



Group Policy: “Handling and Use of Nanomaterials”

1. Objective

The main objective of this policy is the description of the principles in relation to Nanomaterials within Merck KGaA Darmstadt Germany.

2. Scope

The scope of the Group EHS Policy “Use and Handling of Nanomaterials” applies to all locations and the legal entities (subsidiaries and affiliates that our company controls) of Merck KGaA Darmstadt Germany.

Using this standard does not ensure compliance with local regulations. Local legislation must be reviewed along with this standard, and whichever is the higher mandate must be followed. If requirements in this standard conflict with a regulatory requirement, the regulatory requirement takes precedent.

3. Responsibilities

The implementation and execution of the rules laid down in this policy is the responsibility of the Managing Director or Site Managers/ Directors and the department heads of all areas handling Nanomaterials.

All employees must adhere to the rules specified in the document and procedures/regulations issued under its authority.



4. Abbreviations and Definitions

BAuA	<u>Federal Institute for Occupational Safety and Health</u> The Federal Institute for Occupational Safety and Health (BAuA) is a research institution of the Federation, which advises the Federal Ministry of Labor and Social Affairs in all matters of safety and health
AGS	<u>Committee on Hazardous Substances</u> The Committee on Hazardous Substances advises the Federal Ministry of Labor and Social Affairs in all matters of labor protection to hazardous substances, including classification and labeling.
VCi	<u>German Chemical Industry Association</u>
REACH	<u>Registration, Evaluation, Authorization and Restriction of Chemicals</u> European Union regulation dated 18 December 2006 that addresses the production and use of chemical substances

5. Description

Our company is an R&D oriented and innovation driven company. We are always searching for new and innovative products and therapeutics by using state-of-the-art technologies. Nanotechnology makes it possible to develop completely new material properties in a wide variety of application areas and is opening up great opportunities.

Merck KGaA Darmstadt Germany is using nanotechnology in order to offer our customers chemical and pharmaceutical products and systems that help them to be successful in their markets.

Our company has ongoing research and development regarding the usage of Nanomaterials i.e. in the field of "targeted delivery using nanoparticles" for pharmaceutical applications.

We are addressing the risks of nanotechnology and follows the precautionary principle. In research, manufacturing and processing products our company pays strict attention to compliance with all statutory regulations and other applicable standards.

Merck KGaA Darmstadt Germany has a special responsibility towards its employees, customers, suppliers and society but also towards future generations and therefore the following principles are the basis for conducting business:



1. Our company, supported by internal and external ongoing research, develops and uses nanotechnology in order to manufacture products and therapeutics with enhanced performance and/or new properties e.g. enhanced delivery characteristics. Therefore, we are using targeted production and new Nanomaterials.
2. The protection and welfare of human life and the environment is a fundamental principle for Merck KGaA Darmstadt Germany.
3. Our company has a Responsible Care orientated Group Standard on the safe use and handling of Nanomaterials.
4. We identify sources of hazards for our employees in laboratories, production plants, filling and storage facilities and provide appropriate preventive measures to minimize the risk of an incident taking place. In the unlikely event of any health or environmental hazards arising as a result of operations using nanotechnology, our company will take immediate action.
5. Merck KGaA Darmstadt Germany weighs up the opportunities of nanotechnology against potential risks.
6. In the frame of "Responsible Care" our company drives continuous improvement of health, safety and environmental areas. It achieves this objective by meeting or going beyond legislative and regulatory compliance, and by adopting cooperative and voluntary initiatives with government and other stakeholders.
7. Merck KGaA Darmstadt Germany only markets products if their safety and environmental impact can be ensured on the basis of all available scientific information.
8. Merck KGaA Darmstadt Germany provides its customers and partners with information about the safe transportation, storage, safe use, processing and disposal of its products.
9. Economic considerations do not take priority over safety and health issues and environmental protection.
10. Our company is committed to transparency and to an objective and constructive public debate.
11. Merck KGaA Darmstadt Germany discloses new findings to the authorities and the public immediately.
12. Our company abides by the VCI and BAuA respectively AGS guidelines regarding Nanomaterials.

We inform our business partners about our principles and require them to also adhere to them.



6. Annex

List of VCI and BAuA guidelines regarding Nanomaterials

- Implementing Responsible Care® for a Responsible Production and Use of Nanomaterials
- Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials
- Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials
- Guidance for Handling and Use of Nanomaterials at the Workplace
- Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets
- Strategy Paper of the German Chemical Industry on the Standardization of Nanomaterials
- VCI position on the definition of the term Nanomaterials for use in regulations laying down provisions on substances
- Roadmap for Safety Research on Nanomaterials – with a priority list for the European 7th R&D – Framework Programs and national research programs
- Guidance for the Safe Recovery and Disposal of Wastes containing Nanomaterials
- Environmental Aspects of Nanoparticles – with a priority list for the European 7th R&D Framework Program and national research program
- AGS Announcement on Hazardous Substances 527 –“Manufactured Nanomaterials” issued by BAuA

7. Revision History

Version n°	Reason and Description of the Change	Replacement of previous document
1.0	N/A	New document
2.0	revised editorially	Doc ID: 20050251 Vers. 1.0
3.0	Revised due to SIAL integration	Doc ID: 20050251 Vers. 2.0

