



Declaration – REACH regulation

R3-DE-021

Version : 1.2

Date : 09/04/20

LACTIPS produces and sells thermoplastic pellets made of milk proteins.

These pellets are transformable by all conventional plastics processing industry. Pellets are biosourced, biodegradable, water-soluble, edible...

1. Raw materials

Lactips is a downstream user of casein. Casein has the status of natural polymer of amino acids under REACH ⁽¹⁾.

Lactips is a downstream user of other substances **listed in Annex IV to REACH Regulation**, and therefore exempted from the obligation to register, or **listed in Annex V** as substances obtained from natural sources.

If, during scientific advances, LACTIPS is getting to use substances not listed in Annex IV or V, **LACTIPS engages itself to check if the substances require registration.**

2. Manufacturing process

Lactips transforms casein and other substances into thermoplastics pellets, thanks to a twin-screw extrusion process. Transformation is operated at low temperature. Twin-screw extrusion process enables the plastification of casein with glycerol.

Given our current knowledge, no covalent bond is created during the manufacturing process. Only hydrogen or electrostatic bonds are formed.

Thanks to an electrophoresis performed before and after transformation, it has been established that, in the pellets, the proteins keep the same molecular weight⁽²⁾.

As a result we can conclude that **Lactips doesn't produce a substance of Unknown or Variable Composition, Complex Reaction Products or Biological Materials (UVCB).**

Milk protein is a natural protein. As mentioned in the Q&As n° 1134 from ECHA, natural proteins can be considered as polymers under REACH if they meet the definition chapter 3.5 : "Natural proteins may be considered as polymers under REACH provided that they have at least 50 weight percent of polymer molecules (in this case, molecules including a sequence of at least four amino acid monomer units) and the content of molecules presenting the same molecular weight remains below 50 weight percent. "

As mentioned in the patent⁽³⁾, Lactips pellets are composed of 50 to 85% by weight of milk protein, namely the natural polymer.

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Moreover, the amount of polymer molecules presenting the same molecular weight is less than 50% (by weight) ⁽⁴⁾.

Based on this analysis, and according to the criteria proposed in the email from Helpdesk REAC-CLP on the 5th of December 2017, our material can be considered as a natural polymer.

Therefore, we can conclude that **Lactips is producing a natural polymer, and exempted from the registration according to the REACH Regulation.**

- ⁽¹⁾ Declaration on the polymer status of casein derived from milk of the European Association of Dairy Trade (EUCOLAIT) and the European Dairy Association (EDA) (03.11.2010)
- ⁽²⁾ Thèse Imane Belyamani « *Développement d'un matériau thermoplastique biodégradable et hydrosoluble à base d'une protéine de lait* » P.97 à 100
- ⁽³⁾ Brevet Lactips déposé en décembre 2017 « *MATERIAU THERMOPLASTIQUE BIODEGRADABLE A BASE DE CASEINE ET/OU DE CASEINATE* »
- ⁽⁴⁾ Livre « *Structures et technofonctions des protéines de lait* » de philippe Cayot et Denis Lorient – p.23 & p.52

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SUIVI DES EVOLUTIONS DU DOCUMENT			
<i>Date</i>	<i>Indice</i>	<i>Nature des évolutions du document</i>	
11/06/2019	1.1	Intégration de cette version anglaise dans le système qualité	
09/04/2020	1.2	Regarding the update dated 16/01/2020 concerning the 4 new substances added to the list of candidate substances, the Lactips product is not affected by this new update. None of the substances listed are involved in the manufacture of the Lactips product and therefore in the final product.	