

Assessment of regulatory needs

Authority: European Chemicals Agency

Group name: Saccharides

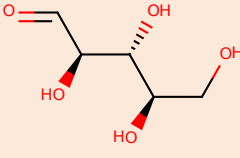
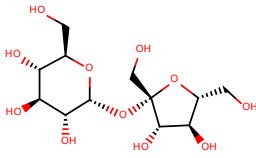
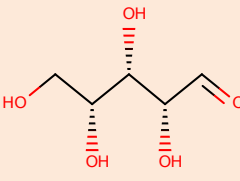
General molecular formula: $C_mH_{2n}O_n$

Revision history

<i>Description</i>		
1.0	13 May 2024	
1.1	24 June 2024	

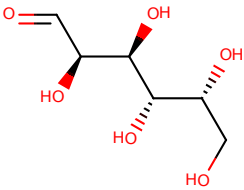
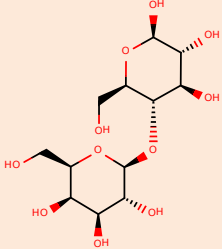
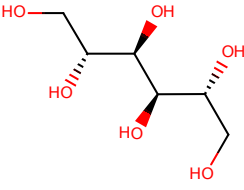
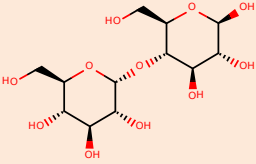
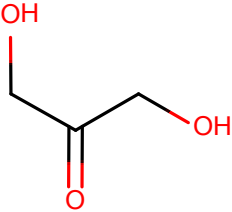
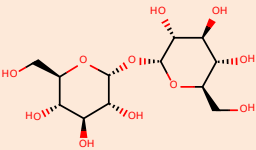
ASSESSMENT OF REGULATORY NEEDS

Table 1: Substances within this group

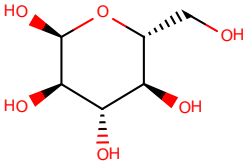
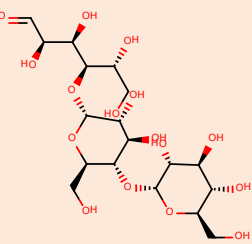
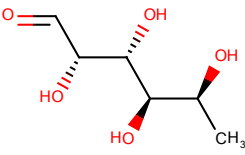
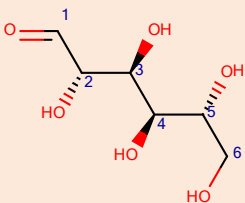
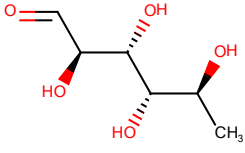
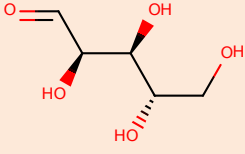
EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
200-059-4	50-69-1	D-ribose		Full, not (publicly) available
200-075-1	50-99-7	Glucose	No Structure	C&L notification
200-333-3	57-48-7	Fructose	No Structure	C&L notification
200-334-9	57-50-1	Sucrose		C&L notification
200-400-7	58-86-6	Xylose		Full, 100-1000

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

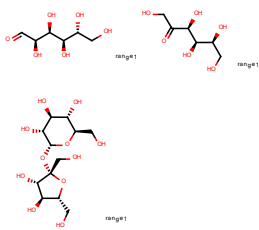
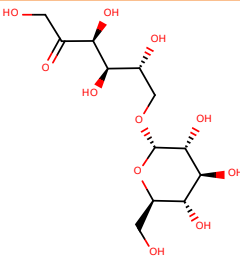
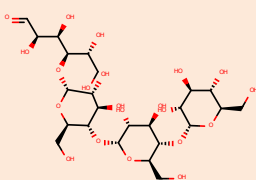

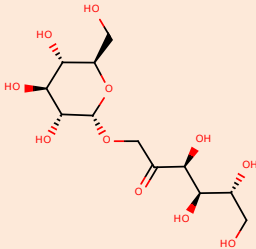
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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
200-416-4	59-23-4	Galactose		C&L notification
200-559-2	63-42-3	Lactose		C&L notification
200-711-8	69-65-8	D-mannitol		C&L notification
200-716-5	69-79-4	Maltose		Full, 1-10
202-494-5	96-26-4	1,3-dihydroxyacetone		Full, 100-1000
202-739-6	99-20-7	Trehalose		Full, 10-100


