



Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y) ¹
308-662-5	98171-53-0	Butanoic acid, 4-amino-4-oxosulfo-, N-coco alkyl derivs., monosodium salts, compds. with triethanolamine	<p style="text-align: center;">R=C12-C18 (even numbered)</p>	Full Tonnage data confidential

Authority: Anses, France

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Revision history

Version	Date

Cover Note

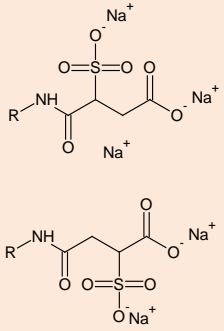
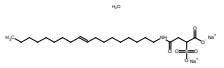
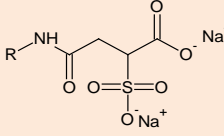
This document has been prepared by the evaluating Member State given in the CoRAP update.

¹ Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

1. Background

1.1 Analogue substances

Analogue substances listed below are amides from sulfosuccinates based on the assessment of regulatory needs (ARN) on Sulfocarboxylic acids and esters (no succinates).²

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y)
939-691-7	-	Butanoic acid, 4-amino-4-oxo-2(or 3)-sulfo-,N-(C16-C18 (even numbered), C18 unsaturated alkyl)), disodium salts	 <p>R= C16, C18, C18'</p>	Full ≥ 100 to < 1 000
261-222-3	58353-68-7	disodium (Z)-4-(9-octadecenylamino)-4-oxo-2(or 3)-sulphonatobutyrate		No active registrations
273-537-3	68988-69-2	Butanoic acid, 4-amino-4-oxosulfo-, N-tallow alkyl derivs., disodium salts	 <p>R= C16, C18, C18'</p>	Not registered (C&L notification)

1.2 Overview of ongoing/ completed/ other processes & other EU legislation

EC/ List number	Evaluation			CLH	Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
308-662-5	No ongoing or completed process					

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)

EC/ List number	Other EU legislation	Previous legislation	Stockholm convention	Other
	PPP/ BPR	NONS/ RAR	POP	(e.g. UNEP)
308-662-5	No ongoing or completed process			

² <https://echa.europa.eu/assessment-regulatory-needs/-/dislist/details/0b0236e184d072e5>

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>].

The CLP Regulation and all published ATPs are available on ECHA website: <http://echa.europa.eu/web/guest/regulations/clp/legislation> .

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
308-662-5	98171-53-0	Butanoic acid, 4-amino-4-oxosulfo-, N-coco alkyl derivs., monosodium salts, compds. with triethanolamine	No harmonised classification	Skin Irrit. 2 H315 Eye Dam. 1 H318	Skin Irrit. 2 H315 (122) Eye Dam. 1 H318 (106) Eye Irrit. 2 H319 (16) Not classified (27)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers. Therefore the number may differ from the C&L inventory which displays number of notifiers.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website)*
308-662-5	Confidential

* The total tonnage band has been calculated by excluding the intermediate uses, - See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11):

https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

3.2 Overview of the Uses

Main types of applications	EC 308-662-5 Key information
Industrial use	use in laboratory, in industrial chemical processes, as dispersing agent
Professional use	use in laboratory, as dispersing agent
Consumer Use	adhesives and sealants, coating and paints, fillers, putties, plasters, modelling clay, metal surface treatment products, non-metal-surface treatment products, inks and toners, leather treatment products and polymers
Article service life	dispersing agent
Intermediate use (if TII)	
Formulation	use in laboratory, in industrial chemical processes, as dispersing agent

4. Justification for inclusion on the CoRAP

4.1 Legal basis

- Article 44(2)³
 Article 45(5)⁴

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	<input type="checkbox"/> Carcinogenic <input type="checkbox"/> Mutagenic <input checked="" type="checkbox"/> Reproductive toxicant
Potential ED	<input checked="" type="checkbox"/> Human Health <input checked="" type="checkbox"/> Environment
Suspected Sensitiser	<input type="checkbox"/> Respiratory <input type="checkbox"/> Skin
Specific target organ toxicity – repeated (STOT RE)	<input type="checkbox"/> (as defined in section 4.3 below)
Suspected PBT/ vPvB Suspected PMT/ vPvM	<input type="checkbox"/> Persistent <input type="checkbox"/> Bioaccumulative <input type="checkbox"/> Mobile <input type="checkbox"/> Toxic (as defined in section 4.3 below) <input type="checkbox"/> very Persistent <input type="checkbox"/> very Bioaccumulative <input type="checkbox"/> very Mobile
Other human health hazard(s)	<input type="checkbox"/> (as defined in section 4.3 below)
Other environmental hazard(s)	<input type="checkbox"/> (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	<input type="checkbox"/>
Consumer use	<input checked="" type="checkbox"/>
Exposure of workers	<input checked="" type="checkbox"/>
Exposure of sensitive populations	<input type="checkbox"/>
Exposure of environment	<input checked="" type="checkbox"/>
Cumulative exposure	<input type="checkbox"/>
High RCR	<input type="checkbox"/>
High (aggregated) tonnages	<input type="checkbox"/>
Others (to be specified)	<input type="checkbox"/>

³ “The Agency shall use the criteria in paragraph 1 [...]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment.”

⁴ “A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. [...]”.

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern

As indicated on ECHA website and in the ARN dedicated to Sulfo-carboxylic acids and esters (no succinates)⁵, Butanoic acid, 4-amino-4-oxosulfo-, N-coco alkyl derivs., monosodium salts, compds. with triethanolamine (EC 308-662-5), hereinafter the Substance, has a potential for ED properties. Indeed, a decrease in the anogenital distance was observed in male pups in an OECD TG 422 study. Modification of the anogenital distance is a marker of potential endocrine disruption therefore a concern for ED is identified and the potential for ED properties needs to be further investigated.

Additionally, based on the effects observed in the structurally related substance EC 939-691-7, a concern exists also for reproductive and developmental toxicity. Indeed, in an OECD TG 422 study, an increase in pre- and post-implantation losses and reduced gestation and birth index are observed. This related substance has a self-classification as Repro 1B.

The assessment will mainly focus on ED properties for human health but ED properties for the environment may be considered in a comprehensive approach.

Other relevant information to justify the inclusion in CoRAP

The Substance has a potential for consumer, worker and environmental exposure.

Information to be potentially requested

An EOGRTS with a design fit for purpose may be requested in order clarify both reproductive and ED concern.

Possible follow-up (demonstrating the improvement of risk management measures)

EC/ List number	Harmonised C&L	Restriction	Authorisation	Other
308-662-5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

⁵ <https://echa.europa.eu/fr/assessment-regulatory-needs/-/dislist/details/0b0236e184d072e5>