Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Amylase, α-
Chemical Group:	Enzyme
EC Number:	232-565-6
CAS Number:	9000-90-2
Submitted by:	UK
Published:	26/03/2014

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Amylase, α-
IUPAC name:	Alpha-amylase IUBMB 3.2.1.1
Index number in Annex VI of the CLP Regulation	647-015-00-4
Molecular formula:	Not available
Molecular weight or molecular weight range:	> 40000 < 80000
Synonyms/Trade names:	None listed

Type of substance ☐ Mono-constituent ☐ Multi-constituent ☒ UVCB

Structural formula: Not available

1.2 Similar substances/grouping possibilities

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement(s)
Resp. Sens 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

2.2 Self classification

- In the registration

  The self classification in the registration is identical with the harmonized classification in Annex VI of the CLP.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Classification	
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**
Acute Tox. 3	H301
Acute Tox. 4	H312
Acute Tox. 3	H331
Skin Corr. 1B	H314
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No current proposals to amend the Annex VI entry.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Please provide further details if appropriate		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

This enzyme is manufactured in the EU. It is used as a processing aid, it is formulated into various cleaning products that are supplied for professional or consumer use and it is incorporated into laundry detergents. The PROC codes that have been listed for some scenarios include PROC 11 (non-industrial spraying) and/or PROC 13 (treatment of articles by dipping and pouring).

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☒ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☒ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☒ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)
This enzyme is classified as a respiratory sensitiser. Uses have been identified which have the potential to create exposures sufficient to produce adverse reactions in workers or consumers if suitable controls are not implemented. It is important to clarify the approach that has been taken to assess exposures for the manufacture and use of this enzyme and the benchmarks (DMELs) against which the acceptability of exposure has been judged.		

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
n/a	

[1] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

4.5 Preliminary indication of information that may need to be requested to clarify the concern

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

Depending on the outcome of the evaluation, a request may be made for further exposure data to clarify the levels of exposure that arise during various uses. This could include industrial, professional or consumer uses.

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☒ Other (provide further details)

Follow up actions will be considered once the exposure information and risk characterisation approach has been evaluated, but it is possible that any of the above may be required.