Superwool Prime is the newest evolution of our Superwool Low Biopersistent Fibre (LBP) portfolio. Superwool Prime, our latest fibre chemistry, is developed for high-performance applications with a classification temperature of 1300°C (2370°F), featuring exceptional thermal and physical properties. The chemistry of Superwool Prime fibre is sufficiently similar to our existing Superwool Alkaline Earth Silicate (AES) fibres that a new exoneration certification is not required.

Historically several variations in chemistry under the Unknown of Variable Composition (UCVB) substance definition are tested using Note Q tests. Most commonly, the short term biopersistence test by intratracheal instillation is an example that includes chemistry that falls within the Superwool Plus and Superwool HT fibres.

In recent years Morgan has decided to minimise animal testing and look for alternatives wherever possible, following the principles of Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the 3R's of animal testing.

Whilst the exact chemical range that Superwool Prime encompasses has not been subject to in vivo testing, it is essential to consider that Superwool Prime chemistry is within the chemical range accepted by European Chemicals Agency (ECHA) for the existing AES fibre registration and like other specific sub-chemistries that have already demonstrated low biopersistence. Re-analysis of what is ostensibly the same REACH registered UVCB substance by animal testing should not be taken lightly and is actively discouraged under the REACH testing requirements.

Instead, Morgan has used chemico comparisons between the chemistry variations to ensure a high degree of safety of marketed fibres and fulfil our duties to avoid unnecessary animal testing.

The physicochemical properties of fibre, including bio-durability, composition, size and shape, play a leading role in biopersistence and potential for retention in the lung. Significant differences in these properties may suggest divergence in biopersistence values and hence, the need for independent testing. However, where test samples show a high degree of similarity across critical parameters, then they are likely to behave in a very similar manner, limiting the justification for further testing, mainly where it requires animal testing.

Comparison Data of Superwool AES Low Biopersistent Fibres

Fibre Product Brand Name	SiO_2 (wt%)	Total Alkali Earth Oxides (wt%)	Solubility in simulated lung fluid (pH 7.4) (ng/cm²hr)	Average Fibre Diameter (µm)
Superwool Plus	62-68	29-40	379	2.5-3.4
Superwool HT	70-80	18-25	125	3.5-5.0
Superwool Prime	64-70	29-35	337	2.4-3.4

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Thermal Ceramics is a business of Morgan Advanced Materials

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Conclusion

Superwool® Prime falls within the chemistry already defined for AES fibres under the REACH registration, with fibre diameters similar to that of the existing marketed products indicating that the product would not be significantly more respirable than the existing products.

The similarity in these key physciochemical properties is reflected in the biosolubility of the fibres which show Superwool Prime fibres falling within the range produced by the existing products.

It is evident that these samples all behave similar from the perspective of bio-durability and together with their shared morphological properties, can be reasonably expected to show similar biopersistence profile in vivo. Therefore, based on comparative data across several key parameters there is no scientific justification to warrant testing of the Superwool Prime sub-chemistry. Indeed, conducting in vivo biopersistence testing of Superwool Prime, when chemistries within the UVCB definition have already been tested, passed and exonerated is likely to create significant challenges for ethical approval for repeat testing. Not least as the test results presented herein provide no grounds for consideration of Superwool Prime fibres as a 'new substance' and instead confirm similarity and support applicability of other AES fibre chemistry biopersistence findings for Superwool Prime.

Appendix

Chemical substance identity

Morgan Advanced Material is the leading producer of AES fibres globally. These products are marketed under several different trade names, however, for the purposes of Classification and Labelling (CLP) (EC/1272/2008) and REACH (EC/`1907/2006) AES fibre is considered as a single UVCB substance which meets the criteria of CLP entry 650-016-00-2. Machine made vitreous (silicate) fibres (MMVF) with random orientation and alkaline oxide/alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content greater than 18% by weight.

It's chemical identity is further defined by the 436083-99-7 CAS number definition:

- Chemical substances manufactured in the form of fibres. This category encompasses substances produced by blowing or spinning a molten mixture of alkaline earth oxides, silica and other minor/trace oxides. It melts around 1500°C (2732°F). It consists predominately of silica (50 - 82wt%) calcia and magnesia (18 - 43 wt%), alumina titania and zirconia (less than 6%) and trace oxides.

Regulatory exoneration process (Europe)

Under CLP they are classified as a category 2 carcinogen with the following hazard codes – H351: Suspected of causing cancer. However, under Note Q of the regulation it states that classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:

- short term biopersistence test by inhalation has shown that the fibres longer than 20 µm have a weighted half-life less than 10 days; or
- short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days; or
- appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or
- absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.

