SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	HELIX
UFI	KU70-70K5-H001-1Y38
Product code (UVP)	05988667

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use	Fungicide

1.3 Details of the supplier of the safety data sheet

Supplier	Bayer CropScience Ltd Bayer Ltd 1st Floor, The Grange Offices The Grange, Brewery Road Stillorgan A94 H2K7 Co. Dublin Ireland
Telephone	+353 1 216 3300
Responsible Department	Email: gb-bcs-crop-regulatory-affairs@bayer.com

1.4 Emergency telephone no.

Emergency telephone no.	00800 1020 3333 (24 hr) (not available on non-contract mobile phones)
For Medical Professionals:	You can also contact Dublin NPIS.
For Members of the Public:	You can also contact 01 809 2166 (for Republic of Ireland).

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Acute toxicity: Category 4
H302 Harmful if swallowed.

Acute toxicity: Category 4
H332 Harmful if inhaled.

Skin irritation: Category 2
H315 Causes skin irritation.

Eye irritation: Category 2
H319 Causes serious eye irritation.

Specific target organ toxicity - single exposure: Category 3
H335 May cause respiratory irritation.

Specific target organ toxicity - repeated exposure: Category 2
H373 May cause damage to organs (Eyes) through prolonged or repeated exposure.

Reproductive toxicity: Category 2
H361d Suspected of damaging the unborn child.

Acute aquatic toxicity: Category 1
H400 Very toxic to aquatic life.

Chronic aquatic toxicity: Category 1
H410 Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Hazard label for supply/use required.

Hazardous components which must be listed on the label:

- Prothioconazole
- Spiroxamine
- N,N-Dimethyl decanamide

Signal word: Warning

Hazard statements

H302 + H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H373	May cause damage to organs (Eyes) through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H361d	Suspected of damaging the unborn child.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
EUH208	Contains 2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione, Spiroxamine. May produce an allergic reaction.

Precautionary statements

P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P312	Call a POISON CENTER/doctor/physician if you feel unwell.
P410	Protect from sunlight.
P501	Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site, except for triple rinsed empty containers which can be disposed of as non-hazardous waste.

2.3 Other hazards

No additional hazards known beside those mentioned.

Prothioconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB). Spiroxamine: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB). N,N-Dimethyldecanamide: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical nature

Emulsifiable concentrate (EC)
Prothioconazole/Spiroxamine 160:300 g/l

Hazardous components

Hazard statements according to Regulation (EC) No. 1272/2008

Name	CAS-No. / EC-No. / REACH Reg. No.	Classification REGULATION (EC) No 1272/2008	Conc. [%]
Prothioconazole	178928-70-6	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	16.3
Spiroxamine	118134-30-8	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT RE 2, H373 Repr. 2, H361d Aquatic Acute 1, H400 Aquatic Chronic 1, H410	30.6
N,N-Dimethyl decanamide	14433-76-2 238-405-1 01-2119485027-36-XXXX	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412	> 20

Further information

Prothioconazole	178928-70-6	M-Factor: 10 (acute), 1 (chronic)
Spiroxamine	118134-30-8	M-Factor: 100 (acute), 100 (chronic)

For the full text of the H-Statements mentioned in this Section, see Section 16.

Particle characteristics

This substance/ mixture does not contain nanoforms

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Inhalation	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
Skin contact	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a physician or poison control center immediately.
Ingestion	Do NOT induce vomiting. Rinse mouth. Call a physician or poison control center immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms	No symptoms known or expected.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	Treat symptomatically. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. There is no specific antidote.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable	High volume water jet
5.2 Special hazards arising from the substance or mixture	In the event of fire the following may be released:, Hydrogen chloride (HCl), Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO), Sulphur oxides, Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters	In the event of fire and/or explosion do not breathe fumes. In the event of fire, wear self-contained breathing apparatus.

