

To Whom It May Concern

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DKJPD/DKABI

Coloplast A/S  
Høldedam 1  
3050 Humlebæk  
Denmark  
Tel: +45 4911 1111  
www.coloplast.com  
CVR-nr. 69749917

### **Guideline on the use of animals**

Jane Møll Pedersen  
Director

GRD Regulatory Affairs

dkjpd@coloplast.com

Coloplast constantly develops new products to improve the quality of life of disabled persons. To ensure user safety and product efficacy and to meet regulatory requirements for medical devices, Coloplast uses animal testing within product development. We minimise this form of testing, however, always looking for alternative test methods to reduce the number of animals used.

Typically, the following kind of tests in living animals are performed when making new products for contact with skin or wounds: Test of irritative potential (test animal: rabbit) and test of allergic or sensitisation reactions (test animal: guinea pig). Further, special tests simulating e.g. wound healing are performed in other animal models, typically in pigs. In general, lower animals such as rodents are preferred to higher animals such as cats and dogs.

**The following principles must be adhered to whenever animals are used:**

#### **The use of animals must comply with relevant legislation**

- Animal welfare is in focus when planning animal tests, and all animal studies are performed according to international guidelines regarding animal welfare issues (from the EU (Committee for Proprietary Medicinal Products), OECD and US Food and Drug Administration).

#### **For ethical reasons, the use of animals must be kept at a minimum using alternative test methods whenever possible**

- When performing biological evaluations of medical devices, international guidelines for selection of tests (ISO 10993) are typically followed.
- Literature findings may reduce or eliminate the need for animal testing by using materials tested for other purposes.
- Cell cultures will in many instances mimic cell interactions in vivo, and can therefore replace toxicity testing in animals.

#### **All tests involving living animals must be conducted at research and contract laboratories approved by Coloplast in respect of animal welfare, ethical considerations, staff training and quality standards**

- Coloplast uses only respected research and contract laboratories with high standards of business conduct. The laboratory animals, which are used, have been bred specifically for experimental purposes, wherever possible.

**All tests involving animals must be properly planned and documented**

- Coloplast carefully plans and documents all animal tests in cooperation with the respective research and contract laboratories. Conclusions are summarised as part of the risk evaluation of new products before releasing these for human use.

**Animal testing Survey in Coloplast (excl. Skin Care, former Mentor and Por-ges)**

Division	Animal species	2002	2003	2004	2005	2006	2007 YTD
Coloplast Research	Rodents	36	0	0	62	30	0
	Rabbit	3	0	0	3	2	0
	Pig	0	0	0	2	0	0
	Sheep	0	0	0	0	0	0
	Dog	0	0	0	0	0	0
Continence Care	Rodents	70	0	66	30	30	90
	Rabbit	9	41	5	3	2	6
	Pig	0	0	3	0	0	0
	Sheep	0	33	0	0	0	0
	Dog	2	0	0	0	0	0
Ostomy Care	Rodents	60	0	0	15	30	23
	Rabbit	3	3	0	3	2	9
	Pig	0	0	0	0	0	0
	Sheep	0	0	0	0	0	0
	Dog	0	0	0	0	0	0
Wound Care	Rodents	144	152	270	95	115	106
	Rabbit	24	9	21	6	27	3
	Pig	2	0	0	0	8	0
	Sheep	0	0	0	0	0	0
	Dog	0	0	0	0	0	0
<b>Total</b>		<b>353</b>	<b>238</b>	<b>365*</b>	<b>219</b>	<b>246</b>	<b>237</b>

\* In 2004 there is a peak in number of animals used for testing due to a high number of new developed wound care products.

Yours sincerely  
 Coloplast A/S



Jane Møll Pedersen  
 Director, GRD Regulatory Affairs