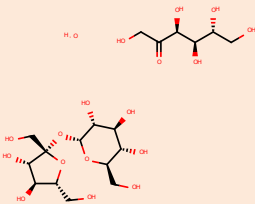
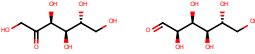


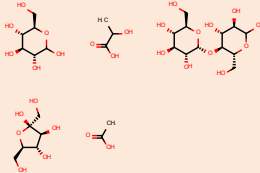
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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
207-757-8	492-62-6	α -D-glucose		C&L notification
214-174-2	1109-28-0	O- α -D-glucopyranosyl-(1 \rightarrow 4)-O- α -D-glucopyranosyl-(1 \rightarrow 4)-O- α -D-glucopyranose		C&L notification
219-452-7	2438-80-4	6-deoxy-L- β -galactose		C&L notification
222-392-4	3458-28-4	D-mannose		Full, 10-100
222-793-4	3615-41-6	6-deoxy-L-mannose		Full, 10-100
226-214-6	5328-37-0	L-arabinose		Full, 10-100

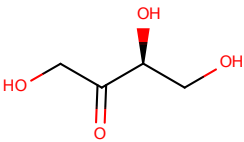
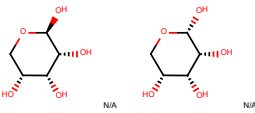
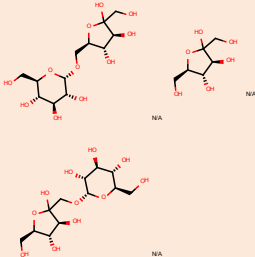
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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
232-393-1	8013-17-0	Sugar, invert		Full, > 1000
232-541-5	9000-40-2	Carob gum	No Structure	C&L notification
237-282-1	13718-94-0	6-O-α-D-glucopyranosyl-D-fructose		C&L notification
252-111-0	34612-38-9	O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-glucose		C&L notification
254-409-6	39300-88-4	Tara gum	 UVCB	Full, not (publicly) available
257-183-7	51411-23-5	1-O-α-D-glucopyranosyl-D-fructose		Not registered

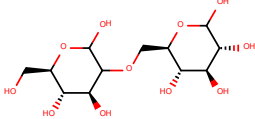
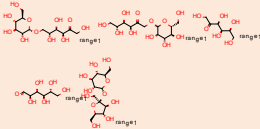
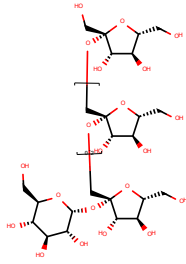
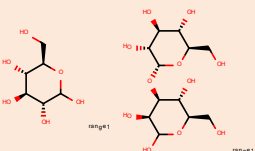
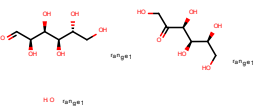
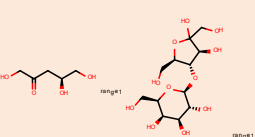
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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
283-619-0	84695-99-8	Chestnut, <i>C. sativa</i> , ext.	 <p>UVCB</p>	Full, not (publicly) available
284-634-5	84961-45-5	Ceratonia siliqua, ext.		Full, 10-100
290-179-3	90082-87-4	Plum, ext.		Full, not (publicly) available
290-271-3	90106-48-2	Rye, ext.	 <p>UVCB</p>	Full, not (publicly) available
296-251-0	92456-72-9	Cassava, ext.	 <p>UVCB</p>	Full, not (publicly) available
309-358-5	100209-50-5	Wheat, ext., hydrolyzed		OSII or TII

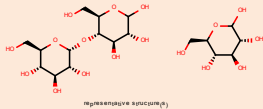
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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
443-800-9	533-50-6	(3S)-1,3,4-Trihydroxy-2-butanone		Full, 10-100
607-053-4	223751-74-4	Enzymatic hydrolysis products of <i>Palmaria palmata</i> extract	☐ UVCB	Full, not (publicly) available
607-980-4	26655-34-5	α-D-Glucopyranose	No Structure	Not registered
613-294-6	6363-53-7	2-(hydroxymethyl)-6-[4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxane-3,4,5-triol	No Structure	C&L notification
700-481-3	10257-32-6	D-Ribopyranose		Cease manufacture
700-515-7	1236007-63-8	Reaction mass of 6-O-α-D-glucopyranosyl-D-fructofuranose and 1-O-α-D-glucopyranosyl-D-fructofuranose and D-fructofuranose		Full, not (publicly) available

