Risk Management Option Analysis Conclusion Document

Substance Name: 1,2-CYCLOHEXANEDICARBOXYLIC ACID, DIISONONYL ESTER (DINCH®)

EC Number: 431-890-2

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Authority: France

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Legal instrument	EU/national	Status of DINCH
Regulation EU No. 10/2011 on substances in contact with food Based on EFSA opinion	Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) - 12th list of substances for food contact materials	In September 2006 the scientific panel on AFC from EFSA evaluated the safety of DINCH. The substance was then authorized to be used in food contact materials. A TDI of 1 mg/kg bw/day was derived.
European References	Harmonised Standards EN 71-3 (Safety of toys - Part 3: Migration of certain elements); EN 71-5 (Safety of toys - Part 5: Chemical toys (sets) other than experimental sets) and EN 71-9 (Safety of toys – requirements concerning organic chemical compounds)	According to BASF DINCH satisfies the requirements of these standards.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	x

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

No need for follow-up regulatory action at EU level.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

No need for action other than EU regulatory action.

5. NO ACTION NEEDED AT THIS TIME

DINCH is a substance that has been developed to replace phthalates in various applications, especially in sensitive ones like medical devices or toys. In the framework on the French National Strategy on Endocrine Disruptors in 2014, the French Competent Authority requested ANSES to evaluate its toxicological profile and verify whether risk management measures should be necessary for this substance.

It should first be recognized that DINCH is a well studied substance for which several recent long term studies have been provided. All the requirements as described in the annexes VII, VIII, IX & X have been fulfilled. It should also be noted that two Member States (Denmark and Sweden) have performed comparative evaluations of alternative plasticisers such as DINCH and both concluded that DINCH is a promising alternative included for sensitive uses like medical devices.

Based on available data, exposure to DINCH lead to modifications of thyroid gland volume and therefore induced adenoma and hyperplasia in rodents. Based on the fact that, compared to humans, rodents have a specific thyroid morphology and have therefore an increased susceptibility to develop thyroid cancer and since the doses leading to effects are very high, it is very unlikely that DINCH is a carcinogenic substance for humans.

The non relevance for humans of such effect on thyroid observed in rodent has been recently questioned. It has lately been showed that a possible link could exist between hypothyroid and hepatic cancer in humans (Hassan *et al*., 2009). However, it should be noted that the relevance of effects on thyroid observed in rodents is not specific to the DINCH itself but is a general question. This topic has to been touched upon at the European level, as asked by FR in the ECHA ED expert group in November 2014. Indeed, the publication cited above shows new highlights on the relevance of thyroid effects observed in animals (especially rodents) and therefore the choice of the species to use when new studies need to be conducted.
The levels of thyroid hormones have only been measured in the 90-d study and were not affected despite a significant increase of TSH in females. Therefore an effect on circulating thyroid hormones levels is not expected.

However, it has been pointed out that early thyroid hormones disruption (during pregnancy or early life) may lead to neuro-cognitive impairments like effects on the IQ or development impairments (Haddow *et al*., 1999). The sensitivity of developing fetuses to hormonal level, combined to the fact that DINCH is intended to replace phthalates in medical devices in neonatal services, leads to identify a remaining uncertainty when a very sensitive population, i.e. premature babies, may be exposed to DINCH. In the publication by Bhat *et al*. (2014), a MoS was calculated leading to an absence of risk when exposed to PVC tubing containing DINCH. Nevertheless, the mode of action of the substance remains unknown and the risk for this type of sensitive population has to be carefully assessed since the number of premature births is increasing these days due to a growing number of IVF for instance. However, this remaining uncertainty is related to a use that is outside the scope of REACH. Therefore there is no justification to put this substance on CoRAP in order to get additional information on this specific use in medical devices.

Additionally, since the levels of DINCH are increasing, due to an extensive use as an alternative to restricted phthalate, when more exposure data has become available from biomonitoring data programs and survey, it should be examined whether margins of exposure are still sufficient.

Based on these information, and taking into account that DINCH is developed as a substitute for phthalates, FR-CA believes that with the data in hands at this time, DINCH requires for the moment no further risk management measures under this regulation.