

Status: Sep. 2019

The following studies concerning Hexamoll® DINCH are available:

BASF studies

Environmental fate:

- Biodegradation in water
- Biodegradation in soil
- Bioaccumulation: aquatic
- Adsorption / desorption

Ecotoxicological information:

- Short term toxicity to fish
- Short term toxicity to aquatic invertebrates
- Long term toxicity to aquatic invertebrates
- Toxicity to aquatic algae
- Toxicity to microorganisms
- Toxicity to soil macroorganisms
- Toxicity to terrestrial plants
- Toxicity to soil microorganisms (C- and N-transformation)

Toxicological information:

- Toxicokinetics, metabolism and distribution
- Acute toxicity: oral, dermal and intravenous administration
- Skin irritation
- Eye irritation
- Skin sensitization
- Repeated dose toxicity oral: 28d and 90d
- Repeated dose toxicity intravenous: 5d and 28d (+14d recovery)
- Genetic toxicity in vitro (Ames, Chromosome Aberration, HPRT)
- Genetic toxicity in vivo (MNT)
- Combined chronic toxicity and carcinogenicity
- Toxicity to reproduction (2-Gen)
- Developmental toxicity / teratogenicity (rat and rabbit)
- Specific investigations: Liver enzyme induction, S-Phase response in the liver, Thyroid function

Evaluations

- EFSA (European Food Safety Authority)
- NICNAS (Australian Competent Authority)
- NSF reference dose (National Sanitation Foundation, USA)
- KEMI (Swedish Competent Authority)
- Danish Health Authority / Danish EPA
- French National Evaluation 2014
- ECHA RMOA 2016

Literature

Human biomonitoring/epidemiological information

- Dust samples in German households
- Exposure of German adults (1999-2017), published 2019
- Exposure of adults and children in other EU member states
- Exposure of US adults (2000-2016) NHANES update 2019
- Exposure of general public in Australia
- Opinion of the HBM commission of the German Federal Environment Agency (UBA)
- HBM-I value for children and adults (HBM commission, UBA, Germany)

Medical device development:

- Alternatives to DEHP in P-PVC in Medical Devices
- Red blood cell storage, hemolysis
- Pediatric RBC and platelet storage
- Plasma storage
- Storage of Blood Products

Technical topics:

- Sterilization (Stability / Degradation)
- Device-drug interactions
- Migration
- Indoor air: max gas phase concentration
- Substitution of DEHP by Hexamoll® DINCH regarding mechanical properties

Science

- Short-term *in vivo* Screen using Fetal Testosterone Production
- Human Metabolism
- US EDSP/Toxcast21 battery: no potential endocrine activity
- No obesogenic activity
- PBPK model

Approvals

- European Pharmacopoeia (Plastic Additive No. 24)
- US Pharmacopoeia (Monograph 88, Class VI)
- US FDA Medical Device Master Files (No. 1484; 16323)
- European Commission Regulation (EU) No 10/2011 (Food contact material No. 775)
- Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21, substance identification number 4734)
- Chinese GB Standard GB9685-2016
- US National Sanitation Foundation Standard 61 for drinking water
- NICNAS approval for food packaging in plastics (STD/1259), printing industry (EX/165) and surface coatings (EX/170)