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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
812-241-6	-	Enzymatic hydrolysis products of <i>Ophiopogon japonicus</i> , Liliaceae, root		Full, not (publicly) available
900-501-2	-	Reaction mass of 1-O- α -D-glucopyranosyl-D-fructose and 6-O- α -D-glucopyranosyl-D-fructose and fructose and glucose and sucrose		Full, not (publicly) available
908-300-1	-	Short Chain Fructo Oligosaccharides		Full, 10-100
931-687-3	-	Syrups, wheat, hydrolyzed starch		Full, >1000
932-346-1	-	Reaction mass of glucose and fructose and water		Full, 100-1000
938-691-4	-	Reaction mass of (4S)-1,4,5-trihydroxypentan-2-one and 4-O- β -D-galactopyranosyl-D-fructofuranose		OSII or TII

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EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
944-507-3	-	Polysaccharids of kernel Avena sativa, Poaceae	No Structure	Full, not (publicly) available
944-860-3	-	Amaryllidaceae, Allium Cepa L. (fresh bulb), Rutaceae, Citrus Limon (L.) Burm. F. (fresh pulp), extract, sodium chloride	☐ UVCB	Full, not (publicly) available
946-767-3	-	Saccharides of mannose and galactose from Ceratonia Siliqua seed	☐ UVCB	Full, not (publicly) available
949-975-2	-	Carbohydrates from malted barley		Full, not (publicly) available
950-727-0	-	Extract from the seeds of Trigonella foenum-graecum (Fabaceae) obtained by extraction with polar solvents	☐ UVCB	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation; however, the list is not necessarily exhaustive.

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DISCLAIMER

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Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)². These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level³. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

² [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

³ Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/VPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

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Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website⁴.

⁴ <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the carbohydrate moiety with the indicative molecular formula $C_mH_{2n}O_n$. This group "saccharides" (also called "carbohydrates" or "sugars") consists of 46 substances. There are 28 substances with full registrations, 2 intermediates, and 16 without registrations (some within the exemption under Annex IV to the REACH Regulation). Some are of plant origin (including saccharide-rich UVCBs) and the origin of some is undefined.

Based on information reported in the REACH registration dossiers, nine of the substances are intended only for industrial use and formulation. All of the others appear in professional and consumer products and a few may be present in articles. The substances are used in the majority of the product categories, the most common being the washing and cleaning products, cosmetics, pharmaceuticals, perfumes/fragrances, fillers, and textile dyes. All are used as laboratory chemicals.

On individual level, two of the substances merit a specific mention: the smallest of saccharides, dihydroxyacetone (EC 202-494-5, DHA) as well as L-erythrulose (EC 443-800-9) are used as tanning agents in self-tanning products. They react with the amino acids in skin, producing a brown colour via the Maillard reaction.

It should be noted that for the substances without registration, also use information is lacking. However, most of those (simple saccharides) would be used in the food and pharmaceutical industries as well as in a variety of other industrial applications (such as glucose in leather tanning and sucrose in cosmetic products).

As the substances are often used in professional and consumer products, their use is widespread leading to professional and consumer exposure. As the substances are readily biodegradable, their life-time in the environment is expected to be negligible.

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. 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 substance name	Human Hazard	Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
200-416-4 200-559-2 200-711-8 200-716-5 202-494-5 202-739-6 207-757-8 214-174-2 219-452-7 222-392-4 222-793-4 226-214-6 232-393-1 232-541-5 237-282-1 252-111-0 254-409-6 257-183-7	No hazard or unlikely hazard		Known or potential hazard for aquatic toxicity for 944-860-3. No hazard or unlikely hazard for all other substances	A variety of uses, including in washing and cleaning products, cosmetics, pharmaceuticals, perfumes/fragrances, and textile dyes. High exposure potential for most.	No action <u>Justification:</u> Considering the low hazard nature of the group and high structural similarity among group members, currently no regulatory action is recommended.