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Hannover, March 3, 2016

Certificate

The biopersistence of fibres was investigated after intratracheal instillation within the following study:

Fraunhofer ITEM study no.: 02G99003C
Test substance: Superwool Plus (code name fibre 3)
Sponsor: European Ceramic Fibres Industry Association
Title: The biopersistence of high temperature insulation fibre 3 (CMS) in rats after intratracheal instillation

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law § 19a Appendix 1 pp. 1724-1732, July 25, 1994, amended on May 14, 1997). The protocol of the European Commission (ECB/TM 27 Rev. 7, 1998) with slight changes according study protocol was followed.
The treatment of rats was performed in January 1999 by intratracheal instillation of a total dose of 2 mg per rat. The fibre retention data up to sacrifice date 3 months after instillation were used for analysis.

Following halftimes were calculated by the method according to the protocol of the European Commission:

WHO fibre fraction (L>5 µm, D<3µm, L/D>3/1): **< 40 Days**
In Germany, Man-Made Vitreous (Silicate) Fibres for high temperature applications (classification temperature > 1000°C) with more than 18% of sodium, potassium, calcium, magnesium and barium oxides do not fall under the production and use ban regulation (Appendix IV n° 22 of the German Dangerous Substances Act and Appendix to § 1 section 23 of the German Chemical Ban Regulation) if the WHO fibres halftime is less or equal to 65 days.

Long fibres fraction (length > 20 µm, L/D>3/1): **< 40 Days**
According to Guideline 67/548/EWG (revised by guideline 97/69/EC of the Commission dated 5. December.1997) Appendix Q the classification as carcinogenic material is not applicable for Superwool Plus because the halftime for fibres longer than 20 µm is less than 40 days in the biopersistence test by Intratracheal instillation.

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Hannover,
February 18, 2004

Certificate

The biopersistence of the fibre type Superwool 607 HT was investigated after intratracheal installation within the following study:

Fraunhofer ITEM study no.: 02G03012
Test substance: Superwool 607 HT
Sponsor: Thermal Ceramics Europe

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law § 19a Appendix 1 pp. 2119-2129, June 28, 2002). The protocol of the European Commission (ECB/TM 27 Rev. 7, 1998) with slight changes according study protocol was followed.
The treatment of rats was performed in June 2003 by intratracheal instillation of a total dose of 2 mg per rat. The fibre retention data of sacrifice dates up to 3 months after instillation were used for analysis.

Following halftimes were calculated by the method according to the protocol of the European Commission:

Long fibres fraction (length > 20 µm, L/D>3/1): **< 40 days**

According to Directive *67/548/EEC (revised by guideline 97/69/EG of the Commission dated December 5, 1997) Note Q* the classification as carcinogenic material is not applicable for mineral wools if the halftime for fibres longer than 20 µm is less than 40 days in the biopersistence test by intratracheal instillation.

WHO fibre fraction (L>5 µm, D<3µm, L/D>3/1): **< 65 days**

In Germany, Man-Made Vitreous (Silicate) Fibres for high temperature applications (classification temperature > 1000°C) with more than 18% of sodium, potassium, calcium, magnesium and barium oxides do not fall under the production and use ban regulation (Appendix IV n° 22 of the German Dangerous Substances Act and Appendix to § 1 section 23 of the German Chemical Ban Regulation) if their WHO fibres halftime is less or equal to 65 days.

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Certificate

Hannover, May 04, 2010

The biopersistence of fibres was investigated after intratracheal installation within the following study:

Fraunhofer ITEM study no.:	02G09012
Test substance:	Superwool 1400-EU
Sponsor:	Prof. R.C. Brown, Toxicological Services, UK

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law, §19a Appendix 1, July 02, 2008). The protocol of the European Commission (ECB/TM 27 Rev. 7, 1998) with slight changes according study protocol was followed. The treatment of rats was performed in July 2009 by intratracheal instillation of a total dose of 2 mg per rat. The fibre retention data of sacrifice dates up to 3 months after instillation were used for analysis.

For the long fibres fraction (length > 20 µm, L/D>3/1) the halftime calculated by the method according to the protocol of the European Commission was:

< 40 days

According to Annex VI § 1.1.3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Commission of 16 December 2008 amending and repealing Directive *67/548/EEC Note Q,* the classification as a carcinogen need not apply if the halftime for fibres longer than 20 µm is less than 40 days in the biopersistence test by intratracheal instillation.

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