Further information	Contain the spread of the fire-fighting media. Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Precautions	Avoid contact with spilled product or contaminated surfaces. Use personal protective equipment.
6.2 Environmental precautions	Do not allow to get into surface water, drains and ground water. If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Clean contaminated floors and objects thoroughly, observing environmental regulations. Keep in suitable, closed containers for disposal.
6.4 Reference to other sections	Information regarding safe handling, see section 7. Information regarding personal protective equipment, see section 8. Information regarding waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling	No specific precautions required when handling unopened packs/containers; follow relevant manual handling advice. Ensure adequate ventilation.
Advice on protection against fire and explosion	Keep away from heat and sources of ignition.
Hygiene measures	Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and immediately after handling the product. Wash hands immediately after work, if necessary take a shower. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a place accessible by authorized persons only. Protect from freezing. Keep away from direct sunlight.
Advice on common storage	Keep away from food, drink and animal feedingstuffs.
Suitable materials	HDPE (high density polyethylene)
7.3 Specific end use(s)	Refer to the label and/or leaflet.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components	CAS-No.	Control parameters	Update	Basis
Prothioconazole	178928-70-6	1.4 mg/m3 (SK-ABS)		OES BCS*
Spiroxamine	118134-30-8	0.6 mg/m3 (SK-SEN)		OES BCS*

*OES BCS: Internal Bayer AG, Crop Science Division "Occupational Exposure Standard"

8.2 Exposure controls

Personal protective equipment
In normal use and handling conditions please refer to the label and/or leaflet. In all other cases the following recommendations would apply.

Respiratory protection
Wear respirator with an organic vapours and gas filter mask (protection factor 10) conforming to EN140 type A or equivalent. Respiratory protection should only be used to control residual risk of short duration activities, when all reasonably practicable steps have been taken to reduce exposure at source e.g. containment and/or local extract ventilation. Always follow respirator manufacturer's instructions regarding wearing and maintenance.

Hand protection
Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.
Wash gloves when contaminated. Dispose of when contaminated inside, when perforated or when contamination on the outside cannot be removed. Wash hands frequently and always before eating, drinking, smoking or using the toilet.

Material	Nitrile rubber
Rate of permeability	> 480 min
Glove thickness	> 0.4 mm
Protective index	Class 6
Directive	Protective gloves complying with EN 374.

Eye protection
Wear goggles (conforming to EN166, Field of Use = 5 or equivalent).

Skin and body protection
Wear standard coveralls and Category 3 Type 6 suit.
Wear two layers of clothing wherever possible. Polyester/cotton or cotton overalls should be worn under chemical protection suit and should be professionally laundered frequently.
If chemical protection suit is splashed, sprayed or significantly contaminated, decontaminate as far as possible, then carefully remove and dispose of as advised by manufacturer.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form	Liquid, clear to slightly turbid
Colour	yellow to brown
Odour	aromatic
Odour Threshold	No data available
Melting point/range	No data available
Boiling Point	No data available
Flammability	No data available
Upper explosion limit	No data available
Lower explosion limit	No data available
Flash point	139 °C
Auto-ignition temperature	315 °C
Self-accelarating decomposition temperature (SADT)	No data available
pH	6.0 - 8.0 (1 %) (23 °C) (deionized water)
Viscosity, dynamic	No data available
Viscosity, kinematic	No data available
Water solubility	emulsifiable
Partition coefficient: n-octanol/water	Prothioconazole: log Pow: 3.82 (20 °C) (pH 7) Spiroxamine: log Pow: 2.8 - 3.0 (20 °C) (pH 7) N,N-Dimethyldecanamide: log Pow: 2.46
Vapour pressure	No data available
Density	ca. 0.98 g/cm³ (20 °C)
Relative density	No data available
Relative vapour density	No data available
Assessment nano particles	This substance/ mixture does not contain nanoforms
Particle size	No data available

9.2 Other information

Explosivity	Not explosive 92/69/EEC, A.14 / OECD 113
Oxidizing properties	No oxidizing properties
Evaporation rate	No data available
Other physico-chemical	Further safety related physical-chemical data are not known.

