Regulatory Management Option Analysis (RMOA)

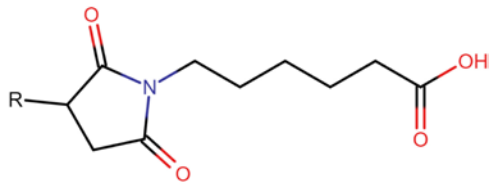
Conclusion Document

Authority: Austria

Date: June 2024

Substance name: 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid

General structure:

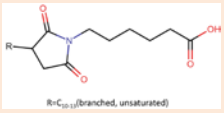


$R=C_{10-13}$(branched, unsaturated)

(**source:** European Chemicals Agency)

Revision history

Version	*Date*	*Description*
1	June 2024	Final version for publication
2		

EC/List number	CAS number	Substance name [and Substance name acronyms (*)]	Chemical structure(s)	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y)
701-118-1[1]	2156592-54-8	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid [Tetra-PSCA]	 **(source:** European Chemicals Agency**)**	Registered, full 10-100t

[1] For the substance EC number and name have been changed in the course of a CCH from EC 800-770-5 to 701-118-1 (SID adaptation request) (ECHA correspondence May, 2017).

Contents

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ATP	Adaptation to Technical Progress
ART	Advanced REACH Tool
BPR	Biocidal Products Regulation
CA	Competent Authority
CCH	Compliance Check
CLH	Harmonised Classification and Labelling
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
LEV	Local Exhaust Ventilation
LOAEL	Lowest Observed Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
OEL	Occupational Exposure Limit
OSII or TII	On-site Isolated Intermediate or Transported Isolated Intermediate
PPE	Personal Protective Equipment
PROC	Process Category
RCR	Risk Characterisation Ratio
RMOA	Regulatory Management Options Analysis
RRM	Regulatory Risk Management
SEv	Substance Evaluation
SVHC	Substance of Very High Concern
Tetra-PSCA	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid
UVCB	Unknown or variable composition

1 Overview of the substance / group of substances

EC 701-118-1 (6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid; Tetra-PSCA) is a UVCB substance with a full registration. The substance is manufactured and used in the EU at 10-100 tpa. Tetra-PSCA has a harmonized classification as Repr. 1B, H360FD.
Based on the information in the REACH registration Tetra-PSCA is used in following product categories: lubricants, greases, release products and metal working fluids. The registration covers industrial and professional uses, consumer uses were not registered. There are several uses with high potential for exposure.

2 Conclusions and proposed actions

The conclusion and action proposed in the table below is based on the REACH and CLP information available at the time of the assessment. The main source of information is the registration dossier. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
EC 701-118-1	Known or potential hazard For reproductive toxicity	No hazard or unlikely hazard	Industrial and professional use in lubricants, greases, release products and metal working fluids Uses with high exposure potential	**SVHC identification** Justification: EC 701-118-1 has a harmonized classification as Repr. 1B, H360FD and fulfils the REACH, Article 57(c) criteria. There are several uses with high potential for exposure (close to one or even higher).

3 Justification for the need for regulatory risk management action at EU level

EC 701-118-1 has a harmonized classification as Repr. 1B, H360FD and fulfils the REACH Article 57(c) criteria. Tetra-PSCA is manufactured and used in the EU in medium tonnages.

Tetra-PSCA is registered for use in lubricants, greases, release products and metal working fluids. The registration covers industrial and professional uses. Consumer uses were not registered.

DNEL derivation by registrant is not strictly following ECHA guidance und should be lower. Further, exposure predictions are not considered to be performed properly and are deemed too low. Given that there are several uses with high potential for exposure a concern for these used has been identified and further risk management measures are deemed necessary.

Authorisation is considered the best suited RMO for Tetra-PSCA. Identification as an SVHC and subsequent authorisation would increase incentives for industry to progressively substitute uses by suitable alternatives. For specific uses for which this might not be possible within a short time, authorisation would allow for continued use and, at the same time, ensure that for these uses workers are well protected.

Annex 1: Overview of classifications

Data consulted on 26/03/2024

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
701-118-1	2156592-54-8	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	*Eye Irrit. 2, H319* *Repr. 1B, H360FD*	*Eye Irrit. 2, H319* *Repr. 1B, H360FD*

Annex 2: Overview of uses based on information available in registration dossiers

Data consulted on 26/03/2024

Main types of applications structured by product or article types	EC/ List 701-118-1
Use in Hydraulic fluids	F, I, **P**
Use in Lubricants, greases, release products	F, I, **P**
Use in Metal working fluid	F, I, **P**

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data consulted on 26/03/2024

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
701-118-1	-	-	-	-	Yes	-