Product Information Sheet

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Hexamoll® DINCH

Rev. 4

BASF Trade Name	Hexamoll® DINCH (Hereinafter "Product")
Chemical Name	1,2-Cyclohexanedicarboxylic acid, diisononyl ester
CAS-No.	166412-78-8 Europe and Asia 474919-59-0 USA and Canada
EC-No.	431-890-2
REACH-Registration	Registered by BASF SE 01-0000017810-74-0001

Chemical inventory status

Switzerland (CHEMINV)	No	
USA (TSCA)	Yes	
Canada (DSL)	Yes	
Japan (ENCS)	Yes	3-2435
South Korea (ECL)	Yes*	2003-3-2499
Australia (AICS)	Yes**	(secondary notification conditions apply)
Philippines (PICCS)	Yes	
China (IECSC)	Yes	
New Zealand (NZIOC)	Yes ***	

*The Act on Registration and Evaluation, etc. of Chemical Substances (known as "Korea REACH") has been amended with enforcement date of January 1st, 2019.
A major change is that all existing chemical substances including polymers with an annual volume above 1 t/a manufactured in or imported into Korea require a pre-notification before the registration phase.
The pre-notification period for existing chemical substances (listed on KECL) is from January 1st until June 30th, 2019.
Importers of this BASF SE product, as such or in formulations, that clear customs in Korea bear a basic legal obligation to do a pre-notification and registration.

** It is recommended to enquire with the national authority prior to importing the substance.

***May be used as a single component chemical under appropriate group standard

SVHC Declaration

For a statement on “Candidate List “substances according to Article 59 (1) of the REACH-Regulation, please request a up to date version of our SVHC Declaration for plasticizers.

Certificates

The Regional Business Unit Industrial Petrochemicals Europe has implemented and maintains:

- a Quality Management System that fulfills the requirements of the ISO 9001:2015 standard.
- an Environmental Management System that fulfills the requirements of the ISO 14001:2015 standard.
- an Energy Management System that fulfills the requirements of the ISO 50001 standard

Toys Certificate

We hereby confirm that the Product complies with

- EU Toy Safety Directive 2009/48/EC
- European Toys Standard DIN EN 71-3
  (Safety of toys Part 3, Migration of certain elements) with regard to metal content; the content of heavy metal traces is far below the required limits specified in this standard.
- European Toys Standard EN 71-5
  (Safety of toys – Chemical toys (sets) other than experimental sets) and can be used as plasticizer in ‘oven hardening plasticized PVC modelling clay sets’ and can also be used as plasticizer in adhesives and solvent-borne paints, lacquers, thinners, white spirit.
- European Toys Standard DIN EN 71-9
  (Safety of toys – Part 9: Organic chemical compounds – Requirements)
  The Product is not listed in EN 71-9.
- US-CPSC toy safety specification ASTM F963
- GB 6675-2014 Chinese Toy Safety Standard

Medical device regulations

We hereby confirm Hexamoll® DINCH is suitable to produce medical devices that comply with **Regulation (EU) 2017/745.** In addition, the use of Hexamoll® DINCH is <u>not</u> subject to the phthalate labelling requirements of medical devices.

Hexamoll® DINCH is listed via its chemical name (cyclohexane-dicarboxylic acid, 1,2-diisononyl ester) is listed as plastic additive 24 in the **European Pharmacopoeia (Ph. Eur.).**

Hexamoll® DINCH based medical devices produced by customers passed the respective tests according to **DIN EN ISO 10993**, e.g. cytotoxicity (ISO10993-5), haemolysis (ISO 10993-4), absence of pyrogens (ISO10993-11), irritation and sensitization (ISO 10993-10 and ISO 10993-10/A).

No cytotoxicity occurred with Hexamoll® DINCH up to the highest concentration tested (1000 µg/ml) in the Balb 3T3 cellular in-vitro test system. Further, all regulatory mandated studies undertaken with Hexamoll® DINCH in the framework of chemicals legislations did not show any indication for cytotoxicity. In the meantime, lack of cytotoxicity is also confirmed by independent third party studies as published in per-reviewed journals.

Furthermore, PVC compound based on Hexamoll® DINCH passed the systemic injection, intracutaneous and implant tests to fulfill the requirements of **United States Pharmacopoeia (USP),** Monograph 88, Class VI.

For the United States of America, **FDA Medical device master Files** (Nos. 1484 and 16323) can be referred to, e.g. in a 510(k) pre-marketing notification.

