4. SUMMARY

Assessment of acute oral toxicity with ENVIPLAST in the rat (Acute Toxic Class Method).

The study was carried out based on the guidelines described in:
OECD No.423 (2001) "Acute Oral Toxicity, Acute Toxic Class Method"
Commission Regulation (EC) No 440/2008, B1 tris: "Acute Oral Toxicity, Acute Toxic Class Method"
EPA, OPPTS 870.1100 (2002), "Acute Oral Toxicity"
JMAFF guidelines (2011) including the most recent partial revisions.

ENVIPLAST was administered by oral gavage to two subsequent groups of three female Wistar rats at 2000 mg/kg body weight. Animals were subjected to daily observations and weekly determination of body weight. Macroscopic examination was performed after terminal sacrifice (Day 15).

No mortality occurred.

Piloerection and/or hunched posture were noted among the animals on Day 1 only.

The body weight gain for all animals over the study period was considered to be similar to that expected of normal untreated animals of the same age and strain.

No abnormalities were found at macroscopic post mortem examination of the animals.

The oral LD50 value of ENVIPLAST in Wistar rats was established to exceed 2000 mg/kg body weight.

According to the OECD 423 test guideline, the LD50 cut-off value was considered to exceed 5000 mg/kg body weight.

Based on these results, ENVIPLAST does not have to be classified and has no obligatory labeling requirement for acute oral toxicity according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) of the United Nations (2011) and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

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