properties

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	No hazardous reactions when stored and handled according to prescribed instructions.
10.4 Conditions to avoid	Extremes of temperature and direct sunlight.
10.5 Incompatible materials	Store only in the original container.
10.6 Hazardous decomposition products	No decomposition products expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in regulation (EC) No 1272/2008

Acute oral toxicity	LD50 (Rat) > 500 - < 1,000 mg/kg
Acute inhalation toxicity	LC50 (Rat) ca. 2.212 mg/l Exposure time: 4 h Irritating to respiratory system.
Acute dermal toxicity	LD50 (Rat) > 4,000 mg/kg
Skin corrosion/irritation	Irritating to skin. (Rabbit)
Serious eye damage/eye irritation	Irritating to eyes. (Rabbit)
Respiratory or skin sensitisation	Non-sensitizing. (Guinea pig) OECD Test Guideline 406, Magnusson & Kligman test

Assessment STOT Specific target organ toxicity – single exposure

Prothioconazole: Based on available data, the classification criteria are not met.
Spiroxamine: Based on available data, the classification criteria are not met.
N,N-Dimethyldecan-1-amide: May cause respiratory irritation.

Assessment STOT Specific target organ toxicity – repeated exposure

Prothioconazole did not cause specific target organ toxicity in experimental animal studies.
Spiroxamine caused specific target organ toxicity in experimental animal studies in dogs in the following organ(s): Eyes.
N,N-Dimethyldecanamide did not cause specific target organ toxicity in experimental animal studies.

Assessment mutagenicity

Prothioconazole was not mutagenic or genotoxic based on the overall weight of evidence in a battery of in vitro and in vivo tests.
Spiroxamine was not mutagenic or genotoxic in a battery of in vitro and in vivo tests.
N,N-Dimethyldecanamide was not genotoxic in a battery of in vitro tests.

Assessment carcinogenicity

Prothioconazole was not carcinogenic in lifetime feeding studies in rats and mice.
Spiroxamine was not carcinogenic in lifetime feeding studies in rats and mice.
N,N-Dimethyldecanamide is not considered carcinogenic.

Assessment toxicity to reproduction

Prothioconazole caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Prothioconazole is related to parental toxicity.
Spiroxamine caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Spiroxamine is related to parental toxicity.
N,N-Dimethyldecanamide is not considered a reproductive toxicant at non-maternally toxic dose levels.

Assessment developmental toxicity

Prothioconazole caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Prothioconazole are related to maternal toxicity.
Spiroxamine caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Spiroxamine are related to maternal toxicity.
N,N-Dimethyldecanamide did not cause developmental toxicity in rats and rabbits.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

No further toxicological information is available.

11.2 Information on other hazards

Endocrine disrupting properties

Assessment	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC50 (Oncorhynchus mykiss (rainbow trout)) 6.57 mg/l Exposure time: 96 h
Toxicity to aquatic invertebrates	EC50 (Daphnia magna (Water flea)) 6.3 mg/l Exposure time: 48 h
Toxicity to aquatic plants	ErC50 (Raphidocelis subcapitata (freshwater green alga)) 0.1 mg/l Growth rate; Exposure time: 72 h

ErC50 (Skeletonema costatum) 0.03278 mg/l
Exposure time: 72 h
The value mentioned relates to the active ingredient prothioconazole.

EC10 (Skeletonema costatum) 0.01427 mg/l
Growth rate; Exposure time: 72 h
The value mentioned relates to the active ingredient prothioconazole.