Hexamoll® DINCH based medical devices, produced by customers, were approved by the **Chinese Food and Drug Administration (CFD), Korean Food and Drug Administration (KFDA) and Japanese Ministry of Health, Labor and Welfare.**

Raw material declaration for "Exclusion Policy for Printing Inks and related Products according to EuPIA – 11/2016, 3nd edition (corrigendum Dec. 2018)"

Hexamoll® DINCH itself does not require classification according to Regulation (EC) No 1272/2008 [CLP]. The product does not contain intentionally added substances which are classified as having one of the following hazard phrases:

Group A	Group B
Acute Toxicity Cat. 1 & 2 [H300, H301, H330]	
Acute Toxicity Cat. 3 (inhalation) [H331]	Acute Toxicity Cat. 3 (oral, dermal) [H301, H311]
Carcinogen or Mutagen Cat. 1A & AB [H350, H340]	
Toxic to Reproduction Cat. 1A & 1B [H360] (non-threshold substances)	Toxic to Reproduction Cat. 1A & A B [H360] (if threshold exists)
STOT Single Exposure Cat. 1 [H370]	STOT Repeated Exposure Cat. 1 [H372]

The substances listed in "Exclusion Policy for Printing Inks and related Products according to EuPIA – 11/2016, 3nd edition (corrigendum Dec. 2018)" have not been used in the manufacture of Hexamoll® DINCH and have not been intentionally added to the product. *

Compliance with Directive 2011/65/EU (RoHS-Requirements)

Due to the production process, the Product does not contain any

- lead
- mercury
- cadmium
- hexavalent chromium
- polybrominated biphenyls
- polybrominated diphenyl ethers

nor are these substances added to the Product otherwise.

In a chemical analysis of the Product, all these substances are below the detection limit of:

Lead	< 0.005 mg/kg
Mercury	< 0.005 mg/kg
Cadmium	< 0.005 mg/kg
Chromium	< 0.005 mg/kg
PBB	< 1 mg/kg as bromine
PBDE	< 1 mg/kg as bromine

The following substances were neither present in the raw materials nor intentionally added to the production process of the Product or added to the Product otherwise

DEHP (Di(2-ethylhexyl)phthalate)

BBP (Benzylbutylphthalate)

DBP (Dibutylphthalate)

DIBP (Diisobutylphthalate)

nor are these substances added to the Product otherwise. *

Note: By using the Product it is possible to comply with the requirements of Annex II of Directive 2011/65/EU and its amendments.

Perfluorooctane sulfonates, PFOS: Compliance with Regulation (EC) No 850/2004

The chemical analysis of the Product shows a fluorine content of less than 1 mg/kg. From this result it can be calculated that there is a content of less than 2 mg/kg of perfluorooctane sulfonates (PFOS) or perfluorooctanoic acid (PFOA). This is significantly less than the limit of 10 mg/kg (0.001%) stipulated by Regulation (EC) No 850/2004. Therefore, by using Product it is possible to comply with the requirements of Regulation (EC) No 850/2004.

Compliance with EU legislation Regulation (EC) No 1907/2006, Annex XVII

Nonylphenol and Nonylphenol ethoxylates

No. 46 (nonylphenol and nonylphenol ethoxylates;
Due to the production process, the Product does not contain any nonylphenol nor nonylphenol ethoxylate nor are these substances added to the Product otherwise.)

Polycyclic aromatic hydrocarbons (PAH)

No. 50 (certain PAHs; the chemical analysis of the Product shows less than 0.5 mg/kg of any of the listed PAHs)
The Product also complies with the 18 US EPA priority PAHs.

In a chemical analysis of the Product (method used HPLC), the following PAHs were analyzed for and found to be below detection limit:

Acenaphthene	< 0.01 mg/kg
Acenaphthylene	< 0.01 mg/kg
Anthracene	< 0.01 mg/kg
Benzo(a)anthracene	< 0.01 mg/kg
Benzo(b)fluoranthene	< 0,01 mg/kg
Benzo(j)fluoranthene	< 0.01 mg/kg
Benzo(k)fluoranthene	< 0.01 mg/kg
Benzo(g,h,i)perylene	< 0.01 mg/kg
Benzo(a)pyrene	< 0.01 mg/kg
Benzo(e)pyrene	< 0.01 mg/kg
Chrysene	< 0.01 mg/kg

Dibenzo(a,h)anthracene	< 0.01 mg/kg
Fluoranthene	< 0.01 mg/kg
Fluorene	< 0.01 mg/kg
Indeno(1,2,3-cd)pyrene	< 0.01 mg/kg
Naphthalene	< 0.01 mg/kg
Phenanthrene	< 0.01 mg/kg
Pyrene	< 0.01 mg/kg

Biocides

Biocides, as mentioned below, have not been used in the manufacture of or were added to the Product. Therefore, the Product has not been analyzed for biocides. *

Biocides	CAS number
BIT	2634-33-5
CIT/MIT	55965-84-9
DCOIT	64359-81-5
MBIT	2527-66-4
MIT	2682-20-4
OIT	26530-20-1
TMAD	5395-50-6
Bronopol	52-51-7
DTBMA	2527-58-4

Analysis of chemical elements

In a chemical analysis of the Product, all of the following elements are below the detection limit of:

