

Health- and ecological criteria offered products

Questionnaire

1. Name of product type: Reusable Medical Temperature Probes - BlueTemp

2. Is halogenated plastics such as PVC used in the product (including the packaging)? ☐ Yes ☒ No
(Halogens = Iodid, Fluor, Chlorine, Bromine)

If yes, please describe:

Principal would like to avoid, to the largest extent possible, the use of halogenated plastics /PVC due to the emissions of dangerous gases during production and combustion of the packaging.

3. Phthalates dangerous for health/environment

Does the product/packaging or the glue contain any of these phtalates dangerous for health/ environment: DEHP, BBP, DBP, DINP, DNOP eller DIDP? ☐ Yes ☒ No

If yes, please specify closer in table

Product part /glue/ packaging	Name of material	Which phtalate (chemical name and/or CAS-NR)	Amount of phtalate in weight-%

4. Other endocrine disrupters

Does the product/packaging or the glue contain other softeners or additives in addition to the phtalates mentioned above (point 3), that may be regarded as a potential endocrine disrupter according to the latest lists published under the EU Community strategy for endocrine disrupters or under official strategies in any Nordic country (see reference below) ? ☐ Yes ☒ No

If yes, please specify closer in table (see reference below):

Product part /glue/ packaging	Name of material	Additives (chemical name and/or CAS-NR)	Amount in weight-%

See the updated EU priority list of substances regarded as potential endocrine disrupters in "Appendix L" in the "Final Report of the DHI-Study" at: http://ec.europa.eu/environment/endocrine/documents/final_report_2007.pdf
All the substances in the updated list in Appendix L are considered to be potential endocrine disrupters.

5. Other substances hazardous to health and the environment

Does the product/packaging or the glue contain other softeners or additives in addition to the phthalates mentioned above (point 3), that may be classified as belonging to any of the following hazard categories described below? (The answer is yes if the summarized content of the classified substances exceed 0.1 % by weight of the product, not including the pharmaceutical inside as well as secondary packaging and transport packaging). ☐ Ja ☒ Nei

If yes, please specify closer in table (see reference below)

Product part /glue/ packaging	Name of material	Additives (chemical name and/or CAS-NR)	Amount in weight-%

Health hazards:

Carcinogenic/mutagenic/toxic for reproduction (CMR):

Carcinogenic, Categories 1 and 2 with T (R45, R49)

Carcinogenic, Category 3 with Xn (R40)

Toxic for reproduction, Categories 1 and 2 with T (R60, R61)

Toxic for reproduction, Category 3 with Xn (R62, R63)

Mutagenic, Categories 1 and 2 with T (R46)

Mutagenic, Category 3 with Xn (R68)

Acute lethal effects:

Very toxic with T+ (R26, R27, R28)

Toxic with T (R23, R24, R25)

Non-lethal irreversible effects after a single exposure:

Very toxic or toxic with T+ or T (R39)

Harmful with Xn (R68)

Severe effects after repeated or prolonged exposure:

Toxic or harmful with T or Xn (R48)

Sensitizing effects:

Harmful with Xn (R42)

Irritant with Xi (R43)

Environmental hazards:

Dangerous for the environment with N (R50, R50/53, R51/53, R59)

Dangerous for the environment without N (R52/53, R52, R53)

The above classification is in accordance with current rules in Denmark, Finland, Iceland, Norway and Sweden. These rules are based on EU Directive 1999/45/EC with subsequent amendments and revisions. Note that it is the manufacturer of the additive or adhesive who is responsible for the classification.

Legally binding and recommended classifications of substances in the EU can be seen at the European Chemical Bureau (ECB) Web site: <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

Suggestions as to self-classification for environmental hazards for a number of substances can be found at a Web site set up by the Nordic Council of Ministers in cooperation with the European Chemical Bureau: <http://apps.kemi.se/nclass/default.asp>

Typical examples of CMR substances are halogenated organic substances and some phthalates (for instance DEHP, DBP and BBP). Many of these substances are also dangerous to the environment. Other substances hazardous to the

environment are lead and lead compounds.

6. Bioaccumulative substances with unpredictable long-term effects

Does the product/packaging or the glue contain substances used in adhesives may have PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) properties, i.e. be listed as such on the official lists published in any Nordic country or the EU?

☐ Yes ☒ No

If yes, please specify closer in table (see reference below)

Product part /glue/ packaging	Name of material	Additives (chemical name and/or CAS-NR)

Substances fulfilling as well as substances forming substances fulfilling the PBT and or vPvB criteria are listed on the European Chemical Bureau (ECB) Web site. "Deferred" substances and substances "Under evaluation" are not considered to have PBT or vPvB properties:

<http://esis.jrc.ec.europa.eu/index.php?PGM=pbt>

Typical examples of PBT or vPvB substances are brominated flame retardants.

I hereby confirm that the information supplied in this questionnaire is given with the best discretion and does contain to our best knowledge only correct information. We are aware that incorrect information may lead to cancellation of the agreement. Furthermore we understand that information available for the public may be obtained.

Place and date: Selmsdorf, 6th January 2020

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