12.2 Persistence and degradability

Biodegradability
Prothioconazole:
Not rapidly biodegradable
Spiroxamine:
Not rapidly biodegradable
N,N-Dimethyldecanamide:
rapidly biodegradable

Koc
Prothioconazole: Koc: 1765
Spiroxamine: Koc: 2415

12.3 Bioaccumulative potential

Bioaccumulation
Prothioconazole: Bioconcentration factor (BCF) 19
Does not bioaccumulate.
Spiroxamine: Bioconcentration factor (BCF) 87
Does not bioaccumulate.
N,N-Dimethyldecanamide:
Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil
Prothioconazole: Slightly mobile in soils
Spiroxamine: Slightly mobile in soils
N,N-Dimethyldecanamide: Slightly mobile in soils

12.5 Results of PBT and vPvB assessment

PBT and vPvB assessment
Prothioconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).
Spiroxamine: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).
N,N-Dimethyldecanamide: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

12.6 Endocrine disrupting properties

Assessment
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Additional ecological information
No other effects to be mentioned.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	It is best to use all of the product in accordance with label directions. If it is necessary to dispose of unused product, please follow container label instructions and applicable local guidelines.
Contaminated packaging	Small containers (< 10 l or < 10 kg) should be rinsed thoroughly using an integrated pressure rinsing device, or, by manually rinsing three times. Add washings to sprayer at time of filling. Dispose of empty and cleaned packaging safely. Follow advice on product label and/or leaflet.
Waste key for the unused product	**02 01 08*** agrochemical waste containing hazardous substances

SECTION 14: TRANSPORT INFORMATION

ADR/RID/ADN

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SPIROXAMINE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES
Hazard no.	90
Tunnel Code	-

This classification is in principle not valid for carriage by tank vessel on inland waterways. Please refer to the manufacturer for further information.

IMDG

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SPIROXAMINE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Marine pollutant	YES

IATA

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SPIROXAMINE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES

14.6 Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

14.7 Transport in bulk according to IMO instruments
No transport in bulk according to the IBC Code.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Republic of Ireland Regulations

This material may be subject to some or all of the following regulations (and any subsequent ammendments). Users must ensure that any uses and restrictions as indicated on the label and/or leaflet are followed.

Supply and Use

European Communities (Prohibition of Certain Active Substances in Plant Protection Products) Regulations 1981 (SI No 320/1981)
European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations 2003 (SI No 83/2003)
European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations 2001 (SI No 624/2001
2010 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (SI No 619/2001)

Waste Treatment

Landfill Directive
Regulation on Substances That Deplete the Ozone Layer 1994 (EEC/3093/94)

Further information

WHO-classification: II (Moderately hazardous)

15.2 Chemical safety assessment

A chemical safety assessment is not required.

SECTION 16: OTHER INFORMATION

Text of the hazard statements mentioned in Section 3

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H361d	Suspected of damaging the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

H412	Harmful to aquatic life with long lasting effects.

Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute toxicity estimate
CAS-Nr.	Chemical Abstracts Service number
Conc.	Concentration
EC-No.	European community number
ECx	Effective concentration to x %
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELV	Exposure Limit Value
EN	European Standard
EU	European Union
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code)
ICx	Inhibition concentration to x %
IMDG	International Maritime Dangerous Goods
LCx	Lethal concentration to x %
LDx	Lethal dose to x %
LOEC/LOEL	Lowest observed effect concentration/level
MARPOL	MARPOL: International Convention for the prevention of marine pollution from ships
N.O.S.	Not otherwise specified
NOEC/NOEL	No observed effect concentration/level
OECD	Organization for Economic Co-operation and Development
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SI	Statutory Instrument
TWA	Time weighted average
UN	United Nations
WHO	World health organisation

The above information is intended to give general health and safety guidance on the storage and transport of the product.
It is not intended to apply to the use of the product for which purposes the product label and any appropriate technical usage literature available should be consulted and any relevant licenses, consents or approvals complied with.
The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or product should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.
The information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate.
No liability will be accepted for any injury, loss or damage resulting from any failure to take account of information or advice contained in this safety data sheet.

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Reason for Revision:	Safety Data Sheet according to Regulation (EU) No. 2020/878. Checked and revised for editorial purposes due to adjustments according to the current Annex II of the REACH regulation.
	The following sections have been revised: Section 12. Ecological information. Section 13. Disposal considerations.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.