Aluminum (Al)	< 0.005 mg/kg
Antimony (Sb)	< 0.005 mg/kg
Arsenic (As)	< 0.005 mg/kg
Barium (Ba)	< 0.005 mg/kg
Beryllium (Be)	< 0.005 mg/kg
Bismuth (Bi)	< 0.005 mg/kg
Boron (B)	< 0.005 mg/kg
Bromine (Br)	< 1 mg/kg
Cadmium (Cd)	< 0.005 mg/kg
Calcium (Ca)	< 0.005 mg/kg
Chlorine (Cl)	< 1 mg/kg
Chromium (Cr)	< 0.005 mg/kg

Cobalt (Co)	< 0.005 mg/kg
Copper (Cu)	< 0.005 mg/kg
Fluorine (F)	< 1 mg/kg
Gold (Au)	< 0.005 mg/kg
Iron (Fe)	0.008 mg/kg
Lead (Pb)	< 0.005 mg/kg
Lithium (Li)	< 0.005 mg/kg
Magnesium (Mg)	< 0.005 mg/kg
Manganese (Mn)	< 0.005 mg/kg
Mercury (Hg)	< 0.005 mg/kg
Molybdenum (Mo)	< 0.005 mg/kg
Nickel (Ni)	< 0.005 mg/kg
Nitrogen (N)	< 2 mg/kg
Phosphorus (P)	< 1 mg/kg
Potassium (K)	< 0.005 mg/kg
Rhodium (Rh)	< 0.005 mg/kg
Selenium (Se)	< 0.005 mg/kg
Silver (Ag)	< 0.005 mg/kg
Sodium (Na)	< 0.005 mg/kg
Strontium (Sr)	< 0.005 mg/kg
Sulfur (S)	< 2 mg/kg
Tantalum (Ta)	< 0.005 mg/kg
Thallium (Tl)	< 0.005 mg/kg
Tin (Stannous) (Sn)	< 0.005 mg/kg
Titanium (Ti)	< 0.005 mg/kg
Vanadium (V)	< 0.005 mg/kg
Wolfram (Tungsten) (W)	< 0.005 mg/kg
Zinc (Zn)	< 0.005 mg/kg
Zirconium (Zr)	< 0.005 mg/kg

The theoretical content of a particular chemical compound containing a certain element can be calculated from the content of the pure element concerned.

Product origin, BSE/TSE-risk, Genetic modified organisms (GMO)

The product is produced solely from synthetic petrochemical raw materials, and no material used during the production process is of bovine or any other animal nor plant origin.

In addition, no materials used are genetically modified substances. Our product does not contain ingoing substances derived from palm oil or palm kernel oil, nor from chemical derivatives of palm oil or palm kernel oil.

Synthetic declaration	We can confirm that the manufacture of this Product meets the following requirements: The raw materials used are not of animal or of plant origin and contain no animal fat or other animal components; No glycerol, monoglycerole, gelatine or fish oil are used; No wine alcohol, cognac, grapes or grape juice are used; No milk produce, e.g. lactose etc. are used. The Product is intended for industrial use.
Animal testing	BASF SE has not performed any animal testing with the Product in order to meet the requirements of Regulation (EC) No 1223/2009 (Regulation on Cosmetic Products). However, animal testing has already been performed with the Product in order to comply with other legal requirements (e.g. Regulation (EC) No 1907/2006) and we reserve the right to do so at any time, if necessary.
MOSH / MOAH	The Product does not contain intentionally added mineral oil components: MOSH (Mineral Oil Saturated Hydrocarbons) or MOAH (Mineral Oil Aromatic Hydrocarbons). *
Silicone nor Siloxane compounds	The product does not contain any intentionally added Silicone nor Siloxane compounds. *
Benzene, Toluene, Styrene, Phenol, Bisphenols, BHT (2,6 di-tert.-Butyl-4-methylphenol), Formaldehyde, Asbestos	The Product does not contain any intentionally added Benzene, Toluene, Styrene, Phenol, Bisphenols, BHT (2,6 di-tert.-Butyl-4-methylphenol), Formaldehyde nor Asbestos. *
	* BASF does not routinely analyze the product nor the raw materials for the presence of these compounds. Based on our knowledge of the manufacturing process and the composition of raw materials and additives involved, it can be stated with a reasonable degree of certainty that these substances should not be present in our Product. However, inherent trace levels cannot be excluded (e.g. resulting from loading and unloading operations).
Conflict Minerals Declaration and Dual Use Declaration	Available on request, please contact: cp-trade-control@basf.com

Note

The data contained in this Product Information Sheet is based on our current knowledge and experience as well as our investigations according to the today's state-of-the-art. In view of the many factors that may affect processing and application of the Product, these data do not relieve processors from carrying out their own investigations and tests; neither do these data imply any guarantee of certain properties, nor the suitability of the Product for specific purpose. No liability of BASF can be derived therefrom. It is the responsibility of the recipient of the Product to ensure that any proprietary rights and existing laws and legislation are observed.

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(Electronically signed, valid without signature)