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Subgroup EC/List substance name	name, no,	Human Hazard	Health	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
283-619-0						
284-634-5						
290-179-3						
290-271-3						
296-251-0						
309-358-5						
443-800-9						
607-053-4						
607-980-4						
613-294-6						
700-481-3						
700-515-7						
812-241-6						
900-501-2						
908-300-1						
931-687-3						
932-346-1						
938-691-4						
944-507-3						
944-860-3						
946-767-3						
949-975-2						
950-727-0						

3 Justification for the no need for regulatory risk management action at EU level

Currently no need to suggest (further) regulatory risk management actions for any of the substances.

Based on currently available information, there is no need for (further) EU regulatory risk management for any of the substances in the group.

The group consists of simple sacharides some of which fall under the REACH registration exemptions according to Annex IV such as Glucose (200-075-1), Fructose (200-233-3), Sucrose, pure (200-334-9), Galactose (200-416-4), Lactose (200-559-2) and L-sorbose (200-711-8) and oligosaccharides that are UVCB substances.

All group members are unlikely to fulfil the PBT/vPvB screening criteria, because they are considered to be readily biodegradable and are unlikely to fulfil the T criterion. All of the substances are highly water soluble and have low log K_{ow} . None are surface-active or ionisable and all are readily biodegradable. Based on the available data none of the substances are bioaccumulative. Some group members are mobile. One substance considered as an outlier of the group (List 944-860-3) is self-classified as Aquatic Chronic 3. Based on the information available, all group members are considered unlikely PBT/vPvB and PMT/vPvM.

No potential hazards are identified for human health for all group members. These conclusions are based on the available data on the registered substances, considerations of the properties due to natural origin of the some group members and the availability as food items as well as extrapolation of hazard hypothesis due to structural similarity.

Mutagenicity studies and skin sensitisation assays are available for several of the group members and do not indicate concern for those hazards.

Experimental data on repeated dose toxicity and reproductive toxicity are limited but the available data does not indicate any concern including absence of hazard for endocrine disruption and carcinogenicity. In addition, general knowledge on the simple sacharides that are also constituents of the UVCB substances in the group as food items does not indicate any hazard potential.

Annex 1: Overview of classifications

Data extracted on 8 August 2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification registrations	in
944- 860-3	-	Extract of Allium Cepa (Amaryllidaceae) bulb and Citrus Limon (Rutaceae) pulp and sodium chloride	-	Eye Irrit. 2B H319 Aquatic Chronic 3 H412	

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

Data extracted on 9 August 2023

EC number	200-059-4	200-400-7	200-716-5	202-739-6	222-392-4	222-793-4	226-214-6	232-393-1	443-800-9	700-481-3	700-515-7	900-501-2	908-300-1	932-346-1	938-691-4	202-494-5	254-409-6	283-619-0	284-634-5	290-179-3	290-271-3	296-251-0	309-358-5	607-053-4	812-241-6	931-687-3	944-507-3	944-860-3	946-767-3	949-975-2	950-727-0	
ph-regulators, etc		f, i, p	f, i, p	i, p	f, i, p																					f, i, p						
Water treatment											p															f, i, p						
Adsorbents					f, i	f, i					f, i															f, i, p						
PC 12: Fertilisers				f, p, c				f, i, p, c				p		f, i, p, c																		
PPP														c												f, i, p, c						
Anti-freeze																										f, i, p, c						
Washing and cleaning			f, i, p					p, c	f, i, p, c					p, c	i											f, i, p, c						
Biocidal products				f				c	f, i, p, c					c												f, i, p, c						
Fragrances	i	f, i, p, c		f, i, c	f, i, p, c	f, i, c		c	f, c					f, c		c	f, c	f, c	f, i	f	f, c	f, c			f, c	f, c		f, c		f, c		f, i

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

Data extracted on 11 August 2023

EC/List No	RMOA, ARN	Authorisation	Restriction*		CLH	Actions not under REACH/ CLP
			Candidate list	Annex XIV		
200-075-1						Food contact material
200-333-3						PPP, BPR
200-334-9						Food contact material, PPP, OEL
202-494-5						Cosmetics: Annex III
309-358-5						Cosmetics: allowed ingredient

There are no relevant completed or ongoing regulatory risk management activities for the other substances.