Teknor Germany GmbH
Regulatory Affairs
Am Rödlein 1
D-91541 Rothenburg ob der Tauber

Regulatory Data Sheet

Product Name(s):

PR-13250 NAT	**2227268**
PR-13230 NAT	**2227269**

The formulation for the Teknor Apex compound(s) listed above was reviewed for compliance with the following topics:

FDA MEDICAL

The components of the above named compound fall under one or more of the following categories:

- Substances that are “generally recognized as safe” (GRAS)
- Substances that are prior-sanctioned
- Substances that, based upon legal opinion and/or supplier certification, are acceptable for food contact applications
- Substances that are subject to an effective Food Contact Notification (FCN)
- Substances that are exempt from regulation under 21CFR170.39 - Threshold of Regulation (TOR)
- Substances identified in one or more of the Title 21 of the Code of Federal Regulations (CFR) published by the U.S. Food and Drug Administration (FDA) (174, 175, 176, 177, 178, 181, 182, 184 and 186)

There is no positive chemical or ingredient listing within 21 CFR for pharmaceutical and/or medical applications. Teknor Apex has not reviewed specific acceptable food types, conditions of use, or any limitations or restrictions of use for the components used in the above named compound. As such, it is the responsibility of the finished article manufacturer or registrant to determine suitability for their end use application.

EU MEDICAL

Every monomer, additive or colorant used to formulate the above named compound is listed in one or more of the following regulations:

- Commission Regulation (EU) No. 10/2011, as amended
- Council of Europe’s AP(89) I Resolution, the French Positive List for Plastic Materials or in the Swiss Ordinance List Annex 6, Part A or B

There is no positive chemical or ingredient listing within Regulation 10/2011 for pharmaceutical and/or medical applications. Teknor Apex has not reviewed for specific migration limits (SMLs), dual use additives per Regulation (EC) No 1333/2008, or any restrictions of use in food, the materials or final article, for the components used in the above named compound. As such, it is the responsibility of the finished article manufacturer or registrant to determine suitability for their end use application.

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ROHS

The RoHS Directive restricts the use of cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP) and limits the levels of all substances, except Cadmium, to 0.1%. Cadmium has been restricted to 0.01%.

On March 31, 2015, the (RoHS) Directive (2015/863/EU), Annex II was amended, adding a threshold level restricted to 0.1% for the following four phthalates: DBP, DEHP, BBP and DIBP. These provisions become effective for Category 8 (medical device) and Category 9 (monitoring and control equipment) on July 22, 2021, unless otherwise exempt.

As formulated, this compound does not contain any substances restricted under the EU RoHS Directive (2011/65/EU) (RoHS 2), (as amended by 2015/863 (RoHS 3)) above threshold levels. In addition, no substances restricted under RoHS were intentionally added during the manufacture of this compound above threshold levels.

REGULATION EC 1907/2006 AS AMENDED: REACH, SUBSTANCES OF VERY HIGH CONCERN (SVHC)

These compounds were not formulated to contain of any of the substances listed on the Candidate List of Substances of Very High Concern (SVHC) under REACH above 0.1%, as per the most recent date of revision. In addition, no SVHCs were intentionally added during the manufacture of these compounds.
Current Number of SVHCs: 205
Most Recent Date of Revision: January 16, 2020

LATEX

The raw materials used to formulate the compound noted above have been reviewed for the presence of latex/natural rubber. This compound was not formulated to contain latex, nor is latex intentionally added during the manufacture of this compound.

CONEG (HEAVY METALS)

This compound complies with the Coalition of Northeastern Governors (CONEG) legislation and was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. In addition, these four elements were not intentionally added during the manufacture of this compound above threshold levels.

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SUBSTANCES OF CONCERN

The raw materials used to formulate the compound noted above have been reviewed for the presence of the following substance(s):

Bisphenol A (BPA)
Phthalates

These substance(s) are not present above 1000ppm. This compound was not formulated to contain these substance(s), nor are they intentionally added during the manufacture of this compound.

TOY STANDARDS:

Consumer Product Safety Improvement Act (CPSIA)
The raw materials used to formulate the compound noted above have been reviewed for any indication of the presence of metals and phthalate plasticizers listed in the Consumer Product Safety Improvement Act of 2008 (CPSIA). There was no indication that metals or phthalate plasticizers are present in this compound above threshold limits.
European Standard EN 71
The raw materials used to formulate the compound noted above have been reviewed for any indication of the presence of metals listed in the EN 71-3:2013 standard. The compound noted above is in compliance with "Table 2-Migration Limits from Toy Materials" of Toy Standard EN 71-3:2013 (2009/48/EC) Metal Migration and does not exceed threshold limits for the specified application.

PROPOSITION 65

These compounds were not formulated to contain of any of the substances listed on California Proposition 65 (Prop 65) as of the effective date of this regulatory data sheet. In addition, no Prop 65 substances were intentionally added during the manufacture of these compounds.

German consumer goods

These compounds comply with the German food, feed and consumer goods act „Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch" (LFGB) dated 1.9.2005.

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CUSTOMER NOTICE

This declaration is based on formulation and supplier information, not based on testing. It does not exclude the presence of traces due to impurities or residuals in the components supplied by third parties and used in our production facilities.

The above named compound is not approved for use in the following medical applications, (a) implants as defined as an entire device below the skin surface, (b) catheter (in-vitro) applications that are considered long term (≥29 days), (c) sensitive applications including mouthing toys or pacifiers for infants or young children <3 years of age, (d) Class III life-sustaining medical applications, or (e) any other medical application that Teknor Apex may designate from time to time. U.S. FDA and/or European Class III medical device applications require prior written approval by Teknor Apex. For more information, please contact your Teknor Apex Sales Representative.

This statement applies to the compound(s) noted above only and does not extend to any substances that may be added by third parties.

This statement applies to the compound(s) noted above as it is manufactured in Germany only.

PRODUCT STEWARDSHIP

This Regulatory Data Sheet has been prepared by Teknor Apex Regulatory Affairs and